Biologics provisions in the final TPP text

Deborah Gleeson, 6 November 2015

Summary:

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.

Detailed comments:

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.

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