

Comparative Analysis of Canadian ‘Certificate of Supplementary Protection’ with USA and Australian ‘Patent Term Extension’ and European ‘Supplementary Protection Certificate’

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As a result of Comprehensive Economic and Trade Agreement (CETA), for the first time, on 21 September 2017, Canada introduced Certificate of Supplementary Protection (CSP) regime. Before CETA was executed, Canada was the only country of G7 (Group of 7) countries not to legislate Patent Term Extension (PTE). This new regime is an important moment for the Canada’s intellectual property (IP) framework. On one hand, this regime provides an opportunity to innovators of pharmaceutical and veterinary products to recover investments made to obtain marketing authorizations for medicinal products, and on other hand, it impacts the timing of entry of generic products in the Canadian market. This article provides comprehensive information regarding the Canadian CSP and its comparative analysis with United States of America and Australian PTE and European Supplementary Protection Certificate (SPC).

Keywords: Certificate of Supplementary Protection, Patent Term Extension, Supplementary Protection Certificate, Comprehensive Economic and Trade Agreement, TRIPS, Canadian Patent Act, Notice of compliance, Patent Term Adjustment, Regulatory Review Period, Investigational New Drug, Investigational Device Exemption, New Drug Application, Biologic License Application, Pre-Marketing Authorization, United States Food And Drug Administration, Therapeutic Goods Administration, Australian Register of Therapeutic Goods, Australian Patent Act, 1990, The Court of Justice of the European Union

Under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, the available term of patent protection must expire no earlier than 20 years from the date of filing the application. Although, the issue of patent term extension to compensate for regulatory delays in the marketing of new pharmaceutical products was raised in the Uruguay Round of negotiations, the TRIPS Agreement does not contain an obligation to introduce such a system. The European Union (EU) and Canada signed ‘Comprehensive Economic and Trade Agreement’ (CETA) on 30 October 2016.¹

Under CETA, Canada agreed *inter alia*, to make number of important changes to intellectual property protection for pharmaceutical patents in order to bring Canadian patent practice more in line with European practice.² As a result of CETA, on 21 September 2017, Canada amended its *Patent Act 1985* and introduced CSP for pharmaceutical and veterinary

products.³ This is a major development as Canada has lagged behind other industrialized countries in the protection of pharmaceutical and veterinary patents, since no extension of patent term was previously available.⁴ The Canadian CSP regime has been created with the aim of meeting obligations under Article 20.27 of CETA, which requires parties to provide an additional period of protection for patent-protected pharmaceutical products, while continuing to balance the interests of stakeholders and the public within the Canadian Patent Act. Consultations with stakeholders were done on the CSP regime outlined in the Canadian Patent Act and the proposed Regulations of CSP as well as the application fee. Both generic and innovative industry members were involved in the consultations.⁵

Canadian Patent Act, 1985

Canadian Patent Act was amended on 21 September 2017, *inter alia*, to introduce CSP regime. The rights provided by Canadian Patent Act with

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respect to patents, give companies the exclusive right to use an invention for a time period, typically upto 20 years from the date of first patent filing. This term of the patent can be extended by CSP. The regulations of CSP provide for various timelines, requirements and procedures needed to carry out the CSP regime as defined in Sections 104 – 134 of the Canadian Patent Act.⁵

Scope of Supplementary Protection in Canada

The issuance of a CSP grants the certificate holder and their legal representatives, during the certificate term, the same rights, privileges and liberties that are granted by the patent set out in the certificate. But these rights, privileges and liberties are granted only with respect to the making, constructing, using and selling of any drug that contains the medicinal ingredient, or combination of medicinal ingredients, set out in the certificate, by itself or in addition to any other medicinal ingredient.⁶ These rights, privileges, and liberties granted by CSP are transferable only if the patent is transferred.⁷ If these rights are violated by anyone then an action for the infringement of a CSP can be brought similar to an infringement of a Canadian patent.⁸ Canada Government may apply to use invention protected by a CSP.⁹ It is not an infringement of the CSP for any person to make, construct, use or sell the medicinal ingredient or combination of medicinal ingredients for the purpose of export from Canada.⁶

