Federal Court Cour fédérale

Date: 20190730

Docket: T-1866-18

Citation: 2019 FC 1014

Ottawa, Ontario, July 30, 2019

PRESENT: The Honourable Madam Justice Roussel

BETWEEN:

THE WINNING COMBINATION INC.

Applicant

and

THE ATTORNEY GENERAL OF CANADA

Respondent

JUDGMENT AND REASONS

I. Overview

[1] The present application for judicial review arises out of a long-standing regulatory relationship between the Applicant, The Winning Combination Inc. [TWC], and Health Canada. For the purposes of this application, there is no need to relate the entire factual background, which can be found in *Canada (Health) v The Winning Combination Inc*, 2017 FCA 101 [*TWC FCA*] and *Winning Combination Inc v Canada (Health)*, 2016 FC 381.

[2] TWC markets natural health products [NHP]. One of the products marketed by TWC is RESOLVE, a smoking cessation aid, which employs a confidential active ingredient [Active Ingredient].

[3] Health Canada, together with some of its subsidiaries, is responsible for administering, marketing and approving for sale certain products under the *Food and Drugs Act*, RSC 1985, c F-27 [FDA] and its regulations, which include the *Natural Health Products Regulations*, SOR/2003-196 [Regulations].

[4] In 2006, TWC purchased the rights to RESOLVE and began to sell the product in Canada in October of that year. The company that sold RESOLVE to TWC had filed a product licence application [PLA] for RESOLVE in 2004 with the Natural Health Products Directorate [NHPD], a division of Health Canada under the Health Products and Food Branch. Relying on the Dictionary of Natural Products [DNP], the NHPD concluded on December 2, 2004 that RESOLVE met the regulatory definition of a NHP.

[5] In December 2006, Health Canada received a complaint from Pfizer Canada Inc. alleging health and safety concerns related to RESOLVE. This complaint triggered an internal inquiry with the Health Products and Food Branch Inspectorate [Inspectorate], responsible for compliance and enforcement activities. The Inspectorate requested that the NHPD conduct a health hazard evaluation of RESOLVE.

[6] In May 2007, TWC received a letter from a drug specialist at the Inspectorate requesting that TWC stop the sale and advertising of RESOLVE and that it recall the product from the market. The request was based on, among other things, an alleged contravention of the FDA and Regulations and a determination that RESOLVE contained a substance derived from passion-flower and posed a health risk. Following several exchanges between TWC and Health Canada officials, the NHPD issued a notice of refusal of the PLA on July 19, 2007 on the ground that TWC had submitted insufficient evidence to support the safety and efficacy of the product. In response, TWC filed both a request for reconsideration and an application for judicial review of the July notice of refusal.

[7] On August 21, 2007, the NHPD issued a second notice of refusal informing TWC that upon further review, it had determined that RESOLVE was no longer considered a NHP but rather a drug, and therefore subject to regulation under the *Food and Drug Regulations*, CRC, c 870. The letter stated that the NHPD had relied, in part, on the DNP for classification, but that a review of the DNP's sources led the NHPD to determine that its inclusion of the Active Ingredient was in error. The NHPD took the position that the Active Ingredient "is in fact a synthetic substance that does