Canadian Patent Term Extension – Draft Treaty

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A First Look at Canada-Europe Free Trade Draft on Patent Term Restoration and Other Exclusivities

Canada and Europe announced in October 2013, an agreement in principle on a Comprehensive Economic and Trade Agreement ("CETA"). Its most significant aspect was the potential increase of some drug patent terms by up to two years. An August 5, 2014 draft of the agreement has been leaked ("CETA Consolidated Text"). The Canadian government has refused to authenticate this as a real draft. This article focuses on pharmaceutical IP, which is primarily covered in Article 9 of Chapter 22 in the draft text.

Background on CETA

CETA was the product of several years of negotiations. It is a wide-ranging trade agreement covering diverse topics such as foreign ownership and investments, access to public procurement contracts, automobiles, food (e.g. beef and dairy products) and agriculture. Pharmaceuticals were also a prominent part of the discussion. The agreement was negotiated in secret. Europe was reportedly pressuring Canada to strengthen exclusivities for brand name drugs. The main pharmaceutical intellectual property issues on the table were: i) providing patent term extension, ii) longer period of data exclusivity protection for brand name drugs to keep generics off the market, and iii) improving the right of pharmaceutical companies to appeal a loss in certain specialized pharmaceutical patent litigation cases called "NOC Proceedings".

Patent Term Restoration

Patents give companies the exclusive right to use an invention for a time period, typically up to twenty years from the patent filing date. Patent term restoration of two to five years must be available under the draft treaty terms[1]. The Canadian government has said that extensions will be capped at a maximum of two years.

According to par. 9.2(2) of the draft treaty text, the restoration is available upon request of the brand name company, provided the drug is being approved by Health Canada for the first time. There will be no stacking of multiple patent term extensions – one restoration of one patent term per drug. Where there are multiple patents, the brand name company may have some flexibility to select the benefiting patent[2]. An eligible patent will have to cover one or more of a product per se (i.e., active ingredient or combination), a process to obtain a product or the use of a product (e.g., medical treatment).

The additional protection of patent term restoration will be limited to the specific compound and its approved uses, not the entirety of the patent (for example, if the patent covers non-commercialized drugs, the non-commercialized drugs will not be protected further[3]. This is a similar concept as U.S. patent term extension for FDA regulatory delays. This extension will be available only to drugs entering the market after the new rules come into effect. The draft CETA text provides an exception under the patent term extension for generic drugs to be exported, which was a carve-out promised by Canada to benefit its generic drug industry[4].

Improved Brand Name Rights of Appeal of Court Decisions

The draft also provides in very general terms for improved brand name company rights to appeal NOC Proceeding court decisions[5]. An NOC Proceeding is a court hearing between a brand name company and generic company that reviews patent issues to determine whether a generic company can get its marketing authorization. There is no further information currently available on the nature of these significant litigation changes that have been sought by Canada's brand name pharmaceutical companies for many years.

Data Protection

Canadian data protection for brand name drug companies was discussed in the CETA negotiations, but not changed. It will remain at eight years, which was the Canadian government's preference. The draft shows that these standards will become a minimum treaty obligation through CETA, which would mean that it is more entrenched, and the time period couldn't be readily reduced in future without Canada being in breach of the trade agreement[6]. During the data protection period, a generic drug company cannot get its

marketing authorization by relying on the brand name company's clinical trial data. The rationale for data protection is that brand name companies spend years, and millions of dollars, generating their clinical trial data – it should then not be made immediately available for generic competitors to use for their own purposes as an inexpensive shortcut to get their approval. This data protection period allows the brand name companies an opportunity to recoup their large R&D investment and make a profit.

The draft also provides for at least ten years of data protection for plant protection products, running from the date of first regulatory authorization[7]. These "products" are not defined, but this draft text will be of significant interest to the agricultural industry.

Government – Company Trade Disputes Over Expropriation

In a development made public for the first time, there is a limited carve-out of certain IP issues from expropriation provisions[8]. The draft text states that limitation of IP rights are not expropriation, to the extent that these measures are consistent with CETA and the WIPO Trade Agreement known as "TRIPS"[9]. As well, any determination of inconsistency does not establish expropriation. This does not appear to go far in protecting the countries from pharmaceutical company trade disputes after patents are invalidated on the basis of Canadian court decisions. The issue is that the Canadian government may want to prevent a pharmaceutical company from taking the position that the court's invalidation of the patent applied judge-made law that is inconsistent with international trade obligations, or effectively an expropriation of IP rights. Canada is currently engaged in a trade arbitration with Eli Lilly & Company under the North American Free Trade Agreement following Canadian court invalidation of a couple of valuable Eli Lilly drug patents.

Next Steps

The next Canadian federal election is expected in 2015, so the government may aim to have the deal completed by then. CETA would be in jeopardy if it remained an agreement in principle at election time and there was a change in power.

The federal governments must then pass new laws to implement the patent provisions of CETA. It is unclear the extent to which the government would consult with Canadian stakeholders prior to bringing in new laws. Implementation of this complex trade agreement would be staged so that different portions of laws come into effect at different times. Stay tuned for more information about the timing of pharmaceutical patent changes coming into force.

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[1]The calculation is as follows in par 9.4(a): "…protection shall be for a period equal to the period which elapsed between the date on which the application for a patent was filed and the date of the first authorisation to place the product on the market of that Party as a pharmaceutical product reduced by a period of five years."

[2]Par 9.2(4).

[3]Par. 9.2(5).

[4]Par. 9.2(5).

[5]Article 9 bis.

[6]Article 10. The draft states that this minimum eight year period will consist of at least six years where a generic company cannot file an abbreviated new drug submission, and at least two years thereafter where a generic company may not get its marketing authorization.

[7]Article 11.

[8]Chapter 10. Investment, Article X.11: Expropriation.

[9]Article X.11(6). TRIPS is the "Agreement on Trade-Related Aspects of Intellectual Property Rights."