Term of the Canadian CSP

The term of CSP is determined by subtracting five years from the period beginning on the filing date of the patent application and ending on the day on which the authorization for sale is issued, but in any event is not more than two years.¹⁰

CSP Term = [Notice of compliance date – Patent filing date] – five years, with a cap of two years.¹⁰

Notice of compliance (NOC) is a notice issued by Government of Canada (Ministry of Health) to a manufacturer following the satisfactory review of a submission for a new drug, and signifies compliance with the Food and Drug Regulations of Canada. Notice of compliance date is the date that a particular therapeutic product was granted market authorization by receiving an NOC. Canadian Minister of Health may reduce the term of the CSP if unjustified delay in obtaining the authorization for sale is found.¹⁰ The CSP takes effect only if the patent remains valid until, and not void before, the expiry of that term.¹⁰ A CSP

issued never takes effect if the calculation of its term produces a result of zero or a negative value.¹⁰

Supplementary Protection for Inventions - Medicinal Ingredients in Canada

In Canadian CSP regime, eligible drugs are defined broadly to include human and veterinary drugs.¹¹ If a drug is authorized for human use and veterinary use, then these are to be treated as different drugs for CSP purpose.¹² Medicinal ingredients with mere prescribed variation or combinations of medicinal ingredients which differ only with respect to a variation in the ratio between those ingredients, are to be treated as the same medicinal ingredient.¹²

As per regulation 2 of CSP, the prescribed variations are (a) a variation in any appendage within the molecular structure of a medicinal ingredient that causes it to be an ester, salt, complex, chelate, clathrate or any non-covalent derivative; (b) a variation that is an enantiomer, or a mixture of enantiomers, of a medicinal ingredient; (c) a variation that is a solvate or polymorph of a medicinal ingredient; (d) an in vivo or in vitro post-translational modification of a medicinal ingredient; and (e) any combination of the variations set out in paragraphs (a) to (d).⁵

Contents and Eligibility for Application for CSP

A patentee may apply to the Minister of Health for a CSP for a patented invention if all of the following conditions are met: (a) the patent is not void and it meets any prescribed requirements (As per Regulation 3 of CSP, the prescribed requirement is that the patent must be in force);⁵ (b) the filing date for the application for the patent is on or after 1 October 1989; (c) the patent pertains to a medicinal ingredient, or combination of medicinal ingredients, contained in a drug for which an authorization for sale was issued on or after the day on which this section comes into force; (d) the authorization for sale is the first authorization for sale that has been issued with respect to the medicinal ingredient or the combination of medicinal ingredients, as the case may be; (e) no other CSP has been issued with respect to the medicinal ingredient or the combination of medicinal ingredients, as the case may be; (f) if an application for a marketing approval, equivalent to an authorization for sale, was submitted in a prescribed country (Regulation 6 (1a) of CSP, prescribed countries are EU, any member country of EU, United

States of America (USA), Australia, Switzerland, and Japan)⁵ with respect to the medicinal ingredient or combination of medicinal ingredients, as the case may be, before the application for the authorization for sale was filed with the Minister of Health, the application for the authorization for sale was filed before the end of the prescribed period (Regulation 6 (1 b) of CSP, prescribed period is (i) 24 months, if the application for CSP was filed no later than the first anniversary of the day on which Section 59 of the CETA Implementation Act comes into force, and (ii) 12 months, in any other case)⁵ that begins on the day on which the first such application for a marketing approval was submitted.¹³ An application for a CSP shall be filed with the Minister of Health before the end of the prescribed period (Regulation 6 (2) of CSP, the prescribed period is 120 days)⁵ that begins on (a) the day on which the authorization for sale is issued, if the patent is granted on or before that day; or (b) the day on which the patent is granted, if the patent is granted after the day on which the authorization for sale is issued.¹³ As per Regulation 9 (1) and (2) of CSP, fees for application of CSP is Canadian \$9,011. Beginning on 1 April 2018, the fee increases annually by an amount equal to 2% of the fee payable in the previous year, rounded up to the nearest dollar.⁵ An application for a CSP shall set out (a) the patent number, the medicinal ingredient or combination of medicinal ingredients, and the number of the authorization for sale; (b) if Paragraph 106 (1)(f) applies with respect to the application, the day on which the first application for a marketing approval that is equivalent to an authorization for sale was made and the country in which that application was made should be specified; and (c) any prescribed information.¹³

