

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

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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)

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| 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 paediatric 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 | <u>Register of Certificates of Supplementary Protection and Applications.</u> | 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 two years. | From patent application filing until first marketing authorization (MA) in the EU/EEA, minus five years, capped at five years (or 5.5 years with pediatric extension). |
| 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 an approved use thereof. |
| 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. |



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| Assertable under Linkage Regulations | Yes (<i>Patented Medicines (Notice of Compliance) Regulations</i>) | N/A |
| Where application filed | Health Canada. | National patent office of each desired country. |
| Deadline for filing application | 120 days of later of NOC date or patent grant date. | 6 months of later of the MA date in the country at issue or patent grant date. |
| Deadline for filing regulatory submission | 12 months 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 |



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

Patent Act, sections 108-111;
CSP Regulations, s. 11.
Highest priority to applications for patents granted on or before the NOC date.

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.