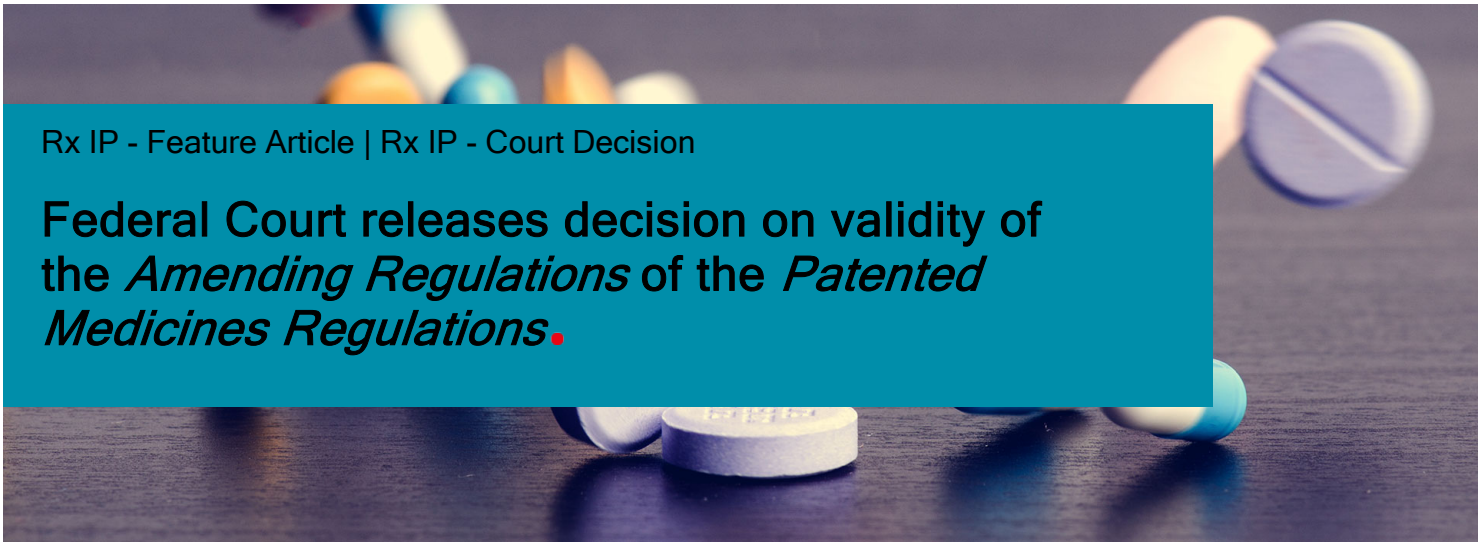

Rx IP - Feature Article | Rx IP - Court Decision

Federal Court releases decision on validity of the *Amending Regulations* of the *Patented Medicines Regulations*.

June 29, 2020

Daphne Lainson, Nancy Pei and Abigail Smith

On June 29, 2020 the Federal Court released its decision in *Innovative Medicines Canada et al. v The Attorney General of Canada et al*, 2020 FC 725.

This judicial review challenged the validity of the *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)* (discussed here), which were published on August 21, 2019.

The Applicants sought:

(i) A declaration that sections 3(4), 4, 6 and the Schedule of the amending *Regulations* are invalid, void and of no force and effect as *ultra vires* the *Patent Act*; and

(ii) An order quashing sections 3(4), 4, 6 and the Schedule of the amending *Regulations* as *ultra vires* the *Patent Act*.

Section 3(4) expanded the reporting requirements for price and revenue information to take into account, *inter alia*, discounts and rebates provided to third parties. Section 4 created new price regulatory factors: pharmacoeconomic value, market size and Gross Domestic Product (GDP) factors. Section 6 amended the basket of reference countries creating the new PMPRB 11.

The Court found Subsection 3(4) invalid, void and of no force and effect and *ultra vires* the *Patent Act*. The remaining amendments were found valid.

It is unclear how the decision will impact on the current Guidelines consultation (see here) for which comments are due by July 20, 2020.

The parties will have 30 days to appeal.

Should you have any questions, please do not hesitate to contact a member of the Pharmaceutical Litigation 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.

RELATED PEOPLE

Daphne Lainson

E dclainson@smartbiggar.ca
T: 613.232.2572

Nancy Pei

E nppei@smartbiggar.ca
T: 416.595.2761

Abigail Smith

E aesmith@smartbiggar.ca
T: 416.595.2768

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