Patents Eligible for Canadian CSP

As per Regulation 3(2) of CSP, patents pertaining to product *per se*, product by process, or its method of use are eligible for CSP.⁵ Each application is permitted to set out only one patent.¹³ As per the Description (c) of CSP regulations, claims that are directed to a formulation containing the medicinal ingredient, including compositions, preparations or similar claim types, do not make a patent eligible for a CSP. A claim to a formulation does not protect the medicinal ingredient or combination of medicinal ingredients *per se*. A claim to a formulation may be directed, for example, to the improvement of the stability of

medicinal ingredients. This is consistent with CETA, which only requires the protection of the medicinal ingredient or combination of medicinal ingredients when claimed “as such”.⁵ Reissued patents are also eligible for CSP.¹² Holder of the certificate or the applicant is obliged to, before the end of prescribed period (Regulation 14 of CSP, the prescribed period is 30 days)⁵ that begins on the day on which the new patent is issued, provide the Minister of Health with written notice of the number of the new patent to which the certificate or application relates.¹⁴ A CSP shall set out (a) the patent number; (b) the medicinal ingredient or combination of medicinal ingredients; (c) a statement as to whether it relates to use in humans or to veterinary use; (d) the number of the authorization for sale; and (e) the day on which the certificate’s term begins and ends.¹⁵

Impeachment in Canada

A CSP or any claim in the patent set out in such a certificate, may be declared invalid or void - including on the basis that the certificate was issued despite of non-compliance with any of the requirements, as they existed at the time that the certificate was issued, of subsection 106(1) or that the patent set out in the certificate no longer complies with the requirements, as they existed at that time, set out in Paragraph 106(1)(c) - by the Federal Court at the instance of the Attorney General of Canada or any interested person.⁸ A CSP or a claim in the patent set out in such a certificate, that is voided by a judgment shall be and be held to have been void and of no effect, unless the judgment is reversed on appeal. Every such judgment and every judgment refusing to do so is subject to appeal to any court having appellate jurisdiction.¹⁶ The Commissioner may exercise any of the powers under any of Paragraphs 66(1)(a), (d) and (e) with respect to an issued CSP, if he or she is satisfied that a case of abuse of the exclusive rights under the patent that is set out in the certificate has been established. The Attorney General of Canada or an interested person may, at any time after a CSP takes effect and after the expiry of three years from the date of the grant of the patent set out in the certificate, apply to the Commissioner alleging that there has been an abuse of the exclusive rights granted under a CSP issued with respect to that patent and asking for relief under the Patent Act. The exclusive rights under a CSP are abused in any of the following circumstances: (a) the demand in Canada for the drug

is not being met to an adequate extent and on reasonable terms; (b) by reason of the refusal of the certificate's holder to grant a licence or licences on reasonable terms, the trade or industry of Canada or the trade of any person or class of persons trading in Canada, or the establishment of any new trade or industry in Canada, is prejudiced, and it is in the public interest that licences should be granted; (c) any trade or industry in Canada, or any person or class of persons engaged in such a trade or industry, is unfairly prejudiced by the conditions attached by the certificate's holder to the purchase, hire, licence, use or working of the invention protected by the certificate.¹⁷

Canadian CSP, USA and Australian 'Patent Term Extension' (PTE) and European 'Supplementary Protection Certificate' (SPC)

Like CSP in Canada, USA and Australia offer PTE and EU offers SPC to recoup time for the clinical trials and regulatory reviews that are required to obtain marketing authorizations for medicinal products.

United States of America (USA)

In USA, extensions of patent term are governed by 35 U.S.C. § 154(b) and 35 U.S.C. § 156.

