



TWN  
Third World Network

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

*TPP Would Limit Access to New Cancer and Other Biotech Medicines –  
But Interpretations of Rule Vary Widely*

November 19, 2015

**Biologics and Cost**

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>1</sup> This is unaffordable even for the U.S. government.

Biologics exclusivity is a special rule that blocks competition from biosimilars, which are the analogues to generic medicines for biologics. Biosimilar competition is an essential tool to reduce biologics prices. The Obama Administration has repeatedly proposed in its budget to reduce the current U.S. period of biologics exclusivity from 12 years to seven, in order reduce the costs of new medicines for Americans.<sup>2</sup>

**Relationship of Biologics Exclusivity to Patents**

Biologics exclusivity is separate from patent protection. Either type of protection may create a monopoly over a particular drug. Biologics exclusivity can block competition even when there is no patent, or after patents have expired, if the exclusivity lasts until a later date. For consumers, therefore, it is important that exclusivity terms are short, so as not to delay cost-cutting competition.

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<sup>1</sup> See Tracy Staton, *Why does Alexion's Soliris cost \$500K-plus? U.K. gatekeepers want to know*, available at <http://www.fiercepharma.com/story/why-does-alexions-soliris-cost-500k-plus-uk-gatekeepers-want-know/2014-03-04> for more examples of the cost of biologics.

<sup>2</sup> E.g. Office of Management and Budget report on Fiscal Year 2016, available at <https://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/budget.pdf>.

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

The Trans-Pacific Partnership (TPP) requires countries to implement one of two options. Countries 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>4</sup>, or
- b) Give **5 years** of market exclusivity<sup>5</sup> counting from the date the biologic is approved in the country concerned<sup>6</sup> and other measures to deliver a comparable market outcome.<sup>7</sup>

A number of TPP governments have already stated that provision (b) does not require them to change their existing systems of 5 years of biologic exclusivity.<sup>8</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 intellectual property (IP) protection (including on medicines) than the U.S. free trade agreement (FTA) text requires<sup>9</sup> and required countries to reduce the effectiveness of their exceptions to IP<sup>10</sup>.

Indeed, since the initial publication of this analysis, policymakers in TPP countries have already come out with conflicting statements regarding biologics exclusivity obligations embodied in this provision. See Appendix I for more information.

### **Applicability: Biologics Definition**

This exclusivity must be provided for medicines that treat or cure human diseases or conditions or prevent them (e.g. vaccines) if they are proteins which are made using a biotechnology process.<sup>11</sup> The majority of biologics are proteins<sup>12</sup>, and so defining biologic to include proteins (most vaccines and blood products) excludes few products. ‘Biotechnology

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<sup>3</sup> Of the type in Article 18.52.1(a)

<sup>4</sup> Article 18.52.1(a)

<sup>5</sup> Of the type in Article 18.52.1(b)

<sup>6</sup> See explanation for option a) and Peru has the same exception here.

<sup>7</sup> Article 18.52.1(b)

<sup>8</sup> E.g. 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: [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>9</sup> Jane Kelsey, Sanya Reid Smith, *Q&A on the US Legal Requirement For “Certification” of Trade Partners’ Compliance Before an Agreement Like the TPPA Goes into Effect*, Third World Network (Aug 2014), available at <http://tpnocertification.org/wp-content/uploads/2014/08/Certification-memorandum.pdf>.

<sup>10</sup> E.g. *How the US Forced Australia to Rewrite Aspects of Its Copyright Law during Certification of Compliance with the AUFTA*, TPP: No Certification, available at <http://tpnocertification.org/australias-experience/>.

<sup>11</sup> Article 18.52.2

<sup>12</sup> Jinyou Zhang, *Mammalian Cell Culture for Biopharmaceutical Product* (Jan 2010), available at [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).

process' can be defined in national law<sup>13</sup>, which allows it to be updated as the science changes.

### **TPP Commission Review**

Whichever option a TPP country implements, the text includes plans for a “TPP Commission” review of the length of the exclusivity period and what types of products receive it.<sup>14</sup> This review could result in more pharmaceutical products receiving longer monopoly protections through biologic exclusivity.

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

The exceptions for health<sup>15</sup> for all TPP countries are those listed in 18.50.3.

Public Citizen, Third World Network and other observers including Professor Carlos Correa<sup>16</sup> have suggested expanded language to provide a clear operational path for health exceptions 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>17</sup> in its law, which Chile can use to override biologics exclusivity.<sup>18</sup>

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<sup>13</sup> In the leaked chapter of the IP chapter (see footnote 64, leaked chapter is available at <https://wikileaks.org/tpp-ip3/>), there was a drafter's note clarifying that “the Parties understand that each Party may determine the meaning of biotechnology processes in its legal system and practice.” This footnote disappeared in the final text but Parties still keep the flexibility and freedom to determine the meaning of biotechnology processes in their legal system and practice.

<sup>14</sup> Article 18.52.3

<sup>15</sup> Although Article 18.6 has Understandings Regarding Certain Public Health Measures, concerns have been raised about the effectiveness of similar wording in previous leaked versions of this chapter, e.g. [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>16</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/>.

