Canada-EU Comprehensive Economic and Trade Agreement Negotiation Completed: Additional Protection for Innovative Pharmaceutical Products

Life Sciences Bulletin

On September 26, 2014, Canada and the EU announced completion of negotiations on the *Canada-EU Comprehensive Economic and Trade Agreement* (CETA)[1]. This follows the agreement in principle reached on October 18, 2013.[2] If ratified, CETA will

be broader in scope and have further reaching consequences than the *North America Free Trade Agreement*.[3] Unlike NAFTA, which dealt primarily with the elimination of tariffs and specifying levels of trade and investment, CETA deals with such diverse matters as government procurement, standards, cross-border services, labour mobility and intellectual property.

Some of the key intellectual property provisions in CETA are specific to innovative pharmaceutical companies. In this regard, CETA will provide the following regimes and protection for innovative pharmaceutical products: 1) a *sui generis* protection regime; 2) an equivalent and effective right of appeal; and 3) data protection.

1. *Sui Generis Protection*

CETA will provide *sui generis* protection for first marketed pharmaceutical products protected by eligible patents in Canada. This will provide pharmaceutical products with a term of protection[4] defined by the length of time elapsed between an application for the eligible patent and the date of the marketing authorization, less 5 years, added to the end of the expiry of the term of the eligible patent. Protection will be subject to the following considerations[5]:

a) Only marketed products protected by "basic patents" will be eligible for the *sui generis* protection (i.e. patents covering a product, process of manufacture or use).

b) Only one term of protection will be granted for any marketed product.

c) Only marketed products that are the subject of the first marketing authorization are eligible for protection (i.e. products approved by New Drug Submission (NDS) versus a Supplement to a New Drug Submission (SNDS) or an Abbreviated New Drug Submission (ANDS)).

Highlights

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d) If multiple basic patents cover a product, a single basic patent must be selected as the basis for the calculation of the term of protection.

e) *Sui generis* protection will be subject to an absolute maximum period of 2 to 5 years, at the option of the party implementing the sui generis protection. Canada has indicated that the period of protection will never exceed two years.[6]

f) Period of sui generis protection may be reduced commensurate with any unjustifiable delays resulting from inactions of the applicant after applying for marketing authorization.

g) *Sui generis* protection may be subject to time limits (i.e. the marketed pharmaceutical product may be subject to a requirement to apply for marketing authorization within a "reasonable time");

h) Requests for *sui generis* protection may be subject to a time limit; i.e. the request may have to be filed no less than 60 days from receipt of marketing authorization (however, where a patent is granted after marketing authorization has issued, patentees must be given at least 60 days from grant of patent to request protection).

i) *Sui generis* protection may be subject to lapse in cases of surrender of protection, failure to pay administrative fees or revocation if the basic patent is rendered invalid or otherwise lapses.

j) *Sui generis* protection may be subject to exceptions yet to be defined.

k) Canada has indicated that the sui generis protection will not apply retroactively to pharmaceutical products that are already approved and on the Canadian market.[7]

2. Right of Appeal under the Patented Medicines (Notice of Compliance) Regulations

CETA will require that all litigants under proceedings involving "patent linkage" mechanisms (i.e. where the grant of marketing authorizations for generic pharmaceutical products is linked to the existence of patent protection) are afforded equivalent and effective rights of appeal[8].

In Canada, this will guarantee a right of appeal for innovative pharmaceutical companies under the Patented Medicines (Notice of Compliance) Regulations.[9] This will effectively reverse the jurisprudential trend in Canada, which barred innovative pharmaceutical companies from their right of appeal, on the basis of mootness, once a notice of compliance had issued to a generic company, following an unsuccessful application for prohibition under the Regulations.[10] Amendments to the Regulations are therefore to be expected.

3. Data Protection

CETA does not include substantial changes to Canada's current data protection regime, which provides for a period of 8 years protection from receipt of a marketing authorization. The request for 10 years of protection sought by the EU

was not accepted. CETA does confirm that the data protection regime applies to biologic and radiopharmaceutical drugs.[11]

If ratified, CETA's intellectual property provisions should provide relief to Canadian innovative pharmaceutical companies, burdened by the inefficiencies of the system currently in place. However, the utility of the provisions can only be assessed once the details on implementation and the exceptions and limitations have been defined.

Ratification will require approval of the Council of the EU and the European Parliament and the provinces and territories of Canada. As a result, the earliest that CETA may come into effect would be 2016.

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[1] *Canada-EU Comprehensive Economic and Trade Agreement*, Canada and the European Union;

[2] Julie Desrosiers & Mélanie Bourassa Forcier, "Canada-EU Comprehensive Economic and Trade Agreement (CETA) reached in principle : What is the impact on pharmaceutical patents?" (22 October 2013)

[3] *North America Tree Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States*, 17 December 1992, Can TS 1994 No 2, 32 ILM 289 (entered into force 1 January 1994);

[4] Often referred to as patent term restoration;

[5] CETA, *supra*, note 1 at Article 9.2;

[6] Technical Summary of Final Negotiated Outcomes, Canada-European Union Comprehensive Economic and Trade Agreement;

[7] *Ibid*;

[8] CETA, *supra*, note 1 at Article 9 bis;

[9] *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133

[10] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359.

[11] CETA, *supra*, note 1 at Article 10.