Patent term restoration in Canada

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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

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