



October 9, 2015

## WikiLeaks Publishes Final TPP Intellectual Property Text

### Analysis<sup>1</sup>:

### Ambiguity Leads to Fallacy: Biologics Exclusivity in the Trans-Pacific Partnership

#### *Leak<sup>2</sup> Shows TPP Would Impose New Monopoly Requirements, Limiting Access to New Cancer and Other Biotech Medicines*

#### What are Biologics?

Biologic medicines are complex molecules such as proteins that are isolated from plants, animals and micro-organisms or made using biotechnology. They can include vaccines, cancer medicines and therapies such as insulin. They are a growing share of medicines and can cost tens or even hundreds of thousands of dollars per patient per year, and are often needed for a lifetime.<sup>i</sup> This is unaffordable even for the U.S. government. The Obama administration has repeatedly proposed in its budget reducing its current 12 years of biologics exclusivity to 7 years.<sup>ii</sup>

Relationship to Patents: Biologics may not be patentable in all cases, as they are naturally occurring products such as insulin or components of human blood.<sup>iii</sup> This leaked text requires TPP countries to stop generic versions of biologic medicines ('biosimilars') from being available to patients, even when there is no patent or beyond the term of a patent.

#### **Exclusivity Term: 5 Year Mandatory Minimum (and mechanisms for further pressure measures)**

The text has two options for TPP countries. They can either:

- a) Give **8 years** of market exclusivity<sup>3</sup> counting from the date the biologic is approved in the country concerned<sup>iv</sup>, or

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<sup>1</sup>Sanya Smith Reid, Legal Advisor, Third World Network & Burcu Kilic Legal & Policy Director, Public Citizen's Global Access to Medicines Program

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

<sup>3</sup> Of the type in Article QQE16.1

- b) Give **5 years** of market exclusivity<sup>4</sup> counting from the date the biologic is approved in the country concerned<sup>5</sup> and other measures to deliver a comparable market outcome.<sup>v</sup>

A number of TPP governments have already stated that this does not require them to change their existing systems of 5 years of biologic exclusivity.<sup>vi</sup> While these countries have stated that they will not go beyond their current levels of biologic exclusivity protection, it remains to be seen if they can maintain that position in the certification process required under the U.S. fast track law, where the U.S. has in the past asked countries for stronger IP protection (including on medicines) than the USFTA text requires<sup>vii</sup> and required countries to reduce the effectiveness of their exceptions to IP<sup>viii</sup>.

### **Applicability: Biologics Definition**

This exclusivity must be provided for medicines that treat or cure human diseases or conditions or prevent them (eg vaccines) if they are proteins which are made using a biotechnology process.<sup>ix</sup> The majority of biologics are proteins<sup>x</sup>, and so defining biologic to include proteins (most vaccines and blood products) excludes few products. 'Biotechnology process' can be defined in national law<sup>xi</sup>, which allows it to be updated as the science changes.

### **TPP Commission Review**

Whichever option a TPP country implements, there will be a review of the length of the biologic exclusivity monopoly and what pharmaceutical products get this biologic exclusivity.<sup>xii</sup> This review could result in more pharmaceutical products getting this biologic exclusivity for longer.

### **Exceptions to Protect Public Health**

The exceptions for health<sup>6</sup> for all TPP countries are those listed in QQE16.3.

Public Citizen, Third World Network and other observers including Professor Carlos Correa<sup>7</sup> have suggested expanded language to provide a clear operational path for health exceptions

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<sup>4</sup> Of the type in Article QQE16.1

<sup>5</sup> See explanation for option a) and Peru has the same exception here.

<sup>6</sup> Although Article QQA7 has Understandings Regarding Certain Public Health Measures, concerns have been raised about the effectiveness of similar wording in previous leaked versions of this chapter, eg [http://www.unitaid.eu/images/marketdynamics/publications/TPPA-Report\\_Final.pdf](http://www.unitaid.eu/images/marketdynamics/publications/TPPA-Report_Final.pdf).

In addition, past USFTAs have not allowed the health exception in the general exceptions chapter to apply to the IP chapter, <https://ustr.gov/trade-agreements/free-trade-agreements>. The Malaysian government's summary of the TPP notes that there is a health exception for the goods and services chapters, but does not mention it applying to the IP chapter, [http://fta.miti.gov.my/miti-fta/resources/Summary\\_of\\_The\\_Trans-Pacific\\_Partnership\\_Agreement.pdf](http://fta.miti.gov.my/miti-fta/resources/Summary_of_The_Trans-Pacific_Partnership_Agreement.pdf). Furthermore [http://fta.miti.gov.my/miti-fta/resources/Summary\\_of\\_The\\_Trans-Pacific\\_Partnership\\_Agreement.pdf](http://fta.miti.gov.my/miti-fta/resources/Summary_of_The_Trans-Pacific_Partnership_Agreement.pdf) indicates that the TPP's health exceptions will use the wording from World Trade Organization (WTO) rules which has been so difficult to use that those general exceptions have only succeeded once out of 44 attempts in the history of the WTO, <http://www.citizen.org/documents/general-exception.pdf>.

