Federal Court Cour fédérale

Date: 20231102

Docket: T-338-20

Citation: 2023 FC 1465

Ottawa, Ontario, November 2, 2023

PRESENT: The Honourable Madam Justice Elliott

BETWEEN:

THE WINNING COMBINATION INC.

Applicant

and

THE ATTORNEY GENERAL OF CANADA

Respondent

JUDGMENT AND REASONS

I. Overview

[1] This is an application under s 18.1 of the *Federal Courts Act*, RSC 1985, c F-7, brought by the Applicant, The Winning Combination Inc. [TWC].

[2] Health Canada oversees the administration and approval of natural health products under the *Food and Drugs Act*, RSC 1985 c F-27 [Act] and its regulations, which include the *Natural Health Products Regulations*, SOR/2003-196 [NHPR].

[3] At issue in this application is the refusal by Health Canada of TWC's Product Licence Application [PLA] for their product called Resolve, a smoking cessation aid comprised of a confidential active ingredient [the Compound], which they allege contains a naturally present constituent of passionflower. As such, the Applicant submits that Resolve is properly categorized as a natural health product [NHP] governed by the NHPR, and not a drug, which is subject to the *Food and Drug Regulations*, CRC, c 870.

[4] The Applicant now seeks judicial review of the decision by Health Canada, made on February 6, 2020, which found that Resolve does not meet the definition of a NHP. As a result of that finding, Health Canada denied the issuance of a NHP licence to TWC.

II. **Procedural History**

[5] There is an extensive procedural history between the parties, dating back to 2004 and continuing up to the present.

[6] The historic details of the facts and arguments between the parties are extensive, as are the judicial rulings and decisions. The history is best summarized in the Federal Court of Appeal Decision [FCA Decision]: *Canada (Minister of Health) v The Winning Combination Inc.*, 2017 FCA 101 at paras 15-35.

[7] This is the third judicial review of this matter, involving the same parties. The FCA heard the appeal of the first judicial review and allowed the appeal in part. It sent the licence application back to the Minister of Health who was directed to make a redetermination within 90 days of the date of the Court's decision.

[8] After the FCA case was finished, there was another judicial review on November 17-18, 2015 in which Mr. Justice Russell determined that Health Canada should issue and grant to TWC a Product Licence Agreement for Resolve within 30 days of the date of the order and, TWC was awarded their cost of the application, calculated on a solicitor and client, full indemnity basis.

[9] An application for leave to appeal to the Supreme Court of Canada was made by TWC. It was dismissed by the Supreme Court on May 15, 2017, with costs.

III. **Decision under Review**

[10] Health Canada conducted the redetermination ordered by the FCA in accordance with the process set out in Annex A to a Health Canada letter dated October 16, 2019.

[11] There were two parts to the redetermination process: laboratory testing conducted by three independent laboratories and, an external panel comprised of three expert scientists.

[12] A redetermination meeting was also convened with representatives from all parties and the Panel members to present their findings.

[13] Lisa Lange, the Director of the Bureau of Product Review and Assessment of the NNHPD (Natural and Non-prescription Health Products Directorate) of Health Canada, was the final decision-maker who assessed the culmination of findings and scientific literature to conclude that there is no reliable evidence that the Compound is a naturally present constituent of passionflower. Therefore, Resolve did not meet the definition of an NHP. TWC's Product Licence Application (PLA) was rejected on that basis.

A. *Laboratory Testing*

[14] Three independent laboratories were asked to determine whether there is reliable evidence that the Compound is a naturally present constituent of the samples of passionflower that were tested. The labs were AGAT Laboratoires Ltée Montreal (AGAT), Alliance Technologies (Alliance) and Myramid Analytical Inc. (Myramid).

[15] At TWC's request, the NNHPD agreed to ask the three labs to use the methods of Dr. Gujral (Method G) and Dr. Kwok (Method K), which TWC had previously used in their own tests. The labs were also allowed to use any additional methods to determine the presence of the Compound in passionflower. The two methods were included in Annex B of the Decision.

B. *External Panel*

[16] An external panel [the Panel] comprised of three scientists was established. The selection ensured fairness for all parties in that the selection of one member was made with input from TWC and the second with input from NNHPD. The Chair of the Panel was selected by the Food

and Drugs Act Liaison Office [FDALO]. The final members were Dr. Gordon McKay, as the Chair, plus Dr. Pauline McGregor and Dr. Susan Murch, whose biographies were found at Appendix B of the Decision.

[17] The Panel's report dated January 29, 2020, unanimously concluded that the test results did not provide reliable evidence that the Compound is a naturally present constituent of passionflower. In its report, the Panel identified the following deficiencies with the design of the study:

- Criteria for determination of LOD was unclear and different labs used different LOD definitions
- Results do not report amount of plant material used. This may bias results if too small samples were used
- Samples were accessed by the labs from various sources; some samples are reported to be degraded
- No control sample was used to compare across labs or methods
- Certified Reference Standard for the Compound was not used in all cases
- All labs did not use LC-MS/MS - this should have been a requirement in the statement of work
- Used only Method G and Method K as per The Winning Combination, however no evidence was shown that verified either method could provide accurate and consistent results. Both methods have a significant flaw in sample processing.
- Some labs did not provide information on replication.
- Labs did not provide % RSD or other reliability data.
- No data on ruggedness within or between labs.
- GC-MS data is not convincing as there are multiple possible hits in the NIST database that match the reported spectrum.

[18] With respect to the original testing conducted by TWC, via Dr. Gujral and Dr. Kwok, the Panel noted “all of the data arising from TWC is based on a single extract made by reflex of a single plant sample with methanol” and “the Compound in the TWC solution may be an artefact of reflex process and data from the Gujral lab that was transferred to the Kwok lab”. TWC could not explain why they used only a single extract of *Passiflora incarnate*.

C. *Redetermination Meeting*

[19] On January 21, 2020, FDALO convened a redetermination meeting, attended by the three Panel members, representatives from TWC and NNHPD, and the decision-maker.

[20] NNHPD reported that the Compound was not detected in either of the two samples tested. None of the three independent laboratories could replicate the findings obtained in Method G and Method K. In addition, a thorough search of the published literature (SciFinder, Scopus, PubMed, Google Scholar, etc.) did not review any other scientific articles that report the Compound is obtained from a natural source. Based on the literature search and the laboratory testing, Health Canada determined that there is no reliable evidence to show that the Compound is a natural constituent of the passionflower samples tested and the product is not a NHP.

[21] TWC presented an overview of the history of its PLA and maintained that the three laboratories did not have enough information to conduct properly the testing since the information provided to them was redacted. TWC stated that the results from Alliance and Myramid demonstrated evidence of the Compound in the samples and asked that the results from

AGA laboratories be rejected for concern over the integrity of the samples. TWC requested an explanation on how the Panel's recommendation was reached.

[22] There was also a discussion about Methods G and K. NNHPD noted that all three laboratories indicated that Method K was only a partial method; Method G was incomplete and, did not have the right parameters to detect the Compound. TWC expressed concern for the redaction of the methods that could have affected the outcome of the testing. Neither AGAT nor Alliance noted that the redacted information was a barrier to testing while Myramid found both methods had flaws, and Method K could not have been used as written.

D. *Conclusion of the Directorate*

[23] Based on the scientific literature, results of the external lab testing, the Panel's report and TWC's original testing using Methods G and K, the Directorate concluded there was no reliable evidence that the Compound is a naturally present constituent of passionflower. Therefore, Resolve did not meet the definition of "natural health product" and there was no authority under the NHPR for a product licence to be issued in respect of it.

IV. **Issues and Standard of Review**

A. *Procedural Fairness*

[24] Mr. Justice Rennie reviewed and confirmed the core principles of procedural fairness in *Canadian Pacific Railway Company v Canada (Attorney General)*, 2018 FCA 69 [*CPR*]. He concluded that whether there has been procedural fairness does not require a standard of review

analysis but “a court must be satisfied that the right to procedural fairness has been met.” In that respect, the ultimate question is whether the Applicant knew the case to be met and had a full and fair chance to respond: *CPR* at paras 49-50, 56.

[25] TWC submits that the NOR (Notice of Rejection) process was procedurally unfair as Health Canada mischaracterized the direction of the Court of Appeal with respect to the scope of the redetermination process. TWC also argues that the FCA referred to the redetermination as being “an expedited redetermination” which was to be “completed within 90 days of the date of the decision, unless extended on consent”. TWC submits that these references did not contemplate the lengthy fact-finding process designed and executed by Health Canada.

[26] In a matter concerning the Employment Insurance Commission, the FCA held “except in the most unusual circumstances, it would be procedurally unfair to remit a matter for reconsideration for the sole purpose of giving one party an opportunity to introduce new evidence that could have been introduced at a prior hearing”: *Francella v Canada (Attorney General)*, 2003 FCA 441 at para 9.

[27] TWC submits that Health Canada devised a process that strays from the jurisprudence on the scope of redetermination as a number of authorities have found that it is procedurally unfair to permit the introduction of new evidence where a matter has been remitted. TWC suggests “Health Canada was attempting to gather new evidence in an attempt to bootstrap its previous rejections of TWC’s PLA.”

[28] TWC also submits that the Health Canada actions were ultra vires. A review of Health Canada's statutory scheme including the Act and the NHPR show that no such power is conferred on Health Canada. Section 9(3) of the NHPR states:

(3) If the applicant makes a request in accordance with subsection (2), the Minister shall	(3) Lorsque le demandeur présente une demande selon le paragraphe (2), le ministre, à la fois :
(a) give the applicant an opportunity to be heard in respect of the application; and	a) donne au demandeur la possibilité de se faire entendre;
(b) reconsider the application after giving the applicant that opportunity.	b) reconsidère la demande de licence après avoir donné au demandeur la possibilité de se faire entendre.

[29] TWC submits the prescribed reconsideration process does not grant Health Canada any power to conduct or order laboratory testing or to otherwise gather or hear additional evidence.

[30] The Respondent submits there is nothing in the Regulations that prohibits laboratory testing. Even if it could be said to contravene TWC's legitimate expectations, TWC had notice of the process, was provided with all of the lab results and had a full opportunity to address both the process, and the results, before the Panel.

[31] I am satisfied based on the foregoing that TWC received procedural fairness. TWC had notice of the process, was provided with all of the lab results and had a full opportunity to address both the process and the results before the Panel.

B. *Reasonableness*

[32] The Supreme Court of Canada has established that when conducting judicial review of the merits of an administrative decision, other than a review related to a breach of natural justice and/or the duty of procedural fairness, the presumptive standard of review is reasonableness: *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 23 [*Vavilov*]. While this presumption is rebuttable, no exception to the presumption, other than procedural fairness as set out above, is present here.

[33] A court applying the reasonableness standard does not ask what decision it would have made in place of that of the administrative decision maker. It does not attempt to ascertain the "range" of possible conclusions that would have been open to the decision maker, conduct a *de novo* analysis or seek to determine the "correct" solution to the problem: *Vavilov* at para 83.

[34] The decision maker may assess and evaluate the evidence before it. Absent exceptional circumstances, a reviewing court will not interfere with its factual findings. The reviewing court must refrain from "reweighing and reassessing the evidence considered by the decision maker": *Vavilov* at para 125.

[35] The Respondent submits the Decision demonstrates a rational chain of analysis that fully considered the Gujral and Kwok reports. The Expert Panel did not accept the conclusions of the Gujral and Kwok reports because they were based on a single extract of a single plant sample, Dr. Gujral's findings were undermined by the possibility that the Compound he identified may

have been an artifact of the method he used to generate the extract, and Dr. Kwok's findings were tainted by the fact that he used Dr. Gujral's plant extracts.

[36] Further, while the Directorate accepted the multiple deficiencies in the study design of the lab tests, the Respondent submits that this does not detract from the conclusion that TWC has not submitted any reliable evidence including laboratory testing or scientific literature, demonstrating that the Compound is present in passionflower.

[37] Finally, the refusal to conduct further testing was justified by the fact that a final decision had been rendered, consistent with the advice of an independent Expert Panel. The finality was particularly significant in the context of previous decision-making, as the lack of finality had led to an endless round of reconsiderations: see FCA Decision at paras 34-35.

[38] The Respondent submits that TWC's request for redetermination based on information submitted prior to the FCA Decision would serve no useful purpose, as it was already considered and was not found to be reliable evidence of the classification of Resolve as a NHP. They add that an order of solicitor-client costs is not warranted as there is no evidence of reprehensible, scandalous or outrageous conduct that would justify such an award: *Salt Canada Inc. v Baker*, 2020 FCA 127 at para 6.

C. *Legitimate Expectations*

[39] Only clear, unambiguous and unqualified representations as to procedure can give rise to a legitimate expectation: *Drabinsky v Canada (Advisory Council of the Order)*, 2015 FCA 5 at para 8.

[40] An important limit on the doctrine of legitimate expectations is that it cannot give rise to *substantive* rights: *Baker v Canada (Minister of Citizenship and Immigration)*, [1999] 2 SCR 817. In other words, "[w]here the conditions for its application are satisfied, the Court may [only] grant appropriate procedural remedies to respond to the 'legitimate' expectation": *C.U.P.E. v Ontario (Minister of Labour)*, 2003 SCC 29, [2003] 1 S.C.R. 539, at para. 131 (my emphasis).

[41] The Respondent submits that it is clearly within the Directorate's discretion to accept or request new information, as TWC well knows. They point out multiple examples of the Directorate making exceptions to its general practice of limiting the scope of redetermination to the information submitted with the original PLA at the request of TWC and its counsel.

[42] The Directorate continuously accepted new materials from TWC over the course of more than four years for its multiple reconsiderations and in fact, the Gujral and Kwok reports that became the foundation for the TWC's position were submitted as new evidence during a reconsideration after Resolve was initially denied an NHP licence.

[43] The Respondent submits, and I agree, that there is nothing in the Regulations that prohibit laboratory testing. Even if it could be said to contravene TWC's legitimate expectations, TWC had notice of the process, was provided with all of the lab results and had a full opportunity to address both the process and results before the Panel.

V. **Analysis**

A. *Was the Decision fair?*

[44] Questions of procedural fairness are not decided according to any particular standard of review, but rather by answering the question of whether the procedure was fair having regard to all of the circumstances.

[45] If so, the question then becomes what degree of procedural fairness is applicable. In related matters, this Court has held that "mid-to-low end of the spectrum" is an appropriate description of the level of fairness owed to applicants under the NHPR: *Canada RNA Biochemical Inc. v Canada (Minister of Health)*, 2020 FC 668 at para 127-128 citing *Apotex Inc. v Canada (Minister of Health)*, 2015 FC 1161 at 82.

[46] Ultimately, reviewing courts must assess whether the applicant knew the case to meet and had a full and fair chance to respond: *Canadian Pacific Railway Canada v Canada (Attorney General)*, 2018 FCA 69 at para 56.

[47] In this case, the common law duty of fairness is supplemented by specific procedural requirements in respect of refusal and reconsideration before a final decision is made*: NHPR,* subsections 9 and 10.

[48] I find the process was procedurally fair to TWC given that the level of fairness owed was in the "mid-to-low end of the spectrum" and TWC was directly involved in the process.

VI. **Conclusion**

[49] As determined above, TWC was fully involved in the various processes to validate the efficacy of Resolve but failed to make their case.

[50] The Expert Panel's conclusion that TWC had not submitted any reliable evidence, including laboratory testing or scientific literature, demonstrating that the Compound is present in passionflower supports the finding that Resolve belongs under the *Food and Drug Regulations, CRC,* c870.

[51] For all the reasons set out above, this application is dismissed, with costs to the Respondent.

JUDGMENT in T-338-20

THIS COURT'S JUDGMENT is that:

1. This application is dismissed, with costs to the Respondent.

"E. Susan Elliott"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-338-20
STYLE OF CAUSE:	THE WINNING COMBINATION INC. v the ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	HELD BY WAY OF VIDEOCONFERENCE
DATE OF HEARING:	MARCH 29, 2022
JUDGMENT AND REASONS:	ELLIOTT J.
DATED:	NOVEMBER 2, 2023

APPEARANCES:

Peter Halamandaris	FOR THE APPLICANT
Karen Lovell Andrea Bourke	FOR THE RESPONDENT

SOLICITORS OF RECORD:

Marr Finlayson Pollock LLP Barristers and Solicitors Winnipeg, Manitoba	FOR THE APPLICANT
Attorney General of Canada Toronto, Ontario	FOR THE RESPONDENT