PMPRB's decision that patent pertains to drug held to be reasonable by Federal Court

January 23, 2024

In *Galderma Canada Inc. v. Canada (Attorney General)*, the Federal Court (FC) judicially reviewed a decision relating to a drug that contains 0.1 per cent of a medicine while the patent is to a 0.3 per cent concentration of that medicine.

Galderma and the Patented Medicine Prices Review Board (PMPRB) have a long-running dispute over whether a particular patent "pertains to" Galderma's Differin® product, under the *Patent Act*. In the most recent judicial review decision, the FC held that the PMPRB's decision that the patent does pertain to the product was reasonable.

History

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, meaning its pricing was no longer under the PMPRB's jurisdiction. The '237 Patent, which is the subject of this dispute, has also now expired. However, the dispute is about whether it pertained to the Differin® product prior to expiry, bringing that product back under PMPRB jurisdiction while the patent was in force.

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, remitting the decision 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.

Furthermore, the FCA held that the metaphor of the "merest slender thread" cannot replace the statutory definition of "pertains to" in the *Patent Act*. The FCA held that "[i]n cases such as this, where the question is whether an invention pertains to a specific

medicine, what kind of clinical similarities would support a finding that the invention of a patent was intended or capable of being used for that medicine?" (para 73).

The parties submitted further written representations before the Board, but no new evidence. In May 2020, the PMPRB again held that the '237 Patent pertains to Differin®. The Board held that Galderma's argument that for an invention to pertain to a medicine under the *Patent Act*, it must encompass the medicine being sold by the patentee, was inconsistent with the wording of the provision and precluded by the decision of the FCA. Furthermore, due to the clinical similarities between the two products, the Board was satisfied that the invention in the '237 Patent could be used for Differin®.

As part of the judicial review, Galderma filed three additional affidavits as evidence before the FC, those of an expert in patent law, a regulatory affairs expert, and a fact witness. On motion, the Court struck the affidavit of the patent expert in full, and the regulatory affairs expert's in part. The fact witness' affidavit was allowed as it contained non-controversial background information.

The Federal Court decision

The FC concluded that the standard of review is reasonableness, which is the same standard previously applied by the FCA. Citing the Supreme Court, the FC held it is only to intervene where "there are sufficiently serious shortcomings in the decision such that it cannot be said to exhibit the requisite degree of justification, intelligibility and transparency." Thus, the reasons must allow an understanding of why the decision was made, as well as a determination of whether it falls within the range of acceptable outcomes defensible in respect of the facts and law (para 34).

The FC dismissed Galderma's argument that the Board's decision was not procedurally fair, as the product monograph (PM) was not mentioned in the Board's Notice of Application. Galderma did not object to this alleged breach before the Board. Furthermore, the PM had been referred to in the Board's initial decision, the FC's previous decision, and by the FCA.

The FC held that the Board's decision that Differin® and Differin XP® "use the same medicinal ingredient, are indicated for the same dermatological disorder and work in the same way," and thus are the same medicine, was reasonably supported by the evidence (para 60). The FC also took no issue with the Board's conclusions that the shared PM supported the existence of a rational connection between the two products. Furthermore, the invention of the '237 Patent and Differin® produced similar clinical effects, with comparable side effects, and while not interchangeable, they were prescribed for similar conditions and could in some circumstances be substituted for each other.

The FC concluded that the FCA had remitted a narrow issue for redetermination and the PMPRB needed to "consider the kind of clinical similarities that would support a finding that the invention of a patent was intended or capable of being used for that medicine" (para 64). The Board found significant clinical similarities, and its decision was reasonable.

Thus, the judicial review was dismissed, with lump-sum costs payable to the Attorney General of Canada.

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