NGO briefing – Leaked TPP IP chapter dated May 2015

Deborah Gleeson, 5 August 2015

Part of the consolidated draft TPP intellectual property chapter dated 11 May 2015 was leaked by Knowledge Ecology International on 5th August 2015. The text pre-dates the Hawaii round of negotiations but provides a good indication of the likely status of the negotiations on intellectual property at, or close to, the beginning of that round.

This briefing note provides preliminary comments on Section E of the draft, focusing particularly the parts concerning patents and the protection of clinical test data. Although the draft will have been superseded at the Hawaii round – and many of the issues are expected to have now been decided – the draft sheds light on some of the risks to public health at this stage in the negotiations.

The brief begins with some general observations on the text and the state of play in May and then discusses the data protection provisions in more detail, as these are understood to be the main issues that are left for ministerial decisions at the end of the Hawaii round in July 2015.

General comments

The text shows that the United States was continuing to push a range of monopoly protections damaging to public health as it entered what was expected to be the final stage of negotiations. These include:

- **A low inventiveness threshold for patents (footnote 58, page 29),** which makes patents very easy to obtain and prevents countries from tightening patent standards in future. All countries appear to have agreed to this low patent standard.

- **Patents for new uses and new methods of using existing products (Article QQ.E.1.2, page 29).** These types of patents encourage evergreening. This provision was still in brackets but only opposed by one country (Chile). Worryingly, this provision, along with Footnote 58, is not included in the provisions covered by the transition period for developing countries.

- **Mandatory patent protection for inventions derived from plants, and for plant varieties (Article QQ.E.4 and FN4, page 29)**; which has implications for food security in developing countries.

- **Mandatory patent term extensions beyond the 20 years required under the World Trade Organization's TRIPS Agreement** to compensate for delays in issuing patents (Article QQ.E.12, pages 37-38) or in processing applications for marketing approval (Article QQ.E.14, pages 43-44).

- **At least 5 years of data protection for small-molecule drugs (Article QQ.E.16.1)** plus an additional **3 years data protection for new clinical information or evidence of prior approval in another territory (Article QQ.E.16.2, page 45).** These provisions will be discussed further below.

- **Mandatory patent linkage (Article QQ.E.17, page 47-50)**, the nature of which appears to have still been hotly contested in May. This provision is intended to prevent marketing

approval of generics during the term of a patent. The generic medicines industry argues that any form of patent linkage acts as a strong deterrent to generic market entry.

- **A special period of data protection for biologic products (Article QQ.E.20, page 50-51).** In the May draft, four options for the length of the period were outlined in the text: 0, 5, 8 or 12 years. The TPP represents the first time a provision specifically relating to biologics has been included in a trade agreement. This provision is discussed further below.

The leaked text is bristling with hundreds of brackets (indicating areas of disagreement) and qualifying footnotes. It indicates continued opposition to most of the US proposals by most of the other countries.

In some areas, the earlier solidarity between most of the countries seems to have broken up under pressure from the US, with countries clearly trying to add qualifications and footnotes to protect or mitigate the effects on their own health systems. However, even if countries succeed in protecting their systems from the obligations in the text (which is unlikely to be fully effective), the substantive obligations will provide a template for future trade agreements that sets a very negative precedent. The substantive obligations are likely to be carried forward in subsequent trade agreements without the qualifying/mitigating footnotes. Countries which sign up to the TPP after negotiations have concluded will have to accept the obligations without the opportunity to argue for accommodating language or insert mitigating footnotes.

The text indicates that transition periods for developing countries are still under consideration. Transition periods cover only the provisions for patent term extensions (for delays in processing applications for marketing approval), data protection, patent linkage and biologics. They do not cover the provisions for patents for new uses and new methods of using existing products, or the low inventiveness threshold. Research suggests that these provisions are likely to contribute to higher costs for essential medicines in countries like Vietnam.

Data protection provisions

Data protection refers to a period where manufacturers of follow on (generic or biosimilar) products cannot rely on clinical trial data produced by the originator obtain marketing approval. Data protection is different to a patent in that it confers an absolute monopoly which operates whether or not there is a patent. Data protection, unlike a patent, cannot be challenged in court. It also presents a potential impediment to compulsory licensing, potentially rendering an important public health safeguard useless.

