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Amendments to the Patented Medicines Regulations Lose Some Teeth

The proposed amendments to the *Patented Medicines Regulations* had the projected effect of lowering drug prices by billions of dollars over the next ten years. But by overreaching its jurisdiction, these amendments have lost some of its bite. The Quebec Court of Appeal determined several provisions to be *ultra vires*.

Since their introduction in August 2019, proposed amendments to the *Patented Medicines Regulations* (the "*PM Regulations*") have faced ongoing scrutiny. The amendments:

i. extend the factors to be considered when assessing whether a patented medicine has been excessively priced;
ii. modify the list of comparator countries; and
iii. broaden the price and sale disclosure requirements for drug manufacturers to include discounts or rebates to third parties.

The proposed amendments were expected to lower drug prices by billions of dollars over the next ten years.

Originally set to come into force on July 1, 2020 the proposed amendments have been delayed by the COVID-19 pandemic and strong opposition, as previously reported here.

In December 2021, the Quebec Court of Appeal (the "QCA") heard a constitutional challenge to the provisions and recently issued their decision in *Merck Canada inc c Procureur général du Canada*. The proposed amendments have lost some of their bite – the QCA held certain provisions to be overreaching and outside the Federal government's jurisdiction.

The Quebec Court of Appeal's Decision

At issue in this appeal was whether the proposed amendments were within the powers of the Federal government to enact, also known as *intra vires*, or whether the proposed amendments encroached on the powers of the provincial governments to regulate drug prices and were therefore ultra vires.

Section 91(22) of the *Constitution Act*, 1867 grants the Federal government and, in turn, the Patented Medicine Prices Review Board's (the "PMPRB") jurisdiction over patented medicines. This provision narrowly gives the Federal government and its administrative bodies power to regulate patents of invention and discovery, as primarily embodied by the *Patent Act* and its associated regulations. Section 91(22) does not provide a wholesale grant of power to regulate all aspects of pharmaceuticals.

In its analysis, the QCA sought to determine whether the proposed amendments fell within or outside the powers allocated by the *Constitution Act*, and in turn, the *Patent Act*. The QCA determined the purpose of the *PM Regulations*, the purpose of the proposed amendments, as well as the purpose of the powers conferred on the PMPRB in the *Patent Act*. In doing so, the QCA considered regulatory impact studies, parliamentary statements, and the updated PMPRB Guidelines (which are themselves the subject of a judicial review proceeding in T-1419-20).

Based on this review, the QCA held that Federal jurisdiction over patents:

i. could not extend beyond the ex-factory price, i.e., the selling price of a drug set by the patentee for a customer to whom he sells directly, which excludes the subsequent resale price of the drug, such as in a sale by a pharmacist to a patient; and
ii. extends only to protect against excessive pricing that arises because of a patent monopoly, i.e., this power does not extend to controlling the price of medicines generally, and is narrowly understood to prevent the abuse of patent rights.

As a result:

i. the proposed amendments that compelled drug manufacturers to disclose discounts or rebates to third parties were held to be *ultra vires*, as this information extended beyond ex-factory pricing;
ii. the proposed amendments to the list of comparator countries used to determine whether prices are excessive was held *intra vires*. The objectives in selecting comparator countries are to promote research and development within Canada while controlling excessive pricing resulting from the

patent monopoly. Both considerations are objectives within the federal jurisdiction over patents; and

iii. the new factors introduced to assess whether a medicine was excessively priced (i.e., the pharmacoeconomic value of the medicine in Canada, the market size of that medicine in Canada and the gross domestic product per capita in Canada) were held *ultra vires*, as they imposed arbitrary price reductions unrelated to patent monopoly.

What's Next?

It remains to be seen whether Canada will seek leave for appeal to the Supreme Court of Canada, and whether the Supreme Court would hear the case. While an appeal would raise issues of national importance, the QCA's reasons were lengthy, thorough, and rely on well-established lines of jurisprudence.

As previously noted, there remain other active challenges to the proposed amendments. One to watch is the appeal of the judicial review in *Innovative Medicines Canada et al v AGC et al* , which was heard by the Federal Court of Appeal (the "FCA") on February 28, 2022. In that case Innovative Medicines Canada and several pharmaceutical companies sought a declaration that the same provisions of the proposed amendments challenged in Quebec were invalid as *ultra vires* the *Patent Act*.

Justice Manson, in rendering the decision at first instance, was aware of the parallel proceeding in Quebec and noted that their analyses need not overlap:

> Constitutional validity is not at issue in the present proceeding. …That said, the question the Court must answer is whether the Governor in Council's decision meets the threshold of acceptability and defensibility characteristic of a reasonable decision in light of the relevant constraints. …

> I need not consider constitutional division of powers limitations as the New Price Calculation is inconsistent with the governing statutory scheme. …This judicial review is about statutory vires alone, and whether the Governor in Council's mandate under the Patent Act is sufficiently broad…

Justice Manson declared the disclosure requirements relating to ex-factory pricing *ultra vires* the *Patent Act*, but held the new

factors in determining excessive pricing and proposed amendments to the list of comparator countries *intra vires*. While the legal issues considered by Justice Manson and the QCA were not the same, it is interesting that the two courts diverged on the appropriateness of the new economic factors to be considered.

In rendering its decision, the QCA cited to Justice Manson's decision in support of its finding that the disclosure requirements were *ultra vires*. Whether or not the QCA's findings will influence the decision of the FCA – and whether the FCA will align its decision on the new factors with the QCA – remains to be seen.