

Preliminary Comments on the Completed Trans Pacific Partnership (TPP) Intellectual Property Chapter

Dr Deborah Gleeson

School of Psychology and Public Health, La Trobe University

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Today, Wikileaks has released the leaked [completed text of the TPP's intellectual property \(IP\) chapter](#). The legal scrub is still to be done, and there could also be side letters between the United States and particular countries revealed at a later stage. But the chapter contains no brackets, indicating that the provisions contained therein were agreed between the parties at the conclusion of the negotiations.

This brief provides some general comments on the pharmaceutical provisions in the final TPP IP chapter and then focuses specifically on problems with the provision for market exclusivity for biologic products.

General comments

The TPP's intellectual property chapter represents nothing less than a disaster for global health. Many harmful provisions still remain in the final chapter, bearing out the concerns of public health advocates. These include:

- Patents for new uses and new methods of using existing products (Article QQ.E.1.2, p. 17);
- A low inventiveness threshold – potentially preventing countries from tightening the criteria for granting patents (Footnote 33, p. 17);
- Patent term extensions to compensate for delays in granting patents (Article QQ.E.12, p. 20) and delays in marketing approval (Article QQ.E.14, p. 22);
- Data protection for small molecule drugs – at least 5 years for new pharmaceutical products plus 3 years for new indications, formulations or methods of administration (Article QQ.E.16, p. 23-24);
- Patent linkage provisions likely to result in delays in marketing approval for generic drugs (Article QQ.E.17); and
- Market exclusivity for biologics, provided through one of two options: at least 8 years of data protection, or at least 5 years of data protection and other measures to “deliver a comparable outcome in the market” (Article QQ.E.20, p. 25-26).

This is the first time a provision for market exclusivity for biologic products has ever appeared in a trade agreement – and this is a new obligation for many TPP countries.

The outcome of this suite of obligations will be delayed competition from follow-on generics and biosimilars – which means delayed access to affordable medicines, placing them out of reach altogether for many people in developing countries. Even countries like Australia, the TPP obligations will lock in current intellectual property standards, making it difficult or impossible to reform our system to improve access to affordable medicines in future.

All countries will eventually have to adopt all the rules in the intellectual property chapter. There are transition periods for the four poorest countries (Malaysia, Mexico, Peru and Vietnam) but [these are far too short](#) for the realities these countries face (only 3-10 years) and apply to only a few of the TPP's obligations. For example, Vietnam will only have 3 years to implement patent term extensions

and patent linkage provisions. It appears that countries will have to graduate to the higher level IP protections regardless of their rate of development.

The pharmaceutical industry has expressed disappointment over the failure of the U.S. to obtain 12 years of market exclusivity for biologics, but in reality it has gained enormous concessions. If the TPP countries ratify the deal, Big Pharma will have succeeded in cementing intellectual property standards that will stymie access to medicines for up to 800 million people in the short term, and more if additional countries sign up in future. Furthermore, the TPP's intellectual property chapter sets a new norm that is likely to become the template for future trade agreements: its implications are global as well as regional.

The governments of TPP countries have been complicit in a global health disaster of unimaginable proportions - a deal that will prevent untold numbers of people from obtaining medicines that those in many developed countries take for granted.

Market exclusivity for biologics

Biologic products are produced through biological processes and include many new treatments for cancer and immune conditions such as rheumatoid arthritis. They include some of the most expensive medicines on the market, some of which cost hundreds of thousands of dollars per patient per year. Monopolies on just ten biologic drugs listed on Australia's Pharmaceutical Benefits Scheme [cost Australian taxpayers over \\$205 million in 2013-14](#).

The United States was seeking 8-12 years of market exclusivity for biologics. Battles over the length of monopolies on clinical trial data submitted to regulatory agencies (such as Australia's Therapeutic Goods Administration) plagued the TPP negotiations, and proved to be an almost insurmountable stumbling block over the final days.

The [Australian Government's brief](#) about the TPP outcomes for biologics says:

In the TPP, Australia has negotiated protections that are consistent with Australian law and practice. Australia is not required to change any part of its current law, including data protection for biologics, or our patent regime. There will be no adverse impact on the Pharmaceutical Benefits Scheme and no price increase for medicines.

But the final text of the TPP's IP chapter contains some problematic language and troubling ambiguities.

Article QQ.E.20.1 (p. 25-26) outlines two options that countries can implement to protect new biologics:

- 1) At least 8 years' protection of clinical trial data (QQ.E.20.1(a)); or
- 2) At least 5 years' protection of clinical trial data along with *other measures to "provide effective market protection" and "deliver a comparable outcome in the market"*

Whatever the understanding reached between parties in the negotiating room, according to the agreed legal text, it appears that the TPP parties are obliged to ensure the same market exclusivity outcomes regardless of which option they choose.

The legal language provides room for the United States to continue to pressure the other TPP countries to ensure that they keep biosimilars (more affordable follow-on products) off the market for eight years, in order to provide equivalent "effective market protection" and a "comparable outcome" to eight years of data protection. This pressure may occur [even before the TPP is](#)

[enforced](#). In the past, the US has applied pressure to countries to adopt stronger IP protection during the period between signing and ratification.

Article QQ.E.20.2 (p. 26) of the leaked IP chapter requires countries to apply the provision on biologics to a very broad range of products:

For the purposes of this Section, each party shall apply this provision to, at a minimum, a product that is, or alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.

Including any product that is, or contains, a protein captures a very broad array of products, and reduces the prospect for governments to narrow the scope of the obligation and define for themselves which products it applies to. While the meaning of biotechnology processes is left to be decided through domestic law and practice in each country, it is unclear how much flexibility this will actually provide.

Article QQ.E.20.3 (p. 26) provides for a review of both the length of the monopoly protection and its scope by the TPP Commission after 10 years (“or as otherwise decided by the TPP Commission”). This could result in countries being pressured to provide market exclusivity for more products, or to lengthen the period of protection.

Conclusions

Despite resistance by the majority of TPP countries to the US pharmaceutical industry agenda throughout the negotiations, many provisions remain in the final text that will dramatically reduce access to affordable medicines, particularly in developing countries. These problems will be exacerbated by limited, short and inflexible transition periods for developing countries to implement the obligations. While the United States has clearly been the demandeur, all TPP countries have been complicit in agreeing to settings that will cost people’s lives.

The provisions relating to biologics are problematic and ambiguous. They appear to commit countries to providing either eight years of clinical trial data protection, or five years of clinical trial data protection along with other measures to deliver comparable outcomes. While the Australian Government has said that the regime for biologics in Australia will not change, the language leaves room for continued pressure by the United States to ensure that TPP countries prevent biosimilars from entering the market for eight years. The definition of biologics is very broad and likely to limit countries’ flexibility in determining the scope of the obligation. A review by the TPP Commission of both the length and scope of protection after ten years provides a further mechanism for US pressure to expand and extend monopolies on expensive biologics.