Parts of amended Patented Medicines Regulations related to the PMPRB struck down

June 30, 2020

On June 29, 2020, the Federal Court issued its decision in the judicial review of recent *Amendments*[1] to the *Patented Medicines Regulations*.[2] These *Regulations* govern the Patented Medicines Prices Review Board (the PMPRB or the Board). The Applicants challenged three provisions of the *Amendments* as being *ultra vires* the *Patent Act*:

1. Section 4 of the *Amendments*: specifying three new mandatory economic factors that the Board must consider when determining whether the price of a patented medicine is excessive and requiring patentees to report related information:
    a. The pharmacoeconomic value of the medicine;
    b. The size of the market for the medicine in Canada; and
    c. The Gross Domestic Product (GDP) in Canada and GDP per capita in Canada.
2. Section 6 and the Schedule to the *Amendments*: changing the "basket" of comparator countries for the purpose of reference pricing; and
3. Section 3(4) of the *Amendments*: providing a new price calculation requiring patentees to take into account discounts and rebates provided to third parties when reporting medicine prices to the Board.

The Court held that the first two impugned *Amendments* were *intra vires* the *Patent Act*, but the third *Amendment* (section 3(4)) was *ultra vires*.

The Court's analysis

The Court applied the recent Supreme Court of Canada (SCC) decision in *Canada (Minister of Citizenship and Immigration) v. Vavilov* (*Vavilov*),[3] holding that jurisdictional questions are not a distinct category of judicial review attracting a correctness review. The Court held that none of the exceptions to the standard of reasonableness that were noted by the SCC in *Vavilov* apply in this application, and thus, this standard applies. However, the Court stated "reasonableness is not a 'rubber-stamping' process" and "does not give administrative decision makers license to enlarge their powers beyond what the legislature intended."[4]

The Court held that a successful challenge to the *vires* of regulations requires a showing that the regulations are inconsistent with the objective of the enabling statute or

the scope of the statutory mandate. A broad and purposive approach must be used to interpret both the challenged regulation and the enabling statute. This type of challenge does not involve assessing the policy merits of the regulations.

The Court cited the SCC's statements in *Celgene Corp v. Canada (Attorney General)* that the Board's purpose is one of consumer protection. The SCC endorsed an approach to the Board's mandate that takes into account its "responsibility for ensuring that the monopoly that accompanies the granting of a patent is not abused to the financial detriment of Canadian patients and their insurers".[5] The Court held that the Board's mandate is limited to the specific abuse of excessive pricing, which is different from the patent abuse provisions of the *Patent Act*. The Court held that the Patented Medicines Regime is effectively a distinct division of the *Patent Act* and the focus should be on the purpose of that regime within the purpose of the *Patent Act* as a whole.

The Court held that the decision at issue is one made by the Governor in Council, which is separate from the Minister of Health. However, the Court also held that the Minister of Health's "comments describing modernizing the Board to 'lower the cost of drugs' are consistent with the explanation for the *Amendments* found in the RIAS, which states that the *Amendments* 'contribute to the Government's commitment [to improve the accessibility, affordability and appropriate use of medicines] by lowering the prices of patented medicines in Canada'".[6] Thus, arguments that the *Amendments* were meant to pave the way to a national pharmacare plan were dismissed. The Court also dismissed arguments that the *Amendments* do not comply with Canada's international treaty obligations.

New mandatory economic factors

The Court agreed with the Respondent, holding that "assessing pharmacoeconomic value is an objective exercise using a standardized measure of benefit."[7] The Court held that "[w]hile the patent monopoly allows patentees to price their products in a competition-free environment, patentees of medicines do not have unfettered pricing discretion. They must comply with Parliament's excessive pricing scheme as contained in the Patented Medicines Regime and implemented by the Board."[8]

In making these findings, the Court also held that the Board must consider all of the factors found in s. 85(1) of the *Patent Act*. The Board cannot ignore one factor or allow a factor to dominate such that the other factors are rendered irrelevant. The new mandatory factors were held to complement the factors already found in s. 85(1). The Court dismissed arguments that the mandatory factors were limited in scope by s. 85(1) of the *Patent Act*, holding that s. 101(1) of the *Patent Act* does not limit the type of factors the Governor in Council may specify by way of regulation. The Court held that its view on whether the *Amendments* will succeed in achieving the statutory objectives is irrelevant.

