

Why Companies May Want to Accelerate Marketing Approval for Their Patented Drugs in Canada

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Patent Term Extensions (e.g., in the United States), Supplementary Protection Certificates (e.g., in Europe), and other similar extensions compensate the owner of a patent covering certain approved medical products for the time the product spent under regulatory review. These extensions can be important contributors to a pharmaceutical company's exclusivity strategy. Many jurisdictions worldwide have provided such exclusivity extensions for decades. In Canada such extensions have become available only fairly recently, in September of 2017, in an effort to maintain Canada's commitment to the Comprehensive Economic and Trade Agreement (CETA) with the European Union. The Canadian "Certificate of Supplementary Protection" (CSP) allows for an extension of patent protection for a maximum period of two years.

The requirements to obtain such protection in Canada overlap in many aspects with those elsewhere, e.g., in the US or Europe. For example, a patent must be in force at the time of regulatory approval and have claims covering the active ingredient of the approved drug or the use of the same, and the CSP application must be based on the first marketing authorization for the drug in Canada.

However, one additional requirement unique to the Canadian law is that, for a drug to be eligible for a CSP, a Canadian New Drug Submission (NDS) must have been filed within 12 months of the earliest corresponding filing on the same drug in the US, the European Union or any of its member countries, the UK, Switzerland, Australia, or Japan. **In other words, if a drug is patented in Canada and is first approved for sale in the US, a company that plans to market the patented drug in Canada and wishes to obtain a CSP, must submit an NDS within 12 months of filing a New Drug Application (NDA) in the US.** This requirement is established by Paragraph 106(1)(f) of the Patent Act with an aim to encouraging new drugs a quick introduction into Canada.

Thus, companies interested in marketing a patented drug in Canada should be aware that waiting too long to request marketing approval in Canada could result in the loss of eligibility to the potential 2-year CSP extension.

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