# Trading places

## Will the TPP top CETA for protection of new drugs and biologics in Canada? Nancy Pei and Daphne Lainson explore

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With the Trans-Pacific Partnership (TPP) on people's minds, the Comprehensive Economic and Trade Agreement (CETA) has become something of a distant memory.[1] In Canada, both agreements are expected to benefit innovators of new drugs, including biologics, but TPP may provide additional protections and potentially more quickly than CETA.

**Highlights**

A significant change under TPP and CETA is patent-term restoration (PTR), which would provide an additional period of protection for pharmaceutical products to address the impact of regulatory delays in bringing a drug to market on effective patent term. The anticipated scheme is likely to mirror the European system of supplementary protection certificates (SPCs).

The TPP further provides patent term adjustments (PTA) based on patent office delays during prosecution, irrespective of technology. CETA does not provide for PTA.

CETA includes a commitment that, where there are patent linkage mechanisms, all litigants are afforded equivalent and effective rights of appeal. This provision is directed to a failure in Canada's linkage regulations (the Patented Medicines (Notice of Compliance) Regulations (PMNOC)) to provide innovators with an effective right of appeal. TPP does not address this issue.

Disappointingly absent in both agreements are extensions to the data exclusivity terms now available under the Food and Drug Regulations for innovative drugs, chemically or biologically derived.

**Overview of TPP commitments**

Agreement on the 12-nation TPP was reached on 5 October 2015 and the text was released a month later. The agreement is currently being reviewed by the Canadian government. In addition to PTR, there are other provisions in the TPP relating to pharmaceutical products. These provisions include a patent-linkage system, a regulatory review exception to patent infringement and protection of clinical data.

As noted above, Canada already has a linkage regime and data protection. In addition, Canada has a regulatory review exception, otherwise known as early-working exception, under the Patent Act. The Canadian government has indicated that the TPP obligations relating to linkage, the regulatory review exception and data protection reflect Canada's existing system.[2]

The TPP provisions relating to the protection of clinical data[3] include a further term of protection for new indications, formulations and methods of administration, which is not reflected in Canada's Food and Drug Regulations. However, this additional exclusivity does not apply if a party meets other minimum requirements such as an eight-year period of market exclusivity for a chemical or biological product that has not been previously approved by that party, which is the case under current Canadian legislation.[4]

In addition to PTR and PTA, the TPP also includes other IP provisions relating to the protection of trademarks and geographical indications, undisclosed test or other data for agricultural chemical products and copyright, and to the enforcement of IP. While some amendments to relevant legislation will be required, for example to enhance protection for geographical indications and extend the copyright term for another 20 years to life of the author plus 70 years, for most of these commitments Canadian legislation appears to be largely compliant.

**Overview of CETA commitments**

Canada and Europe reached an agreement in principle on 18 October 2013 regarding CETA. While the text of CETA was released on 26 September 2014, the agreement has not yet been signed.

In addition to PTR and an effective right of appeal under PMNOC, CETA includes a number of additional IP-related provisions. CETA includes measures for protecting undisclosed data relating to pharmaceutical products, trademarks, copyright, plants and plant protection products, and for IP enforcement. Canadian legislation is already largely compliant with these provisions, although, as with TPP, additional protection for geographical indications will be needed.

**PTR, PTA and linkage: TPP and CETA commitments examined**

**Patent-term restoration**

While both the TPP and CETA include PTR, the TPP provides only a general obligation while CETA includes a clear framework for this protection.

Under Article 18.48, the TPP only requires a commitment to making best efforts to process applications for marketing approval of pharmaceutical products in an "efficient and timely manner, with a view to avoiding unreasonable or unnecessary delays" and a commitment to making available "an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process".

To avoid unreasonable curtailment of patent term, a party may adopt procedures that expedite the processing of marketing approval applications. In addition, rather than providing an extension to the patent term, a party may instead give a period of additional *sui generis* protection.[5] These TPP obligations will only apply to applications for marketing approval filed after the date of entry into force of this article for that party.

The technical summary of negotiated outcomes relating to the TPP suggests that Canada will opt for a period of additional *sui generis* protection rather than patent-term extension. The technical summary further indicates that the CETA negotiated outcomes with respect to this form of *sui generis* protection are TPP compliant.

