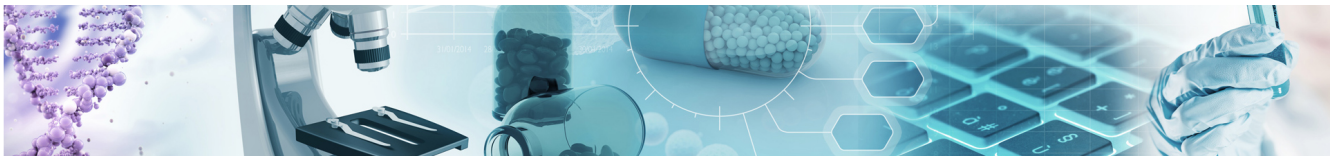

Extension of Drug Patent Terms in Canada – Certificates of Supplementary Protection (CSPs)

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The vast majority[1] of Canadian patents currently in force carry a term limited to twenty years from the filing date. However, as part of Canada's obligations under CETA[2] certain patents relating to drugs authorized for human or veterinary use now qualify for up to two additional years of protection[3] through a Certificate of Supplementary Protection (CSP). This article provides a brief overview of this new form of patent term extension including what patents are eligible, timing considerations and the requirements for an application.

Eligible Patents

To be eligible for a CSP, the patent must be in force and have issued from an application filed on or after October 1, 1989. The patent must also pertain to a medicinal ingredient or a combination of medicinal ingredients contained in a drug for which a notice of compliance (marketing authorization) has issued on or after September 21, 2017.

A patent pertains to a medicinal ingredient or combination thereof if it contains a claim for:

(a) the medicinal ingredient or combination of all the medicinal ingredients;

(b) the medicinal ingredient or combination of all the medicinal ingredients as obtained by a specified process; or

(c) a use of the medicinal ingredient or combination of all the medicinal ingredients,

contained in the drug for which the notice of compliance issued. Claims that are directed to formulations comprising a medicinal ingredient in combination with other elements are not eligible for a CSP.[4] Uses of such formulations are also likely not eligible for a CSP. This reflects the language of CETA which refers to patents that protect "a product as such".[5] The claimed use does not need to match the use approved in the notice of compliance; it merely needs to include use in humans or animals, as the case may be.[6]

The notice of compliance must be the first that has been issued with respect to a medicinal ingredient or combination thereof. Additionally, there may only be one CSP issued in respect of a medicinal ingredient or combination thereof.[7] The *CSP Regulations*[8] set out a number of variations in structure of a particular medicinal ingredient which would result in a finding that they are the same medicinal ingredient.[9] In addition, for the purposes of CSPs, if combinations vary only with respect to the ratio between the medicinal ingredients, they are treated as the same combination. However, if a medical ingredient or combination of medicinal ingredients contained in a drug is authorized for both human and veterinary use, these are treated as different medicinal ingredients or combinations.

Timing Considerations

To be eligible for a CSP, the application for marketing approval in Canada must have been made within a certain period from the time the first marketing approval was submitted in any one of the following countries/regions: the European Union (and any country that is a member of the European Union), the United States, Australia, Switzerland and Japan. If the CSP application is filed up until September 21, 2018 the period of time is 24 months. After this day, the period of time will be 12 months.

If the patent was already granted at the time the notice of compliance issues, the CSP application must be filed within 120

days from the day on which the notice of compliance issued. If the patent application is still pending at the time the notice of compliance issues, the CSP application must be filed within 120 days from the time the patent is granted.

Application Formalities

The contents of the CSP application are not onerous. The application requires two forms; the "Certificate of Supplementary Protection (CSP) Application Form" and the "Advance Payment Details for Drug Submissions and Master Files for Human and Disinfectant Drugs, and Certificate of Supplementary Protection Applications Form" and paying the required fee. The information needed for these forms is generally clerical in nature.

The application fee for a CSP was initially CDN $9,011. Beginning on April 1, 2018, the fee increased annually by 2% of the fee payable in the previous year, rounded up to the nearest dollar. This means the fee is currently CDN $9192.

Outlook

According to the register maintained by Health Canada, eighteen applications for CSPs have now been filed for human use and one has been filed for veterinary use. Of the applications, twelve have issued, four are still pending and only three have been rejected. All of the CSPs which have issued to date are for the maximum term of two years.

Patentees interested in seeking CSP protection for a patent relating to a drug should be mindful of the important timing requirements both in respect of the filing of applications for marketing approval and the CSP application itself. Patentees should also be aware that the subject-matter eligible for a CSP does not completely overlap with that eligible for listing on Health Canada's Patent Register. Accordingly, if there is interest down the line in seeking a CSP for a patent application that is still pending at the Canadian Patent Office, patentees may wish to consult with their agent to ensure, where possible, claims are included that fit within the above-discussed categories of eligible subject-matter. To this end, because CSPs only recently became available in Canada, it will be some time before we receive any interpretation from the courts regarding these provisions. In the interim, Health Canada has provided some guidance on its interpretation of subject-matter eligibility, including assessment of variations between medicinal ingredients.

1There still remain a few "Old Act" patents in force which have been granted from applications filed before October 1, 1989 and have a term of seventeen years from the issue date.

2*Canada-European Union Comprehensive Economic and Trade Agreement*, 30 October 2016 (entered into force 21 September 2017) ["*CETA*"].

3The term is calculated by subtracting five years from the period beginning on the filing date of the application for the patent and ending on the day on which the notice of compliance set out in the certificate is issued, up to a maximum of two years. It may be reduced if there is a finding of unjustified delay in the process of obtaining the notice of compliance.

The scope of a CSP is generally narrower than the protection afforded by the corresponding patent in that it only pertains to the making, constructing, using and selling of any drug that contains a claimed medicinal ingredient or combination thereof and does not encompass exports.

4*Guidance Document: Certificate of Supplementary Protection Regulations*, Minister of Health, 21 September 2017 [*Health Canada Guidance Document*].

5*CETA*, Article 20.27 [emphasis added].

6*Health Canada Guidance Document*, s 2.2.8.

7This includes circumstances where a CSP has issued and is subsequently held to be void, where the CSP never takes effect (i.e. where the calculation of its term produces a result of zero or a negative result) or where the CSP ceases to have effect. The *Patent Act* also sets out a scheme for determining priority when more than one CSP application sets out the same notice of compliance. Where two or more pending applications have the same priority and different applicants, an applicant may apply to the Federal Court for a declaration that another pending CSP application be declared invalid or void for not meeting the conditions to obtain a CSP.

8*Certificate of Supplementary Protection Regulations*, SOR/2017-165 [“*CSP Regulations*”].

9*CSP Regulations*, s 2. These are: (a) a variation in any appendage within the molecular structure of a medicinal ingredient that causes it to be an ester, salt, complex, chelate, clathrate or any non-covalent derivative; (b) a variation that is an enantiomer, or a mixture of enantiomers, of a medicinal ingredient; (c) a variation that is a solvate or polymorph of a medicinal ingredient; (d) an *in vivo* or *in vitro* post-translational modification of a medicinal ingredient; and (e) any combination of the variations set out in paragraphs (a) to (d).