Certificates of Supplementary Protection

Canada's New Patent Term Restoration Regime

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Certificates of Supplementary Protection

- **As of September 21, 2017, Canada has a form of patent term restoration – called a Certificate of Supplementary Protection (CSP)**

- **Governed by provisions in the *Patent Act*, and the *Certificate of Supplementary Protection Regulations***

- **Interacts with the *Food and Drug Regulations***

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Eligibility

- **To be eligible for a CSP, you need 3 things:**
  1. Eligible authorization for sale
  2. Eligible medicinal ingredient or combination
  3. Eligible patent

1. Eligible Authorization for Sale

- **Notice of Compliance (NOC) pursuant to s. C.08.004 or C.08.004.1 of the *Food and Drug Regulations***
- **Must be the first NOC issued for that medicinal ingredient or combination**
- **NOC must have been issued after Sept. 21 2017**

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1. Eligible Authorization for Sale Cont'd

- **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; and
  - Japan.

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2. 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 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 will not be considered the same if they are approved for human and for veterinary uses**

3. Eligible Patents

- **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

Term of the CSP

- **The period is calculated by:**
  - taking the period beginning on the filing date of the patent application and ending on the day on which the NOC set out in the certificate is issued,
  - subtracting five years,
  - up to a maximum of two years.
- **The CSP will take effect upon expiry of the patent.**
- **Minister can reduce this period if the holder's failure to act resulted in a period of unjustified delay in the process of obtaining the NOC.**

How to Apply

- **Form on Health Canada's website:**
  - https://health-products.canada.ca/forms/csp-cps/certificate-supplementary-protection-form.html
- **Each application can contain only one patent**
  - If the patent is issued before the NOC issues, must apply within 120 days of the issuance of the NOC
  - If the patent is issued after the NOC, must apply within 120 days of patent issuance
- **The prescribed fee will be C$9388 until April 1, 2020.**
  - the fee increases annually by 2% of the previous year's fee, rounded up to the nearest dollar.

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**

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Current Status

- **Since regime started in September 2017, 38 applications for CSPs have been made**
  - 36 human
  - 2 veterinary

- **28 have issued**
- **3 are pending**
- **7 have been refused**

- **Of the refusals, two companies have started judicial reviews of those decisions**

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Judicial Reviews of CSP Refusals

- **GlaxoSmithKline Biologicals – with respect to SHINGRIX**
  - Patent claims use of an immunogenic composition to make a vaccine where the composition contains a gE antigen (truncated), and an adjuvant
  - Vaccine is described in the NDS as a two-component vaccine containing the gE antigen and the adjuvant
  - Minister refused CSP due to patent not claiming a medicinal ingredient or the use of a medicinal ingredient; essentially:
    - SHINGRIX only has one medicinal ingredient – the gE antigen
    - Adjuvant is non-medicinal; other non-medicinal ingredients in claim
    - No provisions for CSP for use of formulation

- **ViiV – with respect to drug JULUCA**
  - Patent claims dolutegravir
  - Drug contains dolutegravir and rilpivirine
  - Minister refused CSP due to patent claiming only one of the two medicinal ingredients in the drug

Rights in a CSP

- **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.**

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How CSPs Fit within Other Regimes

- **CSPs can be listed on the Patent Register**
  - Thus can take advantage of the *Patented Medicines (Notice of Compliance) Regulations*

- **CSP will have to be reported to the PMPRB - soon?**
  - Amendments to the *Patent Act* have been passed but are not yet in force
  - Amendments to the *Patented Medicines Regulations* are proposed
  - Once enacted, the PMPRB will have pricing jurisdiction for both the term of the patent and the CSP

- **CSP will not affect data protection period**
  - Still 6 + 2 + 0.5 years

Thank You

- **Questions?**

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