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Comparing Supplementary Protection Regimes Between Canada (CSPs) and the EU (SPCs)

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In 2017, amendments to the Canadian *Patent Act* and enactment of the *Certificate of Supplementary Protection Regulations* flowing from the Canada-European Union (EU) Comprehensive Economic and Trade Agreement (CETA, see our article here) introduced a new framework in Canada for the issuance of Certificates of Supplementary Protection (CSPs).

CSPs provide an additional patent-like protection term, and are intended to partly compensate the innovator for the time required for research and obtaining regulatory approval in Canada. CSPs are similar to the European system of Supplementary Protection Certificates (SPCs), with a number of key differences, including a shorter capped term of 2 years, as compared to 5 years in the EU. Key aspects of the two regimes are compared in the chart below. A special thank you to Daniel Wise, partner, Carpmaels & Ransford, for contributing the SPC details.

	Canada	**Member States of European Union (EU) and European Economic Area (EEA), and the UK**
Protection	Certificate of Supplementary Protection (CSP)	Supplementary Protection Certificate (SPC)
Governing legislation	*Patent Act*, sections 104-134 *Certificate of Supplementary Protection Regulations*	*Regulation (EC) No 469/2009* (medicinal products) *Regulation (EC) No 1901/2006* (medicinal products for pediatric use) *Regulation (EC) No 1610/96* (plant protection products)
Guidance	Health Canada Guidance Document	No official texts at EU level, but some national patent offices produce their own guidelines.

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Register	*Register of Certificates of Supplementary Protection and Applications.*	Available for each national patent office.
Drugs covered	Human small molecules and biologics, and veterinary small molecules.	Small molecules, biologics, human or veterinary. Also plant protection products and some diagnostic products.
Term	From patent application filing date until NOC date, minus five years, **capped at 2 years.**	From patent application filing until first marketing authorization (MA) in the EU/EEA, minus 5 years, **capped at 5 years** (or 5.5 years with pediatric extension). The term of UK SPCs are calculated in the same way but on the basis of the first marketing authorisation in the EEA or the UK.
Pediatric extension	N/A	Additional 6 months possible.
Reduction in term	Possible if NOC holder is also patentee, and failure to act resulted in unjustified delay in obtaining NOC.	N/A
Eligible patent	Patent must include a product or product-by-process claim for the medicinal ingredient or combination of medicinal ingredients contained in an approved drug; or a use thereof (whether the claimed use is approved or not).	Patent must include a product, product-by-process, or process claim that protects the active ingredient or combination of active ingredients contained in an approved drug; or a use thereof (possibly whether the claimed use is approved or not).

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Scope of protection	Same rights as patent, but only with respect to use etc. of "any drug that contains the medicinal ingredient, or combination of medicinal ingredients [and prescribed variations thereof], set out in the certificate, by itself or in addition to any other medicinal ingredient". Exception: CSP does not apply to use etc. for export.	Same rights as patent but limited to the approved drug at issue and any later approved drugs containing the same active ingredient or combination of active ingredients.
Assertable under Linkage Regulations	Yes (*Patented Medicines (Notice of Compliance) Regulations*)	N/A
Where application filed	Health Canada.	National patent office of each desired country.
Deadline for filing application	Before the end of 120 days beginning on later of NOC date and patent grant date.	6 months of later of the MA or patent grant date in the country at issue.
Deadline for filing regulatory submission	Before the end of 12 months beginning on date of first regulatory submission filing for the medicinal ingredient or combination of medicinal ingredients in EU or any member country thereof, US, Australia, Switzerland, Japan or UK.	N/A
Protection by basic patent in force requirement	N/A	Yes, basic patent must be in force on date SPC application is filed.

First NOC/MA requirement	CSP application must be based on the first NOC (human or veterinary, as the case may be) for the medicinal ingredient, combination of medicinal ingredients or prescribed variations thereof provided such NOC was granted on or after September 21, 2017. Prior approvals for regular sale other than NOCs also preclude a CSP.	SPC application must be based on the first MA (human or veterinary) in that country for a product which incorporates the active ingredient or combination of active ingredients.
Number of CSPs/SPCs per drug product	One	One per patentee per active ingredient or combination of active ingredients.
Third party filing	Yes, possible (i.e. patentee-applicant need not be holder of NOC; patentee can authorize holder of NOC to file on its behalf).	Yes, possible in theory (i.e. patentee-applicant need not be holder of MA), although the law is unclear in this area.
Priority determinations	Yes (see Health Canada Guidance Document).	N/A because multiple patentees may each obtain their own SPC.
Consideration of third party observations during pendency of application review	No indication yet that Health Canada will consider any such observations.	Yes, by some patent offices.
Declaration of invalidity of CSP application/CSP	Federal Court may declare pending CSP application (only at instance of another CSP applicant based on same NOC and having same priority) or CSP void.	Determined by national authorities on application to patent office or court.