<sup>7</sup> "...this language has little or no practical effect. It would not limit in any manner the obligations imposed by the agreement. The referred to Declaration only confirms the flexibilities allowed by the TRIPS Agreement in relation to public health matters (such as compulsory licenses and parallel imports), but it is unlikely to provide a sufficient legal basis to derogate from the obligations established by the TPP", Carlos M. Correa. Intellectual Property in the Trans-Pacific Partnership: Increasing the Barriers for the Access to Affordable Medicines. South Centre Research Paper No. 62, September, 2015, <http://www.southcentre.int/research-paper-62-september-2015/>, .....

to marketing exclusivity. The actual provision does not provide very specific guidance. Nevertheless, it does reference all TPP exclusivity provisions. This should mean Parties may provide health exceptions to marketing exclusivity for biologics. Chile has preserved the health and other exceptions<sup>8</sup> in its law, which Chile can use to override biologics exclusivity.<sup>xiii</sup>

**Concurrent Period:** Peru's Annex incorporates the concurrent period concept from the May 10 Agreement and U.S.-Peru FTA. Peru has the option of starting the exclusivity clock from the date of U.S. marketing approval (or first approval in another TPP Party), rather than from the date of marketing approval in Peru. This applies, however, only so long as Peru approves a product within 6 months of the date an application is filed with the Peruvian authorities. In practical terms, this can shorten the exclusivity period in Peru if the originator takes a long time to apply for marketing approval in Peru.

Other TPP countries which also rely on marketing approval in other countries do not have this exception. This is one way TPP fails to live up to the May 10 standard for other developing countries.

**Access window:** Brunei and Malaysia can require that the originator apply for marketing approval in Brunei/Malaysia within 18 months of first getting marketing approval anywhere in the world, or otherwise forfeit biologic exclusivity under Article QQE20.1<sup>9</sup>.<sup>xiv</sup> This is to incentivise originator companies to bring their new medicines to countries with small populations quickly<sup>10</sup>.

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<sup>i</sup> <http://www.fiercepharma.com/story/why-does-alexions-soliris-cost-500k-plus-uk-gatekeepers-want-know/2014-03-04>. See [http://www.twn.my/title2/FTAs/Intellectual\\_Property/IP\\_and\\_Access\\_to\\_Medicines/TPPanalysisMay2015leakbiologicsdefn.doc](http://www.twn.my/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/TPPanalysisMay2015leakbiologicsdefn.doc) for more examples of the cost of biologics

<sup>ii</sup> eg <https://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/budget.pdf>.

<sup>iii</sup> See [http://www.twn.my/title2/FTAs/Intellectual\\_Property/IP\\_and\\_Access\\_to\\_Medicines/TPPanalysisMay2015leakbiologicsdefn.doc](http://www.twn.my/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/TPPanalysisMay2015leakbiologicsdefn.doc) for examples of biologics

<sup>iv</sup> Article QQE20.1a)

<sup>v</sup> Article QQE20.1b)

<sup>vi</sup> Eg Australia: <http://dfat.gov.au/trade/agreements/tpp/outcomes-documents/Pages/outcomes-biologics.aspx>; Chile: <https://ustr.gov/about-us/policy-offices/press-office/speechestranscripts/2015/october/transcript-trans-pacific>; New Zealand:

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<sup>8</sup> For example, in addition to health, for non-commercial public use, national emergency, other circumstances of extreme urgency declared by the competent authority and national security, termination of the exclusivity is allowed. Compulsory licences, anticompetitive practices by the originator company, failure to commercialise it in Chile for more than 12 months after getting marketing approval in Chile etc result in the protection under this paragraph not applying, [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=270135](http://www.wipo.int/wipolex/en/text.jsp?file_id=270135), [http://www.ifpma.org/fileadmin/content/Publication/IFPMA\\_2011\\_Data\\_Exclusivity\\_En\\_Web.pdf](http://www.ifpma.org/fileadmin/content/Publication/IFPMA_2011_Data_Exclusivity_En_Web.pdf), [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=338935](http://www.wipo.int/wipolex/en/text.jsp?file_id=338935).

<sup>9</sup> Presumably the typographical error in the cross-referencing (Annex refers to **18.E.20.1** whereas the numbering of the biologics provision in the text is **QQE20.1**) will be fixed in legal scrubbing

<sup>10</sup> Additional Exclusivity for Biologics Drugs in the TPP: A Need or Greed?, Public Citizen Report, July 2015, available at: <http://www.citizen.org/documents/public-citizen-report-tpp-biologics-lag-time.pdf>

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[http://tpp.mfat.govt.nz/assets/docs/TPP\\_factsheet\\_Intellectual-Property.PDF](http://tpp.mfat.govt.nz/assets/docs/TPP_factsheet_Intellectual-Property.PDF) ; Singapore:

<https://www.politicopro.com/trade/story/2015/10/pro-trade-tppbiologics-behsudi-059493>

<sup>vii</sup> <http://tppnocertification.org/wp-content/uploads/2014/08/Certification-memorandum.pdf>

<sup>viii</sup> Eg <http://tppnocertification.org/australias-experience/>

<sup>ix</sup> Article QQE20.2

<sup>x</sup> [http://www.researchgate.net/profile/Jinyou\\_Zhang2/publication/225033892\\_Mammalian\\_Cell\\_Culture\\_for\\_Biopharmaceutical\\_Production/links/0fcfd4fbcfaf09b585000000.pdf](http://www.researchgate.net/profile/Jinyou_Zhang2/publication/225033892_Mammalian_Cell_Culture_for_Biopharmaceutical_Production/links/0fcfd4fbcfaf09b585000000.pdf)

<sup>xi</sup> Footnote 65

<sup>xii</sup> Article QQE20.3

<sup>xiii</sup> Annex to IP Chapter 4-Chile

<sup>xiv</sup> Annex to IP Chapter 5 – Brunei and Malaysia