35 U.S.C. § 154(b) relates to "Patent Term Adjustment" which is a mechanism to compensate for delays made by United States Patent and Trademark Office (USPTO) in examining and issuing patents. 35 U.S.C. § 156 relates to PTE which is a mechanism to compensate for delays occurred in regulatory approval for pharmaceutical products.¹⁸ PTE is equal to the summation of one-half of the time in the testing phase and the time in the approval phase, after the date the patent is issued, less any period during which the applicant was not diligent.

$$\text{PTE} = \text{RRP} - \text{PGRRP} - \text{DD} - \frac{1}{2}(\text{TP} - \text{PGTP})$$

Wherein, regulatory review period (RRP) is the time from the date on which the investigational new drug (IND) or investigational device exemption (IDE) became effective until the date on which the new drug application (NDA), biologic license application (BLA) or pre-marketing authorization (PMA) was approved by United States Food and Drug Administration (USFDA). The USFDA is the authority which calculates the regulatory review period. Regulatory review period consists of two phases: the testing phase and the approval phase.

PGRRP is pre-patent grant regulatory review period, DD is time period during which applicant did not act diligently; TP is the period of the testing phase; and PGTP is pre-patent grant testing phase. The testing phase starts from the effective date of the investigational new drug to the filing date of the new drug application. The approval phase starts from the filing date of the NDA to its approval date. The filing date of the NDA is the date when the NDA is initially submitted for drug product under § 351, 505 or 507. For the purpose of determining PTE, an application for approval of a product is initially submitted "on the date it contains sufficient information to allow FDA to commence review of the application." In the case of a rolling submission (in modules) of an NDA, the initial submission is usually considered the date on which the final module of the NDA is submitted to the FDA. However, if the FDA responds to the applicant that the application submitted is not sufficiently complete to permit a substantive review, then the application for approval of the product is not yet "initially submitted," and the approval phase has not commenced. The PTE should not result in total remaining patent term of more than 14 years. Remaining patent term is measured from date of regulatory approval to date of expiration of patent including PTE and any Patent Term Adjustment. Unlike Canada, USA offers upto 5 years of PTE which can further be extended by 6 months by submitting the data of paediatric (PED) studies. In USA, the term of the patent should not have expired before an application is submitted for its extension. Generally, application for an extension should be made within 60 days of approval of the product.¹⁸ In 1993, 35 U.S.C. §156 was amended to provide for interim extension where a product claimed by the patent was expected to be approved, but not until after the original expiration date of the patent. 35 U.S.C. § 156 (e) (2) provides for interim PTE if the patent "would expire before a certificate of extension is issued or denied under Paragraph (1) [35 U.S.C. §156(e) (1)]." Thus, to prevent a patent from expiring while an application for PTE is pending, the patentee can file for one or more interim extensions of up to one year each. Together, all of the interim extensions cannot be longer than the extension that would be obtained under the normal patent term extension regime. 35 U.S.C. §156 (d) (5) sets forth certain criteria that must be met for the PTO to grant an interim extension. Such an application must be

submitted during the period beginning six months, and ending 15 days before the patent is due to expire.¹⁸ Where a product contains multiple active ingredients, if any one active ingredient has not been previously approved, it can form the basis of an extension of patent term provided the patent claims that ingredient.¹⁸ USA also offers 6 months of extension of PTE if paediatric studies are conducted. Term of US patent 5847170 is extended by 5 years from 26 March 2016 to 26 March 2021 under 35 U.S.C. § 156. This new patent term is further extended by 6 months by paediatric extension.¹⁹ Similar to Canada, US PTE provides protection only to the concerned approved product.²⁰

Australia

PTE = [First Australian Register of Therapeutic Goods (ARTG) Registration Date – Standard Patent Filing Date] – 5 Years

As a part of the Department of Health of Australia, the Therapeutic Goods Administration (TGA) safeguards and enhances the health of the Australian community through effective and timely regulation of therapeutic goods. The publicly accessible version of the Australian Register of Therapeutic Goods (ARTG) is the reference database of the Therapeutic Goods Administration (TGA). It provides information on therapeutic goods that can be supplied in Australia. ARTG registration date of the pharmaceutical substance is the date of commencement of the first inclusion in the ARTG of goods that contain, or consist of, the substance.²¹