Data protection for small-molecule drugs

Article QQ.E.16 (pages 44-47) sets out the provisions for data protection for small-molecule (non-biological) pharmaceutical products. The US is seeking 5 years of data protection for new pharmaceutical products (Article QQ.E.16.1) and an additional period of 3 years for "(a) new clinical information (other than information related to bioequivalency) or (b) evidence of prior approval of the product in another territory that requires such new information."

Heavy bracketing in QQ.E.16.1 indicates extensive disagreement over the exact wording of the provision for 5 years of data protection for new pharmaceutical products. However, the entire provision and the 5 year period are *not* bracketed suggesting that Parties have agreed to include such a provision.

In contrast, the entire paragraph regarding the additional 3 years of data protection (QQ.E.16.2) is bracketed and only supported by Japan and the US. This seems likely to be an issue that will be left for ministerial decision in the final stages of negotiations. A footnote (FN 117, p. 46) appears to allow countries that have a different arrangement to retain that system as an alternative to the additional 3 years. This may be intended to allow Australia to retain its current system, as in the Australia-US Free Trade Agreement. However, it is unclear whether this will provide sufficient protection.

Articles QQ.E.16.3 appears to provide a public health exception for data protection, by allowing countries to take measures to protect public health in accordance with the WTO's TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health. However, it is unclear whether TRIPS and the Doha Declaration can be used in the context of overriding TRIPS+ data protection provisions. A somewhat stronger public health exception proposed by Malaysia, Vietnam and Mexico (Article QQ.E.16.6) is opposed by the US and Japan.

Data protection/market exclusivity for biologic products

Article QQ.E.20 (pages 50-51) seeks to provide for data protection for biologic products (products produced through biological processes. The TPP represents the first time a provision specifically relating to biologics has been included in a trade agreement.

There are three pressing problems with the text on biologics: (a) the length of the period, (b) the definition of biologics and (c) the absence of a public health exception.

(a) Length of the data protection period for biologics

Four options for the length of the period are outlined in the text: 0, 5, 8 or 12 years. At the Hawaii round of negotiations, these options were narrowed to 5 or 8 years, with the United States pushing strongly for an 8 year period.

The United States currently has 4 years of data protection and an additional 8 years of market exclusivity for biologics (i.e. a total of 12 years of exclusivity). Japan and Canada both currently have 8 years of data protection; all of the other countries have either five or zero. The current period in Australia is five years for all pharmaceuticals.

Biologics include many new expensive drugs for cancer, rheumatoid arthritis and other auto-immune conditions. Keeping these drugs under monopoly is likely to cost the Pharmaceutical Benefits Scheme in the order of hundreds of millions of dollars per year.

(b) Definition of biologics

The footnotes to the text on biologics include a lengthy discussion of the definition of biologics. An earlier proposal by the US providing a very detailed definition including vaccines, proteins and products derived from blood remains as an option (Approach 1, Footnote 138, page 50) , along with several proposed modifications to this definition. However, all of these definitions – even the apparently simpler modifications – amount to very broad interpretations of what constitutes a biologic and should be rejected by the other countries.

An alternative approach proposed by Australia and New Zealand and supported by Chile (Approach 2, page 51) leaves it to each Party to determine the scope of what constitutes a biologic product under its domestic law. This option is far better, allowing countries scope to limit the breadth of application of the obligation and to preserve future policy space in an evolving field.

(c) Absence of a public health exception

While the provision for data protection for small molecules (Art. QQ. E.16) includes a public health exception, however limited and inadequate*, the provision for data protection for biologics in the May draft does not*. It cross-references Art. QQ.E.16.1 (a) and (b) but not the part of the article that includes the exception (Art. QQ.E.16.3). It is also questionable whether the safeguards in the TRIPS Agreement and Doha Declaration would be sufficient in this context, since the separate treatment of biologics is a new development. Whatever the length of the data protection period, it is clear that a strong public health exception is needed.