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

Beverley Moore

Expertise

Intellectual Property

BLG | Canada's Law Firm

As the largest, truly full-service Canadian law firm, Borden Ladner Gervais LLP (BLG) delivers practical legal advice for domestic and international clients across more practices and industries than any Canadian firm. With over 800 lawyers, intellectual property agents and other professionals, BLG serves the legal needs of businesses and institutions across Canada and beyond – from M&A and capital markets, to disputes, financing, and trademark & patent registration.

blg.com

BLG Offices

Calgary

Centennial Place, East Tower
520 3rd Avenue S.W.
Calgary, AB, Canada
T2P 0R3

T 403.232.9500
F 403.266.1395

Ottawa

World Exchange Plaza
100 Queen Street
Ottawa, ON, Canada
K1P 1J9

T 613.237.5160
F 613.230.8842

Vancouver

1200 Waterfront Centre
200 Burrard Street
Vancouver, BC, Canada
V7X 1T2

T 604.687.5744
F 604.687.1415

Montréal

1000 De La Gauchetière Street West
Suite 900
Montréal, QC, Canada
H3B 5H4

T 514.954.2555
F 514.879.9015

Toronto

Bay Adelaide Centre, East Tower
22 Adelaide Street West
Toronto, ON, Canada
M5H 4E3

T 416.367.6000
F 416.367.6749

The information contained herein is of a general nature and is not intended to constitute legal advice, a complete statement of the law, or an opinion on any subject. No one should act upon it or refrain from acting without a thorough examination of the law after the facts of a specific situation are considered. You are urged to consult your legal adviser in cases of specific questions or concerns. BLG does not warrant or guarantee the accuracy, currency or completeness of this publication. No part of this publication may be reproduced without prior written permission of Borden Ladner Gervais LLP. If this publication was sent to you by BLG and you do not wish to receive further publications from BLG, you may ask to remove your contact information from our mailing lists by emailing unsubscribe@blg.com or manage your subscription preferences at blg.com/MyPreferences. If you feel you have received this message in error please contact communications@blg.com. BLG's privacy policy for publications may be found at blg.com/en/privacy.

© 2026 Borden Ladner Gervais LLP. Borden Ladner Gervais LLP is an Ontario Limited Liability Partnership.