Standard patent is the patent in which (i) one or more pharmaceutical substances *per se* in substance that must be disclosed in the complete specification and in substance fall within the scope of the claims of that specification or (ii) one or more pharmaceutical substances when produced by a process that involves the use of recombinant DNA technology, substance must be disclosed in the complete specification of the patent and substance fall within the scope of the claim or claims of that specification.²¹ PTE term up to 5 years is allowed by the Australian Patents Act, 1990.²¹ According to Section 71 of the Australian Patent Act, 1990, PTE deals with the timing of filing an extension that is within 6 months from the date of first ARTG registration of the substance or the date on which patent is granted. This date is extendable as per the full bench federal court decision dated Nov. 18, 2013.²² Similar to Canada, Australia does not provide

any extension for paediatric studies data.²⁰ Unlike Canada, Australian PTE protection is not restricted to the specific pharmaceutical substance that obtained marketing authorisation. Therefore, if the claims cover more than one pharmaceutical substance, all will have their protection extended by the PTE.²⁰ Swiss type (second medical use) claims cannot form the basis for a PTE in Australia.²³ Similar to Canada, Australia does not provide any interim PTE.

European Union (EU)

Council Regulation (EEC) No 1768/92 which entered into force on Jan. 02, 1993 introduced SPC for medicinal products. Currently, Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products governs the SPC in EU.²⁴ The application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3(b) was granted or date on which the patent is granted (if authorisation is granted before the grant of the patent).²⁵

Term of SPC = [Date of 1st valid authorisation in the European Economic Area (EEA) – Basic Patent Filing Date] – 5 years, with a cap of five years.

A valid authorisation means an authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC.²⁶ A ‘basic patent’ means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a SPC.²⁶ Unlike Canada, this term of SPC in EU can be further extended by 6 months if paediatric studies are conducted as per agreed Paediatric Investigation Plan.²⁶ Thus, in EU, the maximum duration of market exclusivity (patent + SPC) can be up to 15.5 years.²⁷ In some cases, to avail this 6-months extension, EU offers negative SPC also. Negative SPC helps innovator companies to get 6 months paediatric extension even if calculation of SPC term ends up in negative or zero. The Paediatric Regulation (PR) introduced a six month PED extension to a granted SPC, to promote pharmaceutical product development for the paediatric patients. Obtaining a Marketing Authorization (MA) for PED use often takes longer than obtaining a MA for the use in adults. When this PR came into force, companies started applying for SPCs, even though the basic term would be zero or

negative, because a subsequent PED extension could take the effective term up to 6 months. A PED extension can only be obtained if an SPC has been granted.²⁸ The Court of Justice of the European Union (CJEU) concluded (in *Merck* case) that an SPC need not have a positive term. The CJEU found that the basic SPC can have a negative or a zero term, and that a negative term should not be rounded to zero. The 6 month paediatric extension should start at the “end” of the negative term of the SPC, not the patent expiry date. Merck was successful in getting PED extension based on such negative SPC. The basic SPC had a term of minus 3 months and 14 days. The 6 month paediatric extension gave a final term that ended 2 months and 16 days after the expiry of patent.²⁸ Innovative pharmaceutical companies can benefit from PED extensions of their SPCs even when the SPC itself does not extend patent protection. Similar to Canada, interim PTE is not available in EU.

Comparative Analysis of Canadian CSP with USA and Australian PTE and European SPC

Comparative Analysis is provided in Figure 1 and Table 1 In Canada (unlike in USA, Australia, and EU) a patentee may not get ‘CSP’ if an application for marketing approval (MA) was submitted in EU, any member country of EU, USA, Australia, Switzerland, and Japan before Canada and the application for the authorization for sale in Canada was not filed before (i) 24 months, if the application for CSP was filed no

later than 21 September 2018, and (ii) 12 months, in any other case (period begins from first application for MA submission day).^{5,13} In Canada (unlike in USA, Australia, and EU), it is not an infringement of the CSP for any person to make, construct, use or sell the medicinal ingredient or combination of medicinal ingredients for the purpose of export from Canada.⁶ This regime of CSP which does not offer further extension with the submission of paediatric data may affect inventions for paediatric patients in Canada.

