Patent Term Restoration in Canada

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Canada's patent term restoration regime has been up and running for over a year and a half. As of the end of April 2019, there have been 38 applications filed, and 29 granted; seven have been refused and the remainder are pending. The regime seems to be effective for those companies that are able to file their drug submissions in Canada within a year of the first filing in other major jurisdictions.

This one-year deadline is seen as the major impediment for companies that are trying to take advantage of this regime. For many larger companies, it appears that they have been able to move resources around and change their filing strategy in order to meet this deadline, however, smaller biotechnology and pharmaceutical companies do not necessarily have the resources to dedicate to filing in multiple jurisdictions before they have approval in a major market, such as the U.S. or Europe.

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

As the regime seems to be here to stay, companies should take note of its requirements and devise a filing strategy in order to ensure that they are not prevented from taking advantage of the scheme.

There are 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:

- Must be in force and not expired or void;
- Must have been filed after October 1, 1989;
- 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.

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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