The Court held that the new mandatory factors in s. 4 of the *Amendments* are within the scope of the Governor in Council's regulation-making authority, and thus the decision to promulgate this regulation is reasonable.

The "basket" of comparator countries

The Applicants acknowledged that the Governor in Council has the discretion to select the comparator countries; however, they argued that the basis upon which the new basket was selected conflicts with the purpose of s. 85(1) of the *Patent Act*. The Court disagreed, holding that "patentees of medicines do not have unfettered discretion to make their own pricing decisions in Canada."[9] The Court also held that the list of countries does not amount to price control, as simply performing a price comparison does not dictate a specific conclusion. Thus, the decision to amend the basket of comparator countries was found to be reasonable.

The new price calculation

The new price calculation expands the information patentees must take into consideration when reporting the price at which the medicine is sold, requiring a reporting of price information net of discounts and rebates offered to parties further down the supply chain. The Applicants argued that this amendment exceeds the Board's factory-gate jurisdiction under the *Patent Act*. The Court agreed, holding that the *Patent Act* requires reporting on a sale by a patentee to a customer. Thus, any regulations must relate to the sale of medicines by patentees to customers.

The Court held that the *Amendments* in s. 3(4) are not limited to adjustments made by the customer or the patentee and extend to adjustments made by any party. "Requiring patentees to take into account financial transactions with third parties who are not customers — and are strangers to the original sale transaction — exceeds the scope of the Governor in Council's statutory mandate by untethering the price calculation from the sale of the patented medicine."[10]

The Court held that the Board's mandate is not to set prices for patented medicines and that the Board does not regulate profits made by patentees. "The Board's mandate to control prices is only engaged where it finds a patentee has abused its monopoly by charging excessive prices."[11] The Court dismissed the Respondent's argument that the Applicants were making a constitutional argument with respect to this provision. The Court concluded that this provision was *ultra vires* the *Patent Act*.

Conclusions

The Court declared s. 3(4) of the *Amendments* invalid, void and of no force and effect. Section 4(4) of the *Regulations* as it currently reads will continue to operate. The remainder of the *Amendments* were held to be valid. The parties agreed not to seek costs regardless of outcome and thus, no costs were ordered.

[1] *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298 [the *Amendments*].

[2] *Patented Medicines Regulations*, SOR/94-688 (the *Regulations*).

[3] *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65.

[4] *Innovative Medicines Canada, et al. v. The Attorney General of Canada*, 2020 FC 725 at para 64 (*IMC v. Canada*).

[5] *Celgene Corp v Canada (Attorney General)*, 2011 SCC 1 at para 28-29.

[6] *IMC v. Canada*, para 99; *Regulatory Impact Analysis Statement*, *Canada Gazette Part II*, Vol 153, No 17, pp5946-96 at 5949 (the RIAS)

[7] *IMC v. Canada*, para 118.

[8] *IMC v. Canada*, para 127.

[9] *IMC v. Canada*, para 159.

[10] *IMC v. Canada*, para 198.

[11] *IMC v. Canada*, para 199.

By

Beverley Moore, Chantal Saunders

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BLG Offices

Calgary
Centennial Place, East Tower
520 3rd Avenue S.W.
Calgary, AB, Canada
T2P 0R3

T 403.232.9500
F 403.266.1395

Ottawa
World Exchange Plaza
100 Queen Street
Ottawa, ON, Canada
K1P 1J9

T 613.237.5160
F 613.230.8842

Vancouver
1200 Waterfront Centre
200 Burrard Street
Vancouver, BC, Canada
V7X 1T2

T 604.687.5744
F 604.687.1415

Montréal
1000 De La Gauchetière Street West
Suite 900
Montréal, QC, Canada
H3B 5H4

T 514.954.2555
F 514.879.9015

Toronto
Bay Adelaide Centre, East Tower
22 Adelaide Street West
Toronto, ON, Canada
M5H 4E3

T 416.367.6000
F 416.367.6749

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