# Certificates of Supplemental Protection

**September 22, 2017**

Patent term restoration now available in Canada

For the first time, as of September 21, 2017, Canada has a form of patent term restoration. This will restore part of a patent's term in relation to certain drug products in response to delays in receiving marketing authorization from Health Canada.

**What You Need to Know**

**Eligible Authorizations for Sale**

The Authorization for Sale is a Notice of Compliance ("NOC") issued pursuant to s. C.08.004 or C.08.004.01 of the *Food and Drug Regulations*.

It must be the first NOC issued for that medicinal ingredient or combination of medicinal ingredients. The NOC must have been issued on or after September 21, 2017.

If Canada is not the first country for which an application for marketing approval for that medicinal ingredient or combination has been submitted, the application for the NOC in Canada must have been filed within 12 months* of the earliest foreign application for marketing approval in:

- The European Union and any country that is a member of the EU;
- The United States of America;
- Australia;
- Switzerland; and
- Japan

(*This period is 24 months if the application for a Certificate of Supplemental Protection ("CSP") is filed no later than September 21, 2018.)

**Eligible Medicinal Ingredients**

The following "prescribed variations" of medicinal ingredients will be considered to be the same medicinal ingredient for the purposes of determining whether the NOC is the "first":

- Esters, salts, complexes, chelates, clathrates, or other non-covalent derivatives;
- Enantiomers or mixtures of enantiomers;
- Solvates or polymorphs;
- In vivo or *in vitro* post-translational modifications; and
- Any combination of the above variations.

However, a medicinal ingredient or combination will not be considered the same if they are approved for human and for veterinary uses.

There can have been no other CSP issued for the medicinal ingredient.

**Eligible Patents**

For a patent to be eligible, it must meet the following requirements:

- It must be in force (not expired or void).
- It must pertain to a medicinal ingredient or combination of medicinal ingredients in a drug for which the NOC was issued, and contain a claim for:
    - The medicinal ingredient or combination,
    - The medicinal ingredient or combination as obtained by a specified process, or
    - The use of the medicinal ingredient or combination.
- It must have been filed after October 1, 1989.

**How to Apply**

Health Canada has stated there will be a CSP form. If the criteria with respect to medicinal ingredient and patent eligibility are met, then one can apply for a CSP. One must apply within 120 days of the day on which the NOC is issued, if the patent is granted before that day, or with 120 days of the day on which the patent is granted, if the patent is granted after the NOC is issued.

The prescribed fee will be C$9011 until April 1, 2018. Beginning on that date, the feel will increase annually by 2% of the previous year's fee, rounded up to the nearest dollar.

Each application can only set out one patent.

The application must contain:

- The applicant's name and contact information in Canada; including their complete address;
- The filing date, issue date, and expiry date of the patent;
- An attestation that either the applicant is the patentee recorded as patent owner in the Patent Office, or that they are the manufacturer who is authorized to file the application.
    - In order to be authorized to file the application, the manufacturer must hold the NOC.
- An attestation that either when the application for an NOC was filed:
    - no authorization for sale with respect to the medicinal ingredient or combination had been submitted in any of the prescribed countries; or

    - that if an authorization for sale had been submitted in one or more of those countries, the application for the NOC was filed within a year of the filing of the application for marketing authorization in one of those countries.
- A description of the method of payment used to pay the fee.

**The Certificate**

The Minister of Health will issue a CSP if the criteria are met and the period for applying for a CSP has expired and no other application has been filed. (If other applications have been filed; there are a series of priority provisions for determining who has priority to the CSP).

The Certificate will contain:

- the number, as recorded in the Patent Office, of the patent set out in the application;
- the medicinal ingredient or combination of medicinal ingredients set out in the application;
- a statement as to whether the certificate relates to use in humans or to veterinary use;
- the number of the authorization for sale set out in the application; and
- the day on which the certificate's term begins and the day on which the term ends.

The holder of the CSP will have the same rights and privileges as a patentee with respect to making, constructing, using, and selling any drug referenced in the CSP. However, it will not be considered an infringement of the CSP if the medicinal ingredient or combination is made, constructed, used or sold for export.

The CSP will take effect upon expiry of the patent and be valid for a period of not more than two years. It 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 NOC set out in the certificate is issued, but in any event is for a maximum of two years. This period can be reduced if the Minister is of the opinion that that the holder's failure to act resulted in a period of unjustified delay in the process of obtaining the NOC.

The Minister will maintain an electronic register of applications for CSPs and CSPs. Both will list the medicinal ingredient and the date on which the term of the patent expires/date upon which the CSP will take effect and whether the medicinal ingredient is for human or veterinary use. The CSP register will also list the date upon which the term ends.

By

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