Federal Court of Appeal | Cour d'appel fédérale

Date: 20250522

Docket: A-328-23

Citation: 2025 FCA 101

CORAM: **STRATAS J.A.**
GOYETTE J.A.
BIRINGER J.A.

BETWEEN:

THE WINNING COMBINATION INC.

Appellant

and

ATTORNEY GENERAL OF CANADA

Respondent

Heard at Winnipeg, Manitoba, on May 22, 2025.

Judgment delivered from the Bench at Winnipeg, Manitoba, on May 22, 2025.

REASONS FOR JUDGMENT OF THE COURT BY: BIRINGER J.A.

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REASONS FOR JUDGMENT OF THE COURT

(Delivered from the Bench at Winnipeg, Manitoba, on May 22, 2025).

BIRINGER J.A.

[1] The Winning Combination (TWC) appeals from a judgment of the Federal Court (2023 FC 1465, *per* Elliott J.) dismissing TWC's application for judicial review of a Health Canada redetermination decision (Decision). In the Decision, Health Canada refused TWC's product licence application for Resolve, a product which TWC alleges aids smoking cessation

and is a “natural health product” governed by the *Natural Health Products Regulations*, S.O.R./2003-196.

[2] The product licence approval regime for a “natural health product” is distinct from the regime for the approval of drugs under the *Food and Drug Regulations*, C.R.C., c. 870. This Court set out a description of the process and the long procedural history between the parties in *Canada (Health) v. The Winning Combination Inc*., 2017 FCA 101.

[3] Following this Court’s decision in 2017 remitting TWC’s product licence application for redetermination, Health Canada initiated a redetermination process which included testing by three independent laboratories and an external panel review. The sole issue was whether the confidential active ingredient (Compound) in Resolve was set out in Schedule I such that Resolve was a “natural health product”. The process culminated in the Decision under review (February 6, 2020). In denying TWC’s product licence application, Health Canada concluded that there was no reliable evidence that the Compound is naturally present in passionflower and, accordingly, Resolve was not a “natural health product”.

[4] The appellant submits on appeal, as it did in the Federal Court, that the Health Canada redetermination process was procedurally unfair, violated TWC’s legitimate expectations, gave rise to a reasonable apprehension of bias, and was fuelled by improper purposes. These concerns stem largely from Health Canada conducting an independent laboratory testing process, which the appellant says was a departure from past practice. The appellant also submits, as it did in the

Federal Court, that the decision to undertake laboratory testing was *ultra vires*, or if *intra vires*, that the Decision was unreasonable due to deficiencies in the testing.

[5] The test for procedural fairness in a case such as this is whether, considering the context, the parties knew the case to meet and had a full and fair chance to respond: *Canadian Pacific Railway Company v. Canada (Attorney General)*, 2018 FCA 69 at para. 56. Legitimate expectations may arise if a public authority has made clear and unequivocal representations about the procedure it will follow: *Agraira v. Canada (Public Safety and Emergency Preparedness*), 2013 SCC 36 at para. 94; *Canada (Attorney General) v. Mavi*, 2011 SCC 30 at para. 68.

[6] Substantially for the reasons expressed by the Federal Court, we are satisfied that there was no procedural unfairness. TWC had notice of the redetermination process and provided input. Health Canada followed the procedure set out in correspondence with TWC. TWC's legitimate expectations were not violated. TWC also had an opportunity to review the independent laboratories' test results and provide submissions to the expert panel. TWC may be unhappy with Health Canada's way of proceeding and its conclusion, but the procedure was fair having regard to all of the circumstances: *Canadian Pacific Railway* at para. 54; *Canada RNA Biochemical Inc. v. Canada (Health)*, 2021 FCA 213 at para. 27.

[7] While the appellant also alleges bias and improper purposes, we conclude the appellant has not established these. The grounds for an apprehension of bias must be substantial – a real likelihood or probability of bias is required, and the evidence must be clear and cogent: *Germain*

v. Saskatchewan Government Insurance, 2015 SKCA 84 at para. 32: *R. v. S. (R.D.)*, [1997] 3 S.C.R. 484. We find that the redetermination process initiated by Health Canada was an appropriate response to this Court's decision, and that an informed person viewing the matter realistically and practically would conclude that it was done fairly, without bias, actual or apparent: *Committee for Justice and Liberty et al. v. National Energy Board et al.*, [1978] 1 S.C.R. 369 at p. 394; *Wewaykum Indian Band v. Canada*, 2003 SCC 45 at para. 60.

[8] On an appeal from a judicial review decision of the Federal Court, such as here, this Court must determine whether the Federal Court correctly selected and applied the standard of review: *Northern Regional Health Authority v. Horrocks*, 2021 SCC 42 at para. 10; *Agraira* at paras. 45-46. This Court must step into the shoes of the Federal Court and review the administrative decision afresh, essentially engaging in a "do-over" of the review of the administrative decision: *Horrocks* at para. 10; *Sun v. Canada (Attorney General)*, 2024 FCA 152 at para. 4.

[9] The Federal Court correctly concluded that the standard of review for the Decision was reasonableness. While the Federal Court did not address in detail the reasonableness of the Decision, we conclude that it was reasonable. It reflects an internally coherent and rational chain of analysis that is justified in relation to the facts and the law and reaches an acceptable and defensible result: *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, [2019] 4 S.C.R. 653 at para. 85. The results of the independent laboratory tests challenged by the appellant were only part of the evidence considered and the Decision acknowledged the deficiencies in that testing raised by the expert panel.

[10] The Decision also takes into account the initial testing done by TWC's experts and refers to numerous and serious flaws in that testing observed by the expert panel. The absence of a reference in the scientific literature supporting TWC's position is also noted. Health Canada weighed the evidence before it, including the evidence put forward by TWC, and reasonably concluded that there was no reliable evidence of the Compound being naturally present in passionflower, and thus Resolve was not a "natural health product".

[11] We reject the appellant's submission that the Health Canada decision to initiate independent laboratory testing was *ultra vires*. Even if a departure from prior practice, Health Canada was not prohibited from doing so pursuant to the *Natural Health Products Regulations* and doing so was consistent with its decision-making authority. It was within its discretion to design the process to evaluate TWC's claims.

[12] At the end of the day, notwithstanding the supplemental investigative measures undertaken by Health Canada in the redetermination process, TWC alone has always borne the burden of establishing that Resolve is a "natural health product" governed by the *Natural Health Products Regulations*. The fact that this Court ordered a redetermination by Health Canada, and as a result Health Canada chose to embark on more experimental work and reassessment does not change the overall legal burden on TWC. Despite ample opportunity, it has not discharged that burden. The uncertain state of the evidence throughout means that TWC falls way short of the mark in establishing entitlement to a mandatory order that Health Canada recognize Resolve as a "natural health product".

[13] For these reasons, we will dismiss the appeal with costs.

"Monica Biringer"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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