Federal Court of Appeal | Cour d'appel fédérale

Date: 20241203

Docket: A-61-24

Citation: 2024 FCA 208

CORAM: **STRATAS J.A.**
MONAGHAN J.A.
WALKER J.A.

BETWEEN:

GALDERMA CANADA INC.

Appellant

and

ATTORNEY GENERAL OF CANADA

Respondent

Heard at Toronto, Ontario, on November 7, 2024.

Judgment delivered at Ottawa, Ontario, on December 3, 2024.

REASONS FOR JUDGMENT BY: STRATAS J.A.

CONCURRED IN BY: MONAGHAN J.A.
WALKER J.A.

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REASONS FOR JUDGMENT

STRATAS J.A.

[1] Fourteen years ago, the appellant's medicine, Differin, was a patented medicine. While Differin was a patented medicine, the appellant provided pricing and other information about it to the Patented Medicine Prices Review Board. The *Patent Act*, R.S.C. 1985, c. P-4, as amended, and associated Regulations required this.

[2] In December 2009, Differin's patent expired. It was no longer a patented medicine. Thus, the appellant stopped providing information about Differin. Its obligation to do that had ended—or so the appellant thought.

[3] Roughly six years later, in 2016, the Patented Medicine Prices Review Board required the appellant to produce information about Differin—now an unpatented medicine—for periods when the medicine was unpatented (2010-2016).

[4] The appellant objected and refused to provide the information. This was understandable. The Patented Medicine Prices Review Board regulates the pricing of medicines under the market power given by a patent—namely, patented medicines. The Board does not regulate the pricing of unpatented medicines. After all, it's right in the Board's name: the Board is the "Patented Medicine Prices Review Board", not the "Patented and Unpatented Medicine Prices Review Board" or the "All Medicine Prices Review Board".

[5] Decades of consistent jurisprudence from multiple jurisdictions have confirmed and reconfirmed that the Board can regulate the pricing of patented medicines, not unpatented medicines: *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2021 FCA 157, [2022] 1 F.C.R. 153; *Merck Canada Inc. v. Canada (Attorney General)*, 2022 QCCA 240; *Innovative Medicines Canada v. Canada (Attorney General)*, 2022 FCA 210 at para. 19; *Canada (Attorney General) v. Sandoz Canada Inc.*, 2015 FCA 249, 390 D.L.R. (4th) 691 at para. 26; *ICN Pharmaceuticals Inc. v. Patented Medicine Prices Review Board* (1996), 66 C.P.R. (3d) 45, 108

F.T.R. 190, aff'd [1997] 1 F.C. 32, 119 F.T.R. 70 (C.A.); *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 D.L.R. (4th) 485, 70 Man. R. (2d) 141 (Q.B.).

[6] The Board is a federal body, established and empowered under the federal jurisdiction over patents in subsection 91(22) of the *Constitution Act, 1867* (U.K.), 30 & 31 Vict., c. 3, reprinted in R.S.C. 1985, Appendix II, No. 5. Under the *Patent Act*, sections 79-90—carefully drawn to stay within the federal constitutional power over patents—the Board polices the prices of patented medicines to make sure that those who benefit from the market power given by patents do not abuse it.

[7] The Board's work protects consumers of patented medicines: the prices of patented medicines are lower than they might otherwise be. See *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1, [2011] 1 S.C.R. 3 at paras. 25-26. But focusing on those effects to define the Board's mandate would be to let the tail wag the dog. The Constitution, the *Patent Act* and the jurisprudence under each is clear: the Board does not have any freestanding consumer protection or general price regulation mandate. See *Celgene* at paras. 28-29 citing *ICN*; see also *Alexion* at paras. 49-55 and *Innovative Medicines* at para. 19. Absent an emergency, national concern, or some other specific source of federal power, none of which apply here, freestanding consumer protection and general price regulation are provincial responsibilities: *Re: Anti-Inflation Act*, [1976] 2 S.C.R. 373, 68 D.L.R. (3d) 452.

[8] Quite simply, under the Constitution, the *Patent Act* and the jurisprudence under each, the Board does not have the power to regulate the prices of unpatented medicines during the period they are unpatented.

[9] Here, however, the Patented Medicine Prices Review Board ordered the appellant to produce pricing information pertaining to the periods when its medicine, Differin, was unpatented, indeed six years after it became unpatented.

[10] By making that order, the Board crashed through the constitutional, statutory and jurisprudential guardrails. Or to use the more orthodox, formal, administrative law language in *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, [2019] 4 S.C.R. 653, the Board exceeded the constraints acting upon it—some pretty clear, longstanding and well-established ones too. Thus, the Board's order must be set aside.

[11] The Attorney General, defending the Board, says that the Board could regulate the unpatented medicine, Differin, because of a patent (No. 2,478,237) covering a separate medicine, Differin XP, which has a higher concentration of the same active ingredient, adapalene. But the '237 Patent covering Differin XP—a patent different from the expired one that used to cover Differin—does not cover Differin. The '237 Patent does not give the appellant market power over Differin. The unpatented medicine, Differin, off-patent since December 2009, has been open to potential, if not actual, price competition since that time.

[12] The Attorney General resists this conclusion, relying on particular provisions of the *Patent Act*. It submits that a "patentee" under the Act is a "person for the time being entitled to the benefit of the patent for that invention" (s. 79(1)) and "an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine" (s. 79(2)). It says that the "invention" in the '237 Patent (embodied in Differin XP) is the higher concentration of the same active ingredient used in Differin. It adds that the Board found that patients can often use Differin XP and Differin interchangeably. Thus, it says that Differin falls within the scope of the *Patent Act*.