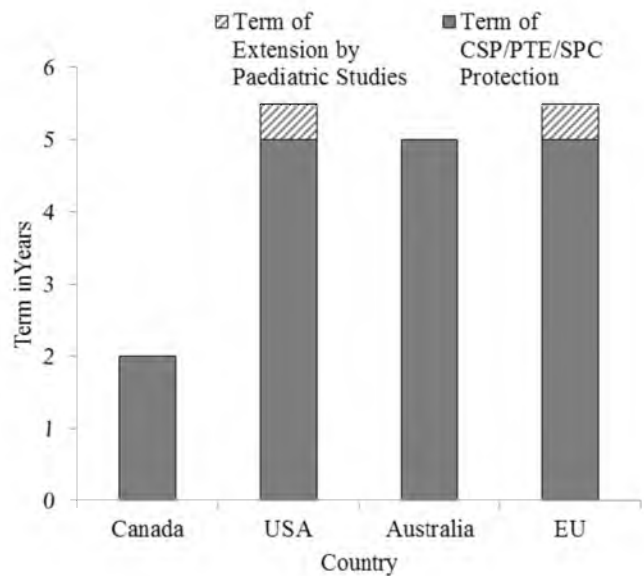


Fig. 1 — Term of CSP, PTE(s), SPC and Paediatric Extensions

Table 1 — Comparative analysis of different regimes of extending patent term in Canada, USA, Australia and EU.

Parameters	Canada	USA	Australia	EU
Regulations/Articles of the Act	Sections 104–134 of The Canadian Patent Act	35 U.S.C. § 154(b) and 35 U.S.C. § 156 of US Patent Act	Section 70 to 79 A of The Australian Patent Act	Regulation (EC) No 469/2009
Extension of Term	Upto 2 years	Upto 5 years	Upto 5 years	Upto 5 years
Paediatric Extension	✗	Upto 6 Months	✗	Upto 6 Months
Overall maximum exclusivity via Patent Term Extension excluding Paediatric Extension	Patent expiry plus upto 2 years	Not more than 14 years from date of approval of product	Patent expiry plus upto 5 years	Not more than 15 years from date of approval of product
Interim PTEs	✗	✓	✗	✗
Export exception during the Term Of Extension Certificate	✓	✗	✗	✗
Multiple extensions per patent	✗	✗	✓	✓
Multiple extensions per product	✗	✗	✓	✓
PTE for Method of use patents	✓	✓	✗	✓
PTE for Enantiomers	✗	✓	✗	✓
Patent Term Adjustment for delay from Patent Offices	✗	✓	✗	✗

Conclusion

It is observed that amongst the countries discussed in this article, Canada is the only country (out of Canada, USA, Australia, and EU) where any person making, constructing, using or selling the medicinal ingredient or combination of medicinal ingredients for the purpose of export does not infringe the certificate of supplementary protection. Despite of CSP, this provision would foster the growth of pharmaceutical industry and export from Canada. This special provision would help Canada to comply CETA obligations but would also help industry to grow. Since the current CSP regime of Canada does not offer any further extension if the sponsor conducts clinical trials on paediatric patients, it may not encourage development of pharmaceutical products for paediatric patients. As compared to US, Australia, and EU, the term of extension is less, but it is beneficial for patients since it will make generic drugs available earlier as compared to other countries. The requirement of filing an application for MA in Canada within provided timelines if the MA application is already filed in EU, USA, Australia, Switzerland, and Japan before Canada, would make newer drugs and thus, their generics available earlier for Canadian public. Thus, Canadians would get better health services and cost effective drugs. USA is the only country that offers interim PTEs and only EU offers negative SPCs. On one hand, this CSP regime is an opportunity to innovators of pharmaceutical and veterinary products to recover investments and on other hand, it impacts the timing of entry of generic products in the Canadian market and thus will impact the cost of healthcare in Canada.

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