

Federal Court



Cour fédérale

Date: 20201207

Docket: T-338-20

Citation: 2020 FC 1102

Vancouver, British Columbia, December 7, 2020

PRESENT: The Honourable Madam Justice Heneghan

BETWEEN:

THE WINNING COMBINATION INC.,

Applicant

and

THE ATTORNEY GENERAL OF CANADA

Respondent

PUBLIC ORDER AND REASONS

(Identical to the Confidential Order and Reasons issued on November 30, 2020)

[1] By Notice of Application issued on March 4, 2020, The Winning Combination Inc. (the “Applicant”) seeks judicial review of the decision of Health Canada made on or about February 6, 2020. In that decision, Health Canada denied the Applicant’s product license application (the “PLA”) in respect of its product “RESOLVE”, pursuant to the *Natural Health Products Regulations*, S.O.R./2003-196 under the *Food and Drugs Act*, R.S.C. 1985, c. F-27.

[2] The present application for judicial review arises in consequence of earlier proceedings.

[3] The Applicant sought a PLA in respect of its product RESOLVE in October 2004. Its application was denied on January 30, 2012, and the Applicant filed an application for judicial review. The application was granted, the Court quashed the negative decision and issued an order of *mandamus* directing the issuance of a PLA; see the decision reported as *Winning Combination Inc. v. Canada (Health)*, 2016 FC 381.

[4] Upon appeal, the Federal Court of Appeal upheld the quashing of the decision, vacated the order of *mandamus* and ordered that the matter be remitted to the decision maker for a redetermination within 90 days; see the decision in *Canada (Health) v. The Winning Combination Inc.* (2017), 413 D.L.R. (4th) 362 (F.C.A.). An application for leave to appeal to the Supreme Court of Canada was dismissed; *Winning Combination Inc. v. Canada (Minister of Health), et al.*, 2018 CanLII 30056 (S.C.C.).

[5] Pursuant to Rule 303(2) of the *Federal Courts Rules*, S.O.R./98-106 (the “Rules”), the Attorney General of Canada is the Respondent (the “Respondent”) to the Application.

[6] Following commencement of the application for judicial review on March 4, 2020, an Amended Notice of Application was filed on August 10, 2020.

[7] By Notice of Motion filed on September 30, 2020 submitted for consideration pursuant to Rule 369, the Respondent seeks an Order to strike the affidavit of Ms. Mariluz Cielo Alejo,

affirmed on August 27, 2020, and filed by the Applicant in support of its Application for judicial review.

[8] In its Notice of Motion, the Respondent also seeks an Order extending the time for serving his affidavits in response to those filed by the Applicant, and the costs of this motion.

[9] The Respondent argues that the affidavit should be struck on the grounds that it is evidence that was not before the decision maker and further, that it is improper opinion evidence that does not comply with the Rules about expert evidence.

[10] Further, the Respondent contends that the exception relating to the admission of extrinsic evidence relates to evidence that could not have been submitted to the decision maker. It argues that the Applicant has not explained why its proposed evidence was unavailable.

[11] The Applicant, in response, submits that a Court will allow the introduction of extrinsic evidence in the circumstances outlined by the Federal Court of Appeal in the decision in *Assn. of Universities and Colleges of Canada v. Canadian Copyright Licensing Agency (Access Copyright)* (2012), 428 N.R. 297 (F.C.A.).

[12] In that decision, the Court found that extrinsic evidence can be admitted where it provides general background information that might assist in understanding the issues relevant to the judicial review; where it addresses issues of procedural fairness that are not otherwise

apparent on the record; or where it highlights a complete absence of evidence before the original decision-maker in respect of a particular finding.

[13] The Applicant argues that the Alejo affidavit is admissible under the first and second exceptions noted above.

