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Changes to List of Comparator Countries Used to Assess Pricing of Patented Medicines Affirmed on Appeal

Mark Davis, A. Chandimal Nicholas, Kassandra Shortt, Carly Valentine

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The Federal Court of Appeal's recent decision in *Innovative Medicines Canada v Canada (AG)*[1] confirmed the scope of the Governor in Council's power to regulate excessive pricing of patented medicines. Specifically, the Court affirmed the validity of amendments to the list of comparator countries to be considered by the Patented Medicine Prices Review Board (PMPRB) in assessing whether prices are excessive — even though the amendments extended beyond the mandate of the PMPRB to the ancillary purpose of cost savings.

Background

Innovative Medicines Canada (IMC) is an industry association representing Canada's innovative pharmaceutical industry. IMC, together with sixteen pharmaceutical companies, applied for judicial review of three amendments made to the *Patented Medicines Regulations*[2] (the *Regulations*) made under the *Patent Act*.[3]

The amendments at issue prescribed and altered the factors the PMPRB must consider in determining whether pharmaceutical prices are "excessive" under section 85 of the *Patent Act*. Among them was a change to the list of comparator countries the PMPRB can consider for pricing information (the Comparator Countries Amendment). Prior to the amendment, the PMPRB considered prices in seven countries. The Comparator Countries Amendment dropped Switzerland and the United States from the list and added Australia, Belgium, Japan, the Netherlands, Norway, and Spain. France, Germany, Italy, Sweden, and the United Kingdom remained on the reconstituted list of 11 countries. That resulted in two countries (namely Switzerland and the United States) being replaced by six countries with comparatively lower prices for patented medicines.

The Federal Court[4] found that the Comparator Countries Amendment was reasonable and made for a permitted purpose within the scope of the *Patent Act*. IMC appealed.

Analysis

Affirming the Scope of the Governor in Council's Regulation-Making Power

The Court began its analysis by considering the proper scope of the Governor in Council's authority under the *Patent Act*.

The Governor in Council is empowered by section 101(1) of the *Patent Act* to make regulations for the purpose of policing excessive pricing. This power must be read in light of section 85 of the *Patent Act*, which is the "core" of the PMPRB's decision-making power for determining whether "medicine is being or has been sold at an excessive price." Under section 85, the PMPRB must consider various factors when reviewing pharmaceutical pricing, including the "prices at which the medicine … [has] been sold in countries other than Canada."

The Court noted that the PMPRB's legislative authority to determine whether medicines were priced excessively has been a "fertile area of litigation." It reaffirmed that the scope of section 85 and the PMPRB's decision-making power is limited to "policing excessive pricing" or "patent abuse" and does *not* extend to price regulation or consumer protection.

Recognizing Additional Elements to the Scope of Section 85 of the *Patent Act*

The Court found that, in practice, the Comparator Countries Amendment provides updated information to the PMPRB on medicine prices. It recognized that purposes beyond the narrow ambit of "policing excessive pricing" — for example, lowering overall costs and creating public savings — are a natural consequence of such regulatory amendments. In its words, "an honest recognition that the amendments may cause overall cost savings as a natural consequence of the measure does not mean that that is the pith and substance of the amendments."

The Purpose of the Comparative Countries Amendment

The Court concluded that the purpose of the Comparative Countries Amendment was not outside the bounds of the Governor in Council's power and did not contravene the purpose of section 85. In doing so, it reaffirmed the purpose of the Comparative Countries Amendment as found by the Federal Court: "the modernization of tools the Board uses to police the excessive pricing of patented medicines." The revised list of comparator countries affected the information available to the Board when comparing pricing information. The Court found that this change did not impact how that information would be used, whether for proper or improper purpose. It specifically noted that, if the PMPRB later used the new information for a purpose beyond its mandate, an aggrieved party could succeed in blocking the misuse on judicial review.

Conclusion

The Court concluded that the Comparator Countries Amendment was properly within the scope set out by the *Patent Act* and was therefore reasonable.

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Key Takeaways

This decision confirms the validity of the Comparator Countries Amendments, which came into force on July 1, 2022. At the same time, it invites parties to carefully monitor the PMPRB to ensure it uses the new comparator country information solely for purposes within its mandate. It may also facilitate future amendments to the PMBRB's mandate that have ancillary effects like cost savings in the future.

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[1] 2022 FCA 210 [*Innovative Medicines*]

[2] SOR/94-688.

[3] RSC 1985, c P-4.

[4] *Innovative Medicines Canada v Canada (AG)*, 2020 FC 725.