The PTR provisions in CETA are set out in Chapter 22, Article 9.2, and appear to be consistent with the governing European legislation relating to SPCs. However, Canada was able to negotiate certain exceptions including an option of limiting the period of protection to a maximum of two years and an export exemption during this period of additional protection.

Under CETA, the period of additional protection is a period equal to the time between the patent application filing date and the date of the first marketing authorisation minus five years, which is then capped at two to five years, subject to a possible pediatric extension. In the October 2013 technical summary of the final negotiated outcomes relating to CETA, the Canadian government indicated that the maximum period in Canada will be two years.

Generally stated, the protection is to apply where a product is protected by a basic patent, the product has been approved, the product has not already been the subject of a period of *sui generis* protection and the approval is the first authorisation to place the product on the market. A basic patent is one protecting a product such as a chemical or biologic drug, a process to produce the product or an application of the product.

The term may only be extended on one patent per product. The period of protection is to take effect at the end of the lawful term of the patent, and is to "confer the same rights as conferred by the patent and shall be subject to the same limitations and obligations". However, the period is only to apply to the approved pharmaceutical product and use.

The period of protection may be limited if the first regulatory submission for marketing approval is not submitted within a reasonable prescribed time limit, or if there are any unjustified delays resulting from inactions of the applicant after applying for the market authorisation.

Parties may impose time limits on when applications for this *sui generis* protection can be submitted, providing that the minimum is no less than 60 days after marketing approval or grant of the patent, if the patent grants after the approval.

The period of protection may be surrendered or lapse if prescribed fees are not paid. Further, the protection may be revoked if the patent is invalidated, the claims of the patent no longer cover the product, marketing approval is withdrawn or if the protection should not have been granted.

Since CETA has not yet been finalised, and neither agreement signed, we have not yet seen draft legislation from the government on precisely how Canada plans on meeting its PTR obligations under either agreement.

**Patent-term adjustment**

The TPP provides for a possible further extension to patent term to account for unreasonable delays by a patent office.[6] Unreasonable delays include delays in issuance of more than five years from the date of filing or three years after a request for examination is made, whichever is later. Parties will be permitted to exclude periods not directly attributable to the granting authority, as well as periods of time attributable to the applicant. Parties may require that a patentee request term adjustment. As with PTR, it is unclear at this stage the precise nature of the amendments that will be made to the Patent Act to meet this TPP commitment.

**Patent-regulatory linkage**

As noted previously, at this time an innovative pharmaceutical company may be unable to pursue an appeal of a negative decision in a proceeding under PMNOC. CETA addresses this issue by requiring all parties to have an effective right of appeal in such proceedings.

There is also the possibility for dual litigation under the current system. The PMNOC regulations provide a summary proceeding in which allegations of patent infringement and patent invalidity are found justified or unjustified. There is no final determination of validity or infringement and thus the same patent can be asserted or challenged as between the same parties based upon the same drug in a separate – dual – proceeding under the Patent Act.

The Canadian government indicated in its technical summary relating to CETA that it will use this opportunity to end dual litigation. There are no details on how these changes in the law will be implemented or whether the system in Canada will ultimately more closely resemble the US scheme for drugs established under the Hatch-Waxman Act.

**Discussion**

There is no information forthcoming from the government as to when CETA may be finalised or the TPP signed. However, newly elected Prime Minister Justin Trudeau has directed the minister of international trade to “develop strategies to implement (CETA) and consult on Canada’s potential participation in the (TPP)” as a top priority.[7] Once the agreement is signed, the process to amend domestic legislation and related regulations may be lengthy. So, while we remain optimistic, the earliest we may see any of the mentioned changes come into effect will be well into 2017.

**Footnotes**

1. The text of the TPP and CETA, as well as the related technical summaries mentioned herein can be found at http://www.international.gc.ca/.

2. “Technical summary of negotiated outcomes”.

3. Article 18.50.

4. TPP text, footnote 55.

5. TPP text, footnote 46.

6. Article 18.46.

7. http://pm.gc.ca/eng/minister-international-trade-mandate-letter

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