[13] On these facts, the *Patent Act* cannot be reasonably read to permit that result for a number of reasons:

- Under subsection 79(1) of the *Patent Act*, after December 2009 the appellant was no longer "entitled to the benefit of the patent for [the] invention", which was a lower, 0.1% concentration of the active ingredient, adapalene, in Differin. Thus, after December 2009 the appellant was no longer a "patentee" under subsection 79(1) for Differin. From December 2009, Differin has been an unpatented medicine.

- The '237 Patent is a "use patent" that covers the use of the 0.3% concentration of adapalene, the active ingredient in Differin XP, not adapalene itself. As a matter of patent law, the Board cannot somehow stretch and pull that "use patent" to cover Differin, which uses a different concentration of adapalene (0.1%). The

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.

- Subsection 79(2) of the *Patent Act* does not give the Patented Medicine Prices Review Board the power to review unpatented medicines. Had it done so, it would have extended the Board’s power beyond its constitutional limits, into the field of regulating the prices of unpatented medicines. In the case of ambiguity—and here there is none—where possible, statutory provisions like subsection 79(2) must be interpreted to stay within the limits of the Constitution: *Hills v. Canada (Attorney General)*, [1988] 1 S.C.R. 513, 48 D.L.R. (4th) 193; *R. v. Monney*, [1999] 1 S.C.R. 652, 171 D.L.R. (4th) 1; *R. v. Nova Scotia Pharmaceutical Society*, [1992] 2 S.C.R. 606, 93 D.L.R. (4th) 36; *Cooper v. Canada (Human Rights Commission)*, [1996] 3 S.C.R. 854, 140 D.L.R. (4th) 193.

- If the appellant is pricing the patented medicine, Differin XP, excessively due to abuse of its market power under the ’237 Patent, the Board can go after Differin XP, not Differin, now unpatented. Nowhere does the *Patent Act* say that the Board can regulate an unpatented medicine just because a patented medicine might be used in its place or because it shares some unpatented properties of the patented medicine (here, the unpatented ingredient adapalene).

[14] The Attorney General also submits that in an earlier decision concerning Differin and Differin XP, this Court encouraged the Board to proceed as it did: *Canada (Attorney General) v. Galderma Canada Inc.*, 2019 FCA 196. This Court did ask the Board 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% 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.

[15] Under subsection 81(1) of the *Patent Act*, the Board can require "a former rights holder for an invention pertaining to a medicine" to provide it with pricing and other information pertaining to the period the medicine was under patent. The Board can require pricing information up to three years after the medicine became unpatented (s. 81(3)). All of that is true. But how about seeking pricing information about an unpatented medicine for the years it was unpatented, and seeking that information six years after the medicine became unpatented? Section 81 cannot be reasonably read to permit that.

[16] The appellant says that the standard of review of the Board's decision to make the order was correctness, not reasonableness. It points to the constitutional limits on the Board's powers. The appellant is right if the Court characterizes the problem as the Board going beyond its constitutional limits. Equally though, as the above analysis shows, the Court can characterize the problem as the Board adopting and applying an unacceptable and indefensible (*i.e.*, unreasonable) interpretation of the *Patent Act*.

[17] In the end, the standard of review does not matter here. This case is like others where, 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: *McLean v. British Columbia (Securities Commission)*, 2013 SCC 67, [2013] 3 S.C.R. 895 at para. 38; see also *Walchuk v. Canada (Minister of Justice)*, 2015 FCA 85, 91 Admin. L.R. (5th) 185 at para. 32, *Canada (Attorney General) v. Abraham*, 2012 FCA 266, 440 N.R. 201 at paras. 42-49, and *Sturgeon Lake Cree Nation v. Hamelin*, 2018 FCA 131, 424 D.L.R. (4th) 366 at para. 45. Here, under either standard of review—correctness or reasonableness—this Court must set aside the Board's order.

[18] In this case, the Federal Court (*per* Fothergill J., 2024 FC 46) found that the Board's decision was reasonable. It upheld the Board's order. Given the foregoing analysis, the Federal Court's finding and result cannot stand.

[19] The Board has an important mandate. Given the importance of that mandate, the Board is dedicated and enthusiastic about pursuing it. That's worthy of praise. But the Board must temper its dedication and enthusiasm with a firm and unwavering obedience to legality and the rule of law. Like all administrative decision-makers, the Board must stay within the constraints imposed by the Constitution, its governing statute (the *Patent Act*, interpreted reasonably in the administrative law sense), and the jurisprudence under each.

[20] Therefore, I would allow the appeal and set aside the judgment of the Federal Court in file T-906-20. Making the judgment the Federal Court should have made, I would grant the

application for judicial review and set aside the order dated May 7, 2020 of the Patented Medicine Prices Review Board. As a result of an agreement on costs between the parties, I would award the appellant its costs here and below, fixed at $20,000 all inclusive.

"David Stratas"
J.A.

"I agree.
K. A. Siobhan Monaghan J.A."

"I agree.
Elizabeth Walker J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-61-24
STYLE OF CAUSE:	GALDERMA CANADA INC. v. ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	NOVEMBER 7, 2024
REASONS FOR JUDGMENT BY:	STRATAS J.A.
CONCURRED IN BY:	MONAGHAN J.A. WALKER J.A.
DATED:	DECEMBER 3, 2024

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