

The TPP's final intellectual property (IP) chapter and access to medicines

Deborah Gleeson, 7 November 2015

1) General comments

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 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.

Harmful provisions still remaining in the [TPP's final Intellectual Property Chapter](#) include:

- Patents for new uses and new methods of using existing products (Article 18.37.1);¹
- A low inventiveness threshold – potentially preventing countries from tightening the criteria for granting patents (Footnote 30);
- Patents for inventions that are derived from plants (Article 18.37.4);²
- Patent term extensions to compensate for delays in granting patents and delays in marketing approval (Article 18.46);³
- Data protection for small molecule drugs – at least 5 years for new pharmaceutical products plus either 3 years for new indications, formulations or methods of administration *or* five years for combination products containing a chemical entity that has not previously been approved (Article 18.50);⁴
- Patent linkage provisions likely to result in delays in marketing approval for generic drugs (Article 18.51);⁵ 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 18.52).⁶
- Enforcement measures that go well beyond the World Trade Organization's TRIPS Agreement (Section I).

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.

¹ This provision has improved in comparison with early drafts. Rather than mandating patents for new forms, uses and methods of using existing products, TPP countries must make patents available for at least one of the following: ‘new uses of a known product, new methods of using a known product, or new processes of using a known product’. It still exceeds the requirements of the TRIPS Agreement.

² This is an issue for food security in developing countries rather than access to medicines.

³ This provision has been mitigated somewhat and is more flexible than early drafts. In some cases, countries may be able to avoid patent term extensions by expediting administrative processes. However it is still TRIPS+ and will potentially delay access to generic and biosimilar medicines.

⁴ Providing the option of a least five years for combination products may reduce the impact of this provision for countries that choose this option. However it is still TRIPS+ and will potentially delay access to generic medicines.

⁵ The original US proposal has been mitigated; regulatory agencies such as the Therapeutic Goods Administration will not have to act as patent police. Still TRIPS+ and likely to delay generic entry.

⁶ 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 biologics provisions are problematic and ambiguous, and leave room for the US to continue to pressure countries to use administrative delays to keep affordable medicines off the market for an equivalent period of time.

The obligations for pharmaceuticals in the TPP's intellectual property chapter are broadly consistent with Australia's existing arrangements. It appears unlikely that the intellectual property chapter will have a direct and immediate impact on the cost of medicines in Australia. But even in wealthy 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 linkage provisions and 5 years to implement patent term extensions for patent office delays (with a possible extension of one additional year). 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.

2) Biologics provisions in the final TPP text

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 Intellectual Property \(IP\) Chapter](#) contains some problematic language and troubling ambiguities.

Article 18.52.1 (p. 18-30 to 18-31) outlines two options that countries can implement to protect new biologics:

- 1) At least 8 years' protection of clinical trial data (Article 18.52.1(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"* (Article 18.52.1(b))

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 18.52.2 (p. 18-31) 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 Article 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 produced using biotechnology processes 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. Previous leaked text showed that the TPP countries were considering a footnote that would have allowed countries some room to determine the definition of biotechnology processes – but this footnote has been removed from the final version of the text.

Article 18.52.3 (p. 18-31) 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.

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.