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Making Your Patent List and Checking It Twice – but Don't Delay in Submitting It!

Engaging Canada's *Patented Medicines (Notice of Compliance) Regulations* (the "*Regulations*") requires pharmaceutical patentees to first submit a list to Health Canada of patents to be included on the register – Canada's equivalent to the Orange Book. Any delay in submitting that list after an eligible patent has been issued can have severe consequences on the scope of a patentee's protections under the *Regulations*. The recent Federal Court decision in *Serono v Canada (Health)* is illustrative.

Background

Merck Serono S.A. ("Serono") had applied for Canadian Patent No. 3,087,419 (the "419 Patent") in December 2005, which eventually issued – 18 years later – on March 7, 2023. After issuance, Serono submitted lists for the 419 Patent to be added to the register against MAVENCLAD, a drug used in the treatment of adult patients with relapsing-remitting multiple sclerosis. Serono waited nine days *after* the 419 Patent had issued to submit its patent lists (on March 16, 2023).

Once lists were submitted, Health Canada carried out a preliminary analysis of the patent's eligibility for listing and informed Serono that its patent lists had been added to the register as of March 23, 2023 (one week after Serono submitted its lists). Notwithstanding, only one day *before* Serono's patent lists were added, Apotex filed its regulatory submission for a generic version of MAVENCLAD on March 22, 2023. Since Serono's patent lists had not yet been added by the time Apotex filed its submission, it appeared Apotex did not have to address the 419 Patent under the *Regulations*.

Serono challenged the listing date of March 23, 2023, arguing, among other things, that the proper date ought to have been the date on which Serono submitted its patent lists (March 16, 2023), thereby requiring Apotex to address the 419 Patent under the *Regulations*. The Minister rejected Serono's argument based on its interpretation of the *Regulations*; a decision which the Court later held was reasonable. The Court found that the *Regulations* require patents to be listed only *after* determining their eligibility. In reaching its decision, the Court

discussed the language in sections 5(1) and 5(4) of the *Regulations*, drawing a distinction between “*submitted*” in subsection 5(1) and “*added*” in subsections 3(2) and 5(4).

An appeal of the *Serono* case is currently pending.

Takeaways

Regardless of the outcome of the pending appeal, listing dates remain critical for pharmaceutical patentees to maximize protection under the *Regulations*. The addition of a patent to the register is not automatic and the timing for Health Canada to determine listing eligibility is out of a patentee’s control. To minimize delay, patent lists should be prepared well in advance for submission as soon as an eligible patent issues.

In circumstances where the benefit of the *Regulations* may not be triggered, patentees can nonetheless pursue enforcement and seek relief under the *Patent Act*.