Rx IP - Court Decision | Rx IP - Market Access / Pricing

Federal Court strikes price calculation provision of amendments to *Patented Medicines Regulations*.

July 15, 2020

Abigail Smith

As briefly reported previously, on June 29, 2020, the Federal Court issued its decision in the application for judicial review of the *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)* (the *Amendments*): *Innovative Medicines Canada vCanada (Attorney General)*, 2020 FC 725. The Court ruled that subsection 3(4), which would expand price calculation requirements in subsection 4(4) of the *Patented Medicines Regulations* (the *Regulations*) to encompass information beyond the first point of sale (*e.g.* confidential third party rebates), was invalid. The balance of the provisions challenged were upheld. In the result, ***existing subsection 4(4) of the Regulations will continue to operate as it currently reads when the Amendments come into force on January 1, 2021*** (see our reporting on the revised date here), while sections 4 and 6 of the *Amendments* will amend the *Regulations* at that time. This article looks more closely into Manson J.'s decision and its implications.

Issues in dispute

The applicants – Innovative Medicines Canada and a number of innovative pharmaceutical companies – challenged three aspects of the *Regulations* on the basis that the associated provisions were *ultra vires* the *Patent Act*, *i.e.*, inconsistent with the statutory purpose of or beyond the legal authority granted by *Patent Act*:

- **Section 4** of the *Amendments*, which will introduce three new price regulatory factors –pharmacoeconomic value, market size, and Gross Domestic Product (GDP) in Canada and GDP per capita in Canada – via new section 4.4 of the *Regulations*, along with associated reporting requirements in new sections 4.1, 4.2, and 4.3;
- **Section 6** and the **Schedule** to the *Amendments*, which will revise the list of countries used to establish price ceilings (the PMPRB 11); and
- **Subsection 3(4)** of the *Amendments*, which would expand the information to be considered in calculating the price of a given medicine (discussed above).

Pursuant to the Supreme Court's recent decision in *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65, the standard of review was reasonableness.

1. Improper purpose of *Amendments* generally

The applicants argued that the *Amendments* were intended to deliver health care savings, whereas the governing provisions of the *Patent Act* were intended to prevent patent abuse via excessive pricing.

In support of this argument, the applicants pointed to language in various public government documents, including references to amending the Patented Medicines Prices Review Board's (PMPRB) regulatory framework to ensure "optimal price setting" of patented medicines. Based on the *Amendments*, their accompanying Regulatory Impact Analysis Statement, and certain extrinsic evidence, the Court nonetheless found that the purpose of the *Amendments* was to modernize the PMPRB and to protect Canadian consumers from the abuse of excessive pricing.

2. Improper purpose of sections 4, 6 and the Schedule to the *Amendments* specifically

i. Section 4 – price regulatory factors

- ***Consistency of pharmacoeconomic value factor with object of Patent Act.*** The applicants argued that this factor required the PMPRB to make systemic judgments on value for all Canadians, a role unrelated to its statutory mandate to regulate patent abuse via excessive pricing. The Court rejected this argument as essentially directed to the wisdom of the policy, which is not relevant to a *vires* challenge.
- ***Consistency of market size and GDP with object of Patent Act.*** The applicants argued that both factors addressed affordability, rather than excessive pricing. The Court found that the PMPRB's consumer protection mandate was directly connected to affordability.
- **Consistency of 3 new price regulatory factors with statutory scheme.** The applicants argued that section 85 of the *Patent Act* required the Board to make assessments based on factors related to price, and only price, and that the new price regulatory factors were not rationally connected to that statutory scheme. The Court found that the Governor in Council's regulation-making authority was not so limited, and that the new price regulatory factors were a proper exercise of that authority.

ii. Section 6 and revised basket of comparator countries

The applicants argued that the section 6 *Amendments*, which will revise the basket of comparator countries to the PMPRB 11, was not directed to preventing excessive pricing. Rather, it was intended to import price controls into the *Patent Act*.

The Court rejected this argument, concluding that the PMPRB 11 did not, in and of itself, constitute a form of price control – it simply required patentees to file certain information, which is then used by the PMPRB to identify prices that appear excessive. Per the Court, performing a price comparison does not dictate that a specific conclusion must follow.

3. Scope of regulation-making authority in revised price calculation in subsection 3(4)

Lastly, the applicants argued that the Governor in Council had exceeded the scope of her regulation-making authority by promulgating the revised price calculation in subsection 3(4) of the *Amendments*.

Subsection 3(4) of the *Amendments* would replace the price calculation in subsection 4(4) of the *Regulations*, expanding its scope to capture discounts and rebates offered to third parties, *i.e.*, beyond the first point of sale. Under the current *Regulations*, patentees are required to report price adjustments at the first point of sale only. The amended price calculation was broadened to capture additional rebates, including the rebates that drug manufacturers often pay to public drug plans and private insurers in exchange for having their products listed on their formularies. See comparison below of current and amended subsection 4(4)(a); subsection 4(4)(b) changes are analogous:

Current s. 4(4)(a)

Amended s. 4(4)(a)

(a) in calculating the average price per package of medicine, the actual price after any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature and after the deduction of the federal sales tax shall be used;

(a) in calculating the average price per package of a medicine, the actual price obtained by the patentee shall be used, taking into account any adjustments that are made by the patentee or any party that directly or indirectly purchases the medicine or reimburses for the purchase of the medicine and any reduction given to any party in the form of free goods, free services, gifts or any other benefit of a like nature;

The applicants first argued that the PMPRB's jurisdiction under the *Patent Act* is limited to the first point of sale. The Federal Court accepted this argument, relying on prior jurisprudence stating that the *Patent Act* contemplates a *sale* by a patentee to a *customer*, not a rebate given to a third party after-the-fact. Because the new price calculation exceeded the first point of sale, it was *ultra vires* the *Patent Act*. The Court rejected the Minister's argument that third party rebates remained appropriate because they were being used to calculate the effective price at the first point of sale.

The Court declined to consider the applicants' further argument distinguishing the price of a medicine from its marketing costs.

Judgment and implications

The Court declared that sections 4 and 6 of the *Amendments* are *intra vires* the *Patent Act*, while subsection 3(4) is *ultra vires* the *Patent Act* and therefore invalid, void, and of no force and effect. Accordingly, ***existing subsection 4(4) of the Regulations will continue to operate as it currently reads when the Amendments come into force on January 1, 2021***, while sections 4 and 6 of the *Amendments* will amend the *Regulations* at that time.

The parties have until September 29 to appeal.

On July 8, the PMPRB announced that in its view, this decision had no impact on the revised draft Guidelines operationalizing the amendments to the *Patented Medicines Regulations*, but invited submissions on the issue as part of the current consultation on the Guidelines. The deadline for submission was simultaneously extended to **August 4, 2020**.

Of note, the revised draft Guidelines direct patentees to the Help section of the yet-to-be-released online filing tool for guidance on how to calculate the net price of a patented medicine, including the treatment of free goods and rebates.

A separate court challenge to the constitutionality of the PMPRB provisions of the *Patent Act*, the *Regulations*, and the *amended Regulations*, brought in the Quebec Superior Court, is scheduled to be heard September 28 – October 2, 2020.

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

Abigail Smith

E aesmith@smartbiggar.ca
T: 416.595.2768

RELATED SERVICES

- Pharmaceutical Litigation

RELATED INDUSTRIES

- Chemical & Biotechnology
- Pharmaceutical & Biologics