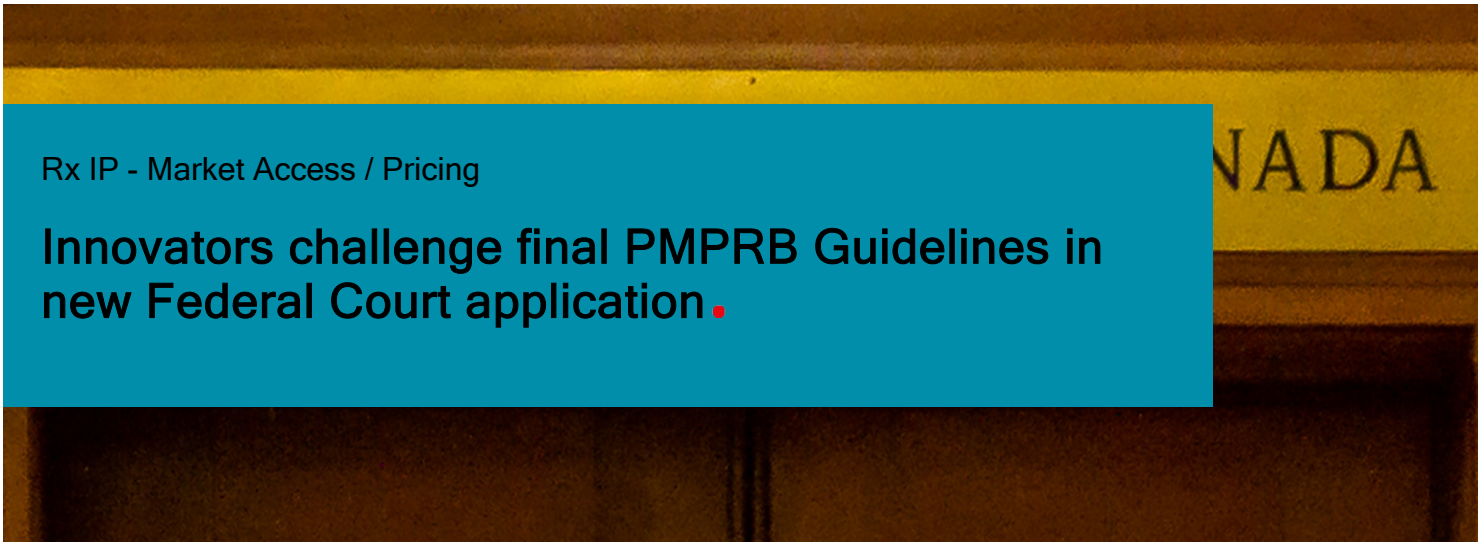

Rx IP - Market Access / Pricing

Innovators challenge final PMPRB Guidelines in new Federal Court application.

November 30, 2020

Abigail Smith

On November 23, 2020, Innovative Medicines Canada (IMC) and a number of research-based pharmaceutical companies commenced an application for judicial review (T-1419-20) of the final Patented Medicine Prices Review Board (PMPRB) Guidelines, which were released on October 23, 2020 (see our article here).The Guidelines are intended to operationalize amendments to the *Patented Medicines Regulations* (the Regulations) scheduled to come into force January 1, 2021.

The amendments themselves have already been subject to judicial scrutiny: on September 10, 2020, the Federal Court struck a price calculation provision that would have expanded the reporting requirements in current subsection 4(4) of the Regulations to encompass information beyond the first point of sale (e.g. confidential third party rebates; see our article here). The Court ruled that because the new price calculation provision exceeded the first point of sale, it was *ultra vires* the *Patent Act*. An appeal and cross-appeal are pending.

In the new application for judicial review, the applicants seek a declaration that the Guidelines are *ultra vires* the *Patent Act* , on the basis that:

1. the price review process described in the Guidelines considers certain rebates – and more specifically, the so-called Maximum Rebated Price, which may be considered at the investigation stage – notwithstanding the Federal Court decision deeming rebates beyond the first point of sale to be *ultra vires* the *Patent Act*;
2. the Guidelines purport to be non-binding on their face, but effectively and improperly prescribe the ceiling prices for patented medicines in Canada; and
3. the *Guidelines* exceed the PMPRB's statutory price-review mandate, which is limited to regulating *excessive* prices.

The hearing of a separate court challenge in the Quebec Superior Court to the constitutionality of the PMPRB provisions of the *Patent* Act, the Regulations, the amended Regulations, and the Compendium of Policies, Guidelines and Procedures (i.e. the guidance that operationalizes the regulations that are currently in force) was completed on November 20, 2020, and a decision was taken under reserve.

Should you have any questions, please do not hesitate to contact a member of the Life Sciences Regulatory & Compliance Group.

The preceding is intended as a timely update on Canadian intellectual property and technology law. The content is

informational only and does not constitute legal or professional advice. To obtain such advice, please communicate with our offices directly.

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