<sup>17</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),

## Concurrent Period

Peru's Annex incorporates the concurrent period concept from the May 10 Agreement<sup>19</sup> and U.S.-Peru FTA. Peru<sup>20</sup> 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, and may lead to early market entry for pharmaceutical products by providing disincentive to companies that may otherwise choose to delay regulatory submissions.<sup>21</sup>

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

Malaysia can require that the originator apply for marketing approval in Malaysia within 18 months of first getting marketing approval anywhere in the world, or otherwise forfeit biologic exclusivity under Article 18.52.1.<sup>22</sup> This is to incentivise originator companies to bring their new medicines to countries with small populations quickly<sup>23</sup>.

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[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>18</sup> Annex 18-B Chile

<sup>19</sup> See e.g. "A New Trade Policy for America," summary by U.S. House Ways and Means Committee, May 11, 2007, available at [http://www.bilaterals.org/IMG/pdf/07\\_05\\_10\\_New\\_Trade\\_Policy\\_Outline.pdf](http://www.bilaterals.org/IMG/pdf/07_05_10_New_Trade_Policy_Outline.pdf).

<sup>20</sup> U.S.-Peru Trade Promotion Agreement Intellectual Property Chapter, available at <https://ustr.gov/sites/default/files/uploads/Countries%20Regions/africa/agreements/pdfs/FTAs/peru/16%20IPR%20Legal.June%2007.pdf>.

<sup>21</sup> Submission lag of information considered in marketing approval processes can be a serious concern for developing countries. For more information on submission lag, see Public Citizen's report, "Biologics & Biosimilars: Additional Exclusivity for Biologic Drugs in the TPP: A Need or Greed?" available at <http://www.citizen.org/documents/public-citizen-report-tpp-biologics-lag-time.pdf>

<sup>22</sup> Annex 18-C Malaysia

<sup>23</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>

## **Appendix I – Disagreeing Interpretations**

White House spokesman Josh Earnest came out after the official publication of the text arguing that option b for biologics exclusivity “actually puts in place an effective standard of eight years among the TPP-member nations.”<sup>24</sup> At a November 10 American University Washington College of Law event on the Trans-Pacific Partnership<sup>25</sup>, USTR Deputy Assistant for the Office of Intellectual Property and Innovation Probir Mehta similarly argued that anyone who interprets option b as requiring only five years of biologics exclusivity is misreading the text of the agreement.

However, senior U.S. Senator and frequent ally of the pharmaceutical industry, Orrin Hatch, disagrees with the Administration position. *Politico* reports<sup>26</sup>: “Five years is ridiculous,” Hatch said. “You may or may not get the other three years, and that is about half of what you need.”

Australian Trade Minister Andrew Robb has made a number of statements suggesting the Australian government disagrees with the Obama Administration interpretation, including, (referring to Australia’s current system of five years exclusivity for biologics) that the TPP would require “not one change to the system”<sup>27</sup> and that “[Australian negotiators] did protect the five-year data protection issue,” continuing, “we haven’t moved one iota on any of that health area.”<sup>28</sup>

New Zealand’s sentiment echoes that of Robb. New Zealand Trade Minister Tim Groser stated upon conclusion of negotiations that “[r]egarding data protection for biologic medicines, New Zealand’s existing policy settings and practices will be adequate to meet the provisions we have finally agreed on.”<sup>29</sup>

*Inside U.S. Trade* reported<sup>30</sup> that at the closing press conference of the Atlanta talks in October, Chilean foreign ministry Director of International Economic Relations Andres Rebolledo stated, “We really think that we have a balanced result.” He continued, “We are going to maintain our internal regulation in data protection, and also we are going to keep the regulation we already have in the [U.S.-Chile] free trade agreement.”

Malaysia’s International Trade and Industry Minister Datuk Seri Mustapa Mohamed has suggested publicly that he also interprets the provision as requiring only 5 years of biologics

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<sup>24</sup> Inside U.S. Trade, *Earnest Defends TPP Biologics Outcome, Rejects Hatch's Call For Renegotiation*. (2015, November 11). Retrieved November 12, 2015, from <https://t.co/LVDAf7IKEs>

<sup>25</sup> Information about the event is available at <https://www.wcl.american.edu/secle/fall/2015/20151110.cfm>, however, no video or transcript of the event had been posted at the time of preparation of this analysis.

<sup>26</sup> Palmer, D. (2015, November 6). *Hatch throws pharma roadblock in TPP path*. *Politico*.

<sup>27</sup> Kelly, J. (2015, November 6). *Robb acknowledges there are still hurdles*. *The Australian*.

<sup>28</sup> Merhab, B. (2015, November 6). *Fears TPP will put medicines out of reach*. *Seven News*.

<sup>29</sup> TPP delivers significant benefits for NZ. (2015, October 6). Retrieved November 20, 2015, from <http://www.beehive.govt.nz/release/tpp-delivers-significant-benefits-nz>

<sup>30</sup> Schewel, M. & Rainey, R. (2015, October 9). *Australia, Chile Say TPP Biologics Deal Will Not Require Them To Change*. *Inside U.S. Trade*.

exclusivity. *The Malaysian Insider* quotes a letter from the minister defending the TPP: “Malaysia has had a pharmaceutical data protection process in place since 2011, where the test data will be protected for a period of five years. The government has agreed to extend similar data protection to biologics products, so as to provide non-discriminatory treatment.”<sup>31</sup>

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<sup>31</sup> Zachariah, E. (2015, November 7). *Drug Prices Stay, Malaysia gains from TPPA, Mustapa tells critics*. The Malaysian Insider.