Patent is NOT listed on Patent Register when Form IV is filed; only when Minister determines it is eligible

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In two recently published decisions, the Federal Court held that a patent is not listed on the Patent Register when the Form IV Patent List is filed, nor when the preliminary review is completed by Health Canada. The patent is only considered to be listed, and therefore required to be addressed by a second person pursuant to the *Patented Medicines (Notice of Compliance) Regulations* (the *NOC Regulations*), once the Minister concludes that it is eligible for listing.

In the first case, *EMD Serono v Canada (Health)*, the timing of relevant events was:

- 7 March 2023 – patent issues
- 16 March 2023 – patent lists submitted
- 17 March 2023 – Health Canada screened the patent lists
- 21 March 2023 – Heath Canada carried out a preliminary analysis of the patent's eligibility for listing; completed the screening and eligibility review form
- 22 March 2023 – Apotex submitted its Abbreviated New Drug Submission (ANDS) for generic version of relevant drug
- 23 March 2023 – Minister determined the patent was eligible for listing; Health Canada advised Serono that patent lists had been added to the Patent Register

A request for reconsideration of the date was made. Serono sought Judicial Review of the Minister's decision refusing to reconsider the 23 March 2023 listing date.

The Court dismissed the judicial review, holding that the decision was not unreasonable in the context of the *NOC Regulations*, the case law, and the facts. The Court held that the evidence showed that the Minister added the patent to the Register the same day it was determined to be eligible; and that the completion of the screening and eligibility review on March 21, 2023, was not the same as the Minister's own determination of eligibility.

As a result, Apotex did not have to address the newly issued patent pursuant to the *NOC Regulations*.

In *Bayer v. Amgen* the timing of relevant events was:

- 22 August 2023 – patent issues
- 22 August 2023 – patent lists submitted
- 24 August 2023 – Amgen submitted its Biosimilar New Drug Submission for biosimilar version of relevant drug
- Heath Canada carried out a preliminary analysis of the patent's eligibility for listing; completed the screening and eligibility review form (although the Court noted that the form is missing the "Eligibility Analysis Date"; "Patent Annotation metadata" appears to show timestamped comments by screening staff as late as 28 August 2023)
- 30 August 2023 – Health Canada advised Bayer that patent lists had been added to the Patent Register

A request for reconsideration of the date was also made. Bayer also sought judicial review of the Minister's decision refusing to reconsider the August 30 2023 listing date.

The same Judge as in *EMD Serono* unsurprisingly came to the same conclusion in the *Bayer* case despite the minor factual differences. As a result, Amgen did not have to address the newly issued patent pursuant to the *NOC Regulations*.

The *EMD Serono* decision is under appeal. The *Bayer* decision is still within the time to appeal.

Key Takeaways

The facts of these two cases demonstrate that timing can have a significant impact on the rights that can be asserted by a first person, even when not all of this timing is within the control of the parties to the eventual litigation. Thus, for innovative drugs that are no longer, or were never, subject to the 6-year data protection period during which generic and biosimilar companies cannot file their drug submissions, regulatory steps such as filing Form IVs, should be prioritized in order to increase the likelihood of being able to assert rights pursuant to the regime set out in the *NOC Regulations*.

By

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