Drug Patent Term Restoration in Canada: Certificates of Supplementary Protection

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Like other patents in Canada, drug patents have a term limited to twenty years from the filing date. However, unlike other products, drugs must undergo extensive clinical testing and a regulatory approval process before they may be marketed. Because drug patents are typically filed at an early stage of development, this means the effective patent term is often significantly shorter than twenty years. Until recently, Canada was the sole G7 nation that did not provide some form of patent term restoration to address such delays. This changed on September 21, 2017 with the provisional implementation of Canada's obligations under the Comprehensive Economic and Trade Agreement (CETA) with the European Union.

Now, certain patents relating to human and veterinary drugs qualify for up to an additional two years of protection via a Certificate of Supplementary Protection (CSP). Amendments to the *Patent Act* provided the legislative framework governing CSPs and the new *CSP Regulations* specify particulars on the numerous formal, subject-matter and timing requirements determining whether a patent is eligible. As CSPs only recently became available, it may be some time before we receive interpretation from the courts regarding these provisions. In the interim, some guidance has been provided by Health Canada, the administrator of the CSP regime. This article provides a brief overview of this new form of protection with a focus on what subject-matter is considered to be eligible and important timing considerations.

To be eligible for a CSP, the patent must be in force and have issued from an application filed on or after October 1, 1989. In addition, it must pertain to a medicinal ingredient or combination of medicinal ingredients in a drug for which a notice of compliance (marketing authorization) issued on or after September 21, 2017. If the approved drug contains one medicinal ingredient, a patent meets this requirement if it contains a claim for the medicinal ingredient (either *per se* or in the form of a product-by-process claim) or a use of the medicinal ingredient. If the approved drug contains more than one medicinal ingredient, this requirement is only met if the patent contains a claim for all of the medicinal ingredients (again, either *per se* or in the form of a product-by-process claim) or a use of all of the medicinal ingredients. Claims that are directed to formulations which include additional components such as adjuvants are not eligible for a CSP. In publically available guidance, Health Canada has indicated the claimed use does not need to match the approved use. It considers any use in humans or animals, as the case may be, to be acceptable.

There may only be one CSP issued for a medicinal ingredient or combination of medicinal ingredients. The notice of compliance must also have been the first that has issued. It is not enough for these purposes that a medicinal ingredient differs from another by certain structural variations that are listed in the *CSP Regulations*. These include salts, enantiomers, polymorphs and others that would be familiar to those working in the drug patent field. Such variations will result in a finding that the medicinal ingredient is the same. Similarly, if combinations vary only with respect to the ratio between the medicinal ingredients, they will be treated as the same combination. However, if a medicinal ingredient or combination thereof in a drug is authorized for both human and veterinary use, these are treated as different.

There are strict timing requirements not only for filing the CSP application itself but also for filing the applications for marketing approval. The latter was implemented with the purpose of incentivizing the early introduction of new drugs into the Canadian market. Accordingly, for CSP applications filed after September 21, 2018 the application for marketing approval in Canada must have been made within a period of 12 months from the time the first submission was made in any one of the following countries/regions: the European Union (and any member country), the United States, Australia, Switzerland and Japan. Companies interested in potentially pursuing CSP protection for a new drug product should

therefore ensure the regulatory strategy includes filing the application for marketing approval in Canada within this period.

Because there can only be one CSP per drug product, is it unlikely there will ever be a deluge of new CSPs in Canada. However, twenty-three applications for human use and one for veterinary use are presently listed on the CSP register maintained by Health Canada. Of the applications, fourteen have issued, only three have been refused and the remainder are still pending. All but one of the CSPs which have issued to date are for the maximum term of two years. The protection afforded by a CSP during this period is narrower in scope than the corresponding patent in that it pertains only to the making, constructing, using and selling of any drug that contains the medicinal ingredient or combination thereof and does not encompass exports. However, it is similar in that an action for infringement of a CSP may be brought and a CSP can also be added to the Patent Register.

The maximum term of two years is still shorter than other jurisdictions that provide for up to five years of patent term restoration. However, the new CSP regime is a step towards better alignment with other members of the G7 in addressing the reduced effective patent term for drug products.

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