The FCA concludes PMPRB decision re Differin® exceeded the Board's jurisdiction

December 05, 2024

The Federal Court of Appeal (FCA) recently issued its decision in the appeal of Galderma's second judicial review of the decision of the Patented Medicines Price Review Board (the PMPRB) that it had jurisdiction over Galderma's Differin® product. In a strongly worded decision, the FCA granted Galderma's appeal and set aside the PMPRB's decision, holding that the PMPRB does not have jurisdiction over the price of the unpatented Differin® product.

History

This is the second time the FCA has adjudicated this dispute between Galderma and the PMPRB over whether Canadian Patent 2,478,237 (the '237 Patent) pertains to Galderma's Differin® product.

Galderma sells two products containing the medicinal ingredient adapalene: Differin® contains 0.1 per cent adapalene whereas Differin XP® contains 0.3 per cent. The patents pertaining to the Differin® product had expired. The '237 Patent relates to the Differin XP® product, and specifically the use of the 0.3 per cent concentration of adapalene. However, the PMPRB asserted that it also pertains to the Differin® product such that Galderma was required to provide pricing and other information about it to the PMPRB.

In 2016, the PMPRB determined that the '237 Patent does pertain to Differin®. However, in 2017, the FC quashed that decision, holding that it was unreasonable for the Board, without explanation, to conclude that a patent relating to a composition of 0.3 per cent adapalene can be used for a medicine with a composition of only 0.1 per cent adapalene.

The Attorney General's appeal to the Federal Court of Appeal (FCA) was granted, and the decision was remitted to the Board for redetermination. The FCA held that the invention of the '237 Patent is a composition with a 0.3 per cent concentration of adapalene for the treatment of dermatological disorders.

In May 2020, the PMPRB again determined that the '237 Patent pertained to Differin®. This decision was upheld by the Federal Court in 2024. A more detailed history and a summary of the Federal Court decision is found here.

The FCA decision

Justice Stratas, writing for the Court of Appeal, held that decades of jurisprudence confirms that the PMPRB can regulate the pricing of patented medicines, but not unpatented ones (para 5). The Court confirmed that the relevant provisions of the *Patent Act* are carefully drawn to give the PMPRB power within the Federal constitutional power over patents. The PMPRB "does not have any freestanding consumer protection or general price regulation mandate." (Para 7) Those are provincial responsibilities.

The Court held that by ordering Galderma to produce pricing information pertaining to its Differin® product after it became unpatented, "the Board crashed through the constitutional, statutory, and jurisprudential guardrails." (Para 10). The Court rejected the Board's argument that the '237 Patent pertained to the Differin® product, writing "[T]he invention in the '237 Patent, the use of the 0.3% concentration of adapalene, cannot (in the words of subsection 79(2)) be "intended or capable of being used" for Differin or for "the preparation or production" of Differin, because Differin does not embody that use at all." (Para 13)

The Court stated that in its earlier decision on this issue, it asked the PMPRB to re-examine the matter "'on the basis that the invention of Canadian Patent No. 2,478,237 is the use of a 0.3 per cent concentration of adapalene for the treatment of dermatological disorders' (at para. 6). But in no way did this Court give the Board a licence to go beyond constitutional, statutory, and jurisprudential limits. Nor could it." (Para 14)

The Court did not decide the standard of review, as it held that "due to the absence of alternative options available to the administrative decision-maker on the facts of the case, correctness review and reasonableness review are indistinguishable and lead to the same result". (Para 17) If the Board adopted and applied an indefensible and unacceptable interpretation of the *Patent Act*, it would be unreasonable. The FCA further confirmed that "the Board must temper its dedication and enthusiasm with a firm and unwavering obedience to legality and the rule of law." (Para 19)

Thus, making the judgment the Federal Court should have made, the FCA granted the application for judicial review, and set aside the PMPRB's order. Costs were agreed between the parties and fixed at $20,000 in the FCA and below.

By

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