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Pharma in brief - Canada

CETA tracker: patent term restoration is coming soon to Canada – what you need to know now

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Treaty/Act: CETA/Bill C-30 (*An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures*)

With Canada moving closer towards implementing the Comprehensive Economic and Trade Agreement (**CETA**), major reforms to Canada's *Patent Act* are coming soon, including the availability of Certificates of Supplementary Protection (**CSPs**): a new form of patent protection (i.e., patent term restoration) for pharmaceuticals in Canada. A CSP may extend the patent term of eligible pharmaceutical products by up to two years.

While further details of the CSP regime will be prescribed by regulations, which have yet to be published, based on Bill C-30 the following considerations can inform preparedness:

- ***CSP eligibility:*** To apply for a CSP for a pharmaceutical product, you must have: (1) an eligible medicinal ingredient that has obtained market authorization (i.e., an NOC); and (2) an eligible patent.

- ***Your NOC must be the first market authorization for that medicinal ingredient:*** Only one CSP will be issued per medicinal ingredient. A first combination of medicinal ingredients can be eligible. Details of what constitutes the "same" medicinal ingredient, including prescribed variations that will not be eligible, will be determined in the regulations.

- ***Your eligible NOC must be obtained after the law comes into effect: CSPs will not apply retroactively.*** Only eligible pharmaceutical products that receive market authorization on or after the day on which the law comes into effect will be CSP eligible.

- ***Coordination of international drug submission filing is important to be CSP eligible in Canada:*** If a marketing authorization application for the same medicinal ingredient has already been submitted in another "benchmark" international jurisdiction (to be specified by regulation), the Canadian application for marketing authorization (i.e., NDS), must be filed within a specific period of time (to be specified by regulation) of the first international filing in order to be eligible for a CSP in Canada.

- ***Your eligible patent does not need to be granted by the time you receive your NOC:*** Patent term restoration can be granted for an eligible patent issued after marketing authorization. The CSP application must be submitted within a time (to be specified by regulation) after patent grant. There can only be one eligible patent per medicinal ingredient. However, in the event of multiple competing CSP applications for the same market authorization, a priority/conflict regime will prioritize patents granted prior to NOC issuance over patents issued post-NOC.

Are you CETA ready? Contact Norton Rose Fulbright with all your CETA questions.

Links

Bill-30, Third Reading (House of Commons)

Text of the final Comprehensive Economic and Trade Agreement

For more information, please contact your IP/Life sciences or healthcare practice professional at Norton Rose Fulbright Canada LLP.

For a complete list of our IP team, click here. For a complete list of our Life sciences and healthcare team, click here.