[14] As well, the Applicant submits that the challenged affidavit represents permissible “lay opinion evidence” on the basis of Ms. Alejo’s personal experience in the pharmaceutical and natural health products industry, including the testing of pharmaceutical and health products. The Applicant argues that Ms. Alejo’s role as Director of Quality and Compliance qualifies her to give lay opinion evidence, on the basis of her “experiential capacity”.

[15] Ms. Alejo is the Director of Quality Compliance for the Applicant. Her affidavit purports to provide her opinion about the reliability of the test results relative to RESOLVE, commissioned by Health Canada, and deficiencies in the methods used by the laboratories. Although the deponent’s *curriculum vitae* is attached to the affidavit, there is no signed certificate attached relative to the Code of Conduct for Expert Witnesses, as required by Rule 52.2(1)(c) of the Rules.

[16] I am in substantial agreement with the arguments raised by the Respondent about the propriety of the Alejo affidavit.

[17] The general rule is that only the evidence that was before a decision maker can be considered by a Court upon judicial review. The exceptions to the general rule are limited and specific.

[18] I do not agree with the submissions of the Applicant that the affidavit falls within the exceptions identified by the Federal Court of Appeal.

[19] The Alejo affidavit addresses various tests that were performed and alleged deficiencies in the tests. In this case, tests, *per se*, are not “background information” that can assist the Court to understand the issues that might arise upon judicial review.

[20] The Applicant raises several issues of natural justice and procedural fairness in its Amended Notice of Application, including the lack of authority to conduct further laboratory testing in the wake of the decision of the Federal Court of Appeal; lack of statutory authority to conduct further testing; use of a flawed testing process; reasonable apprehension of bias on the part of two of three panel members; and breach of its legitimate expectation that Health Canada would follow its usual process with respect to assessing an application for a PLA.

[21] I am not persuaded that the Alejo affidavit is relevant to the issues of procedural fairness which can be addressed in argument, upon the record that is properly before the Court upon the adjudication of the application for judicial review.

[22] The Respondent's objections to the Alejo affidavit as "disguised" opinion evidence are also well founded, in my opinion. Ms. Alejo is offering her personal opinions about the testing conducted by Health Canada, as informed by her personal experiences. According to the decision in *Seklani v. Canada (Minister of Public Safety and Emergency Preparedness)*, 2020 FC 778, this is impermissible evidence.

[23] I acknowledge that usually, a Court will not strike affidavits on an interlocutory basis. However, as noted in the decision in *Bernard v. Canada (Revenue Agency)* (2015), 479 N.R. 189 (F.C.A.) at paragraph 11, the Court will act when addressing the propriety of an affidavit "would allow the hearing to proceed in a more timely and orderly fashion".

[24] For the foregoing reasons, I conclude that the Alejo affidavit should be struck in its entirety, as being extrinsic evidence that does not meet the exceptions identified in the decision in *Assn. of Universities, supra* and as being impermissible lay opinion evidence that does not meet the requirements of expert evidence.

[25] The affidavit will be struck and the Respondent is granted an extension of thirty (30) days from the date of this Order to file its responding affidavits, with costs to the Respondent.

ORDER in T-338-20

THIS COURT'S ORDER is that

1. The Motion is granted and the affidavit of Ms. Mariluz Cielo Alejo is struck.
2. The Respondent shall serve and file his responding affidavits within thirty (30) days of the date of the Order.
3. The Respondent shall have his costs upon this Motion.

“E. Heneghan”

Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-338-20

STYLE OF CAUSE: THE WINNING COMBINATION INC., v. THE
ATTORNEY GENERAL OF CANADA

**MOTION IN WRITING CONSIDERED AT ST. JOHN'S, NEWFOUNDLAND AND
LABRADOR PURSUANT TO RULE 369 OF THE *FEDERAL COURTS RULES***

ORDER AND REASONS: HENEGHAN J.

**CONFIDENTIAL ORDER
AND REASONS DATED:** NOVEMBER 30, 2020

**PUBLIC ORDER AND
REASONS ISSUED:** DECEMBER 7, 2020

WRITTEN REPRESENTATIONS BY:

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