

Patent term restoration in Canada

August 01, 2023

The Certificate of Supplementary Protection (CSP) regime aims to restore some of the time lost to regulatory approval of patented medicines in Canada. Up to two years of patent term can be restored by way of CSP.

Three main requirements

1. Eligible regulatory approval:

- NOC pursuant to Canada's *Food and Drug Regulations*;
- It must be the first NOC for that medicinal ingredient;
- It must have issued after September 21, 2017; and
- 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 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;
 - United Kingdom; and
 - Japan.

2. Eligible medicinal ingredient:

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

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

3. Eligible patent:

- It must be in force and not expired or void;
- It must have been filed after October 1, 1989; and
- It must pertain to the medicinal ingredient or combination of medicinal ingredients in the drug for which the Notice of Compliance (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.

Calculation of time

Period of the CSP

The time to be restored is calculated by subtracting five years from the period beginning on the filing date of the patent application and ending on the day on which the NOC or marketing approval set out in the certificate is issued. From that resulting number, up to a maximum of two years is allowed.

The CSP will take effect upon expiry of the patent and will only restore patent term for the specific molecule approved in the NOC.

The Minister of Health can reduce this calculated period if the holder's failure to act resulted in a period of unjustified delay in the process of obtaining the NOC.

Timing for filing the CSP

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.

Additional details

The prescribed fee is C\$10,152 as of April 1, 2023. The fee will increase annually by 2 per cent of the previous year's fee, rounded up to the nearest dollar.

Health Canada publishes an online CSP Application Form. It must be filed together with advance payment details.

The Minister of Health will issue a CSP if the criteria are met and if 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).

CSPs are eligible for listing on the Patent Register. However, they are also reportable to the PMPRB.

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.

By

[Beverley Moore](#)

Expertise

[Intellectual Property](#), [Patents](#), [Life Sciences](#)

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 725 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.

© 2024 Borden Ladner Gervais LLP. Borden Ladner Gervais LLP is an Ontario Limited Liability Partnership.