Canadian Patent Term Extension - Bill is in the House

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Author: Noel Courage

Canada and Europe finally signed off on the Comprehensive Economic and Trade Agreement ("**CETA**"). Its most significant aspect for the pharma industry is prospect of increased drug patent terms by up to 2 years. Not long after the ink was dry on CETA, an amendment (implementation) Bill was introduced into Canadian Parliament on October 31, 2016. This Bill is the first concrete domestic legislative step toward becoming a law[1].

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.

Patent Term Extension - Supplementary Protection Certificate

Patents give companies the exclusive right to use an invention for a time period, typically up to 20 years from the patent filing date. A maximum two years of additional patent rights for an approved drug will be available by way of a Supplementary Protection Certificate ("**SPC**")[2]. The proposed Canadian SPC system is based on the European SPC system. It provides the same practical effect as as a patent term extension, but the additional patent protection is effected by the SPC. The SPC is limited to the particular medicine that is an approved drug (for example, if the patent covers non-commercialized drugs, the non-commercialized drugs will not be protected further). The additional SPC patent protection will be capped at a maximum of 2 years, as discussed in more detail below.

What drugs and patents qualify?

Eligible drugs are defined broadly to include human and veterinary drugs[3]. This article will focus on human SPC issues. If the same drug is useful for both purposes, they are to be treated as different drugs for purposes of the SPC rules[4]. Variants of a drug will be treated the same (ie. only one SPC, per drug)[5]. Reissued patents are also eligible for an SPC[6].

The SPC is available upon request of the brand name company, for a patent filed on or after October 1, 1989[7]. The patent will have to pertain to a medicinal ingredient, or a combo, that was authorized after a cut-off date to be set by government[8]. *Drugs approved for sale in Canada prior to this cut-off date will not be eligible to apply for a SPC.* The SPC is only available where the drug is being approved by Health Canada (Canada's equivalent of the US FDA) for the first time[9]. There will be no stacking of multiple SPC's – one SPC for one patent per drug.

The SPC Application Process

The main deadline to file an application for SPC protection will be based on a time period to be set by government regulation in future[10]. The time period will start to run on the day that Canadian marketing authorization is granted by Health Canada (assuming

the patent is granted on that date; otherwise, the time period will start to run later, from the date of patent grant).

To qualify for the SPC, there also appears to be a limited time period to file a new drug submission in Canada after filing a corresponding drug submission is filed in certain other countries[11]. This time period will start to run from the date of filing of the corresponding foreign new drug submission. This is intended to encourage companies to promptly file a new drug submission in Canada. It also appears to be a risk for companies to lose the option for Canadian SPC protection, by not paying attention to the timing requirements.

Where there are multiple patents, the brand name company has the flexibility to select the benefiting patent for the drug. Only one patent can be the subject of an SPC[12]. Eligible patents will include one or more claims, such as to a product per se (ie. active ingredient alone or in a combination), a process to obtain a product or the use of a product (eg. medical treatment)[13].

The SPC Rights and Term

The SPC will set out the patent number, identify the drug, as well as the starting and end dates of the SPC protection. It takes effect after the patent expiry date. The term is for a maximum of two years, but may be shorter depending on the patent issue date and how quickly regulatory review proceeded at Health Canada[14]. Health Canada may shorten the SPC term if it believes that the Applicant delayed getting its marketing authorization to try to increase SPC term. Price regulation will continue to apply during the SPC term[15].

The usual exceptions to infringement for work relating to development of information for a regulatory submission continue to apply. There is an additional exception to infringement for generic drugs to be exported, which was a carve-out promised by Canada to benefit its generic drug industry[16].

The SPC is transferrable along with the corresponding whole or a part of the patent.

SPC is presumed valid in litigation[17]. An SPC infringement action may be brought in the same manner as a patent infringement action[18]. If the underlying patent is found invalid in court, the SPC is also void[19]. The Federal Court of Canada has jurisdiction to rule an SPC void[20].

Next Steps

The Bill goes through additional readings in the House of Parliament before it is passed as a law and comes into force. There are likely to be some edits to the Bill along the way, though the substance of the SPC itself is unlikely to change much. There are still a number of important gaps to be filled in by regulators relating to timelines and other issues, and we will provide updates on those issues in future.

Click here for our article on changes to patent litigation under the Bill.

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[1] Bill C-30, An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures, First Session, Forty-second Parliament,64-65 Elizabeth II, 2015-2016 (first reading October 31, 2016).

[2] These new rules are in s. 50 of the amending Act. They are currently intended to be inserted in the Patent Act as Sections 104 onward. The SPC grant is enabled by s.110.

[3] "drug" ***drug*** means a substance or a mixture of substances manufactured, sold or represented for use in 15

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its

symptoms, in human beings or animals; or (b) restoring, correcting or modifying organic functions in human beings or animals.

[4] S.105(2).

[5] S. 105(5).

[6] S. 47(1.1), s.105(1).

[7] S.106(b).

[8] S.106(c).

[9] S.106(d).

[10] S.106(3).

[11] S. 106(f). The other countries will be identified by future regulation.

[12] S. 106(6). There is also a process to resolve competing claims for an SPC.

[13] S. 124. Regulation will set out the categories of patents more specifically, but prior government guidance indicated it will include at least those noted in this article.

[14] The SPC term is calculated by subtracting five years from the patent application filing date and ending on the date of the Health Canada marketing authorization (two years maximum). To get an SPC, the calculation must not produce a zero or negative value.

[15] See the Bill starting at s.46.

[16] S.115(2).

[17] S.116(1).

[18] S.124.

[19] S.125.

[20] S.110(1). See also s. 128 of the Bill re amendments to the *Federal Courts Act* to give the FCC jurisidiction over SPC issues generally.