CERTIFICATES OF SUPPLEMENTARY PROTECTION : ONE YEAR LATER

DANIÈLE ÉTHIER AND AMÉLIE CÔTÉ*
ROBIC, LLP
LAWYERS, PATENT AND TRADEMARK AGENTS

Since September 21, 2017, a new Certificate of Supplementary Protection (hereafter referred to as a "CSP") Regime has been implemented which may allow patent holders to receive up to 2 years of additional patent protection for approved medicines. In the past year, several CSP applications have been submitted and reviewed, which gives us insight as to how this additional protection is granted and how the CSP regulations are interpreted by Health Canada.

THE CSP SCHEME AND ELIGIBILITY

The CSP regime was implemented to compensate patent holders for time spent in research and development for drugs containing patented medicinal ingredients. A CSP may allow a patent holder to benefit from up to two additional years of patent protection on the approved medicinal ingredient or combination of medicinal ingredients.

Once a Canadian patent is granted, a patent holder or manufacturer can apply for a CSP if all of the following conditions are met:

- The patent is in force and is based on an application which was filed in Canada after October 1, 1989[†];
- The patent relates to the same medicinal ingredient or a combination of the same medicinal ingredients contained in a medicine for human or veterinary use[‡];
- The first marketing authorization (i.e. notice of compliance) for the medicinal ingredient or a combination was issued after September 21, 2017[§];
- The application for market authorization was filed in Canada within 1 year (or 2 years for the first year of application of the CSP scheme) after the date on which the first equivalent application was submitted in a country of the European Union, the United States, Australia, Switzerland or Japan;
- No other CSP has been granted for the medicinal ingredient or a combination of the same medicinal ingredients[**];

* Danièle Ethier is a partner, biochemist and Canadian patent agent and Amélie Côté is an articling student working at ROBIC, LLP, a firm of lawyers, patent and trademark agents.
[†] *Patent Act, RSC 1985, c P-4, s. 106(1)a) and b); Certificate of Supplementary Protection Regulations, SOR/2017-165, s. 3(1).*
[‡] *Certificate of Supplementary Protection Regulations, SOR/2017-165, s. 3(2).*
[§] *Patent Act, RSC 1985, c P-4, s. 106(1)c.*
[**] *Id., s. 106(1)e).*

- The applicable regulatory taxes are paid; and

- The CSP Application is filed with Health Canada within 120 days from the later of (i) the first market authorization of the medicinal product; or (ii) the grant of the patent[††].

As will be seen below, failure to meet any one of the conditions above may result in the CSP application being refused.

SUMMARY OF PAST APPLICATIONS

Health Canada maintains a Register which includes information from CSPs and CSP applications. As of October 26, 2018, twenty-six CSP applications were filed, fifteen CSPs were granted and three applications have been rejected.

CSP application 900001 was the first CSP application filed and was rejected because the market approval was issued prior to September 21, 2017. Therefore, the conditions of section 106(1)c of the *Patent Act* were not met.

Based on the information provided by Health Canada, CSP application 900011 was rejected because the market authorization for the drug was not the first marketing approval as required by the *Patent Act* and the *Certificate of Supplementary Protection Regulations*. A prior approval was issued for a prescribed variation of the medicinal ingredient. In this case, the variation was a post-translation modification of the medicinal ingredient (pegylation and/or glycosylation).

CSP application 900006 with respect to the drug SHINGRIX® was rejected because the claims of the patent did not contain an eligible patent claim. The claims in the patent in question are directed to the use of a composition comprising a gE antigen and a selected adjuvant to make a vaccine. According to the court documents, the CSP application was rejected on the grounds that the claims are directed to a formulation comprising medicinal and non-medicinal ingredients. According to the CSP Regulations, only patent containing claims for the medicinal ingredients, combinations of the medicinal ingredient, uses and processes for making same are eligible for a CSP[‡‡].

The Applicant for CSP Application Number 900006 recently applied for a judicial review of their refused application[§§]. The Applicant essentially claims that the Minister misinterpreted the CSP regime in finding that adjuvants are not medicinal ingredients[***]. The determination of the court has yet to be made. Nonetheless, being the first review of a decision made by the Health Canada under these new regulations, the decision will hopefully clarify the extent and limits of this new CSP regime.

IMPORTANCE OF FULFILLING THE CONDITIONS

CSPs allow patent holders to benefit from an additional protection for their patented drugs. To benefit from this recent regime, it is however crucial that the CSP Application fulfill all of the

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[††] *Id., s. 106(3); Certificate of Supplementary Protection Regulations, SOR/2017-165, s. 6(2).*
[‡‡] *See Federal Court Notice of Application No. T-1603-18: https://www.robic.ca/publications/federal-court-glaxosmithkline-biological-s-minister-health/*
[§§] *Id.*
[***] *Id., para. 34.*

conditions set out in the *Patent Act* and the *Certificate of Supplementary Protection Regulations*. As can be seen from the cases discussed above, failing to properly ensure that all the eligibility conditions are met may result in the refusal of the CSP application. Our team of experts can help you strategically coordinate your patents and CSP applications, all while ensuring that regulatory measures are met. We invite you to contact us for additional information.