

Goodmans^{LLP} Update

Every Day Counts in the Life of Your Patent!

Pursuant to its Comprehensive Economic and Trade Agreement commitments, Canada recently enacted patent term adjustment provisions which can extend the 20-year period of patent protection for up to an additional two years.

The “Certificate of Supplementary Protection” regime permits patentees to seek an additional two years of protection for patents that pertain to a medicinal ingredient, or combination of medicinal ingredients, contained in a drug for which the authorization for sale is the first authorization for sale issued with respect to the medicinal ingredient or the combination of medicinal ingredients.

The period of extension is computed by reference to the time taken for approval by the Minister of Health under the *Food and Drug Regulations*. Importantly, the two-year extension may be reduced where the Minister of Health is of the opinion that a person’s failure to act resulted in a period of unjustified delay in the process of obtaining the authorization for sale.

Few certificates of supplementary protection have been granted in Canada and there has been no consideration of what circumstances, if any, would constitute a failure to act sufficient to reduce the two-year maximum.

The U.S. Court of Appeals for the Federal Circuit recently considered a potentially analogous issue. In *Supernus Pharmaceuticals v Iancu*, the Court found that the United States Patent and Trademark Office exceeded its statutory authority by subtracting days from Supernus’ patent term adjustment where the company had *not* failed to make reasonable efforts to prosecute its application. The test applied by the Court was whether the applicant in the period of its purported delay could have taken any steps. If not, its actions were not unreasonable.

While the decision considers the use of patent term adjustment to compensate for delays in the patent office, and not regulatory approval, it may nonetheless provide insight into the considerations the Minister may undertake when considering a patent extension in Canada.

A copy of the decision can be found [here](#). Should you have any questions, please contact any member of our [Intellectual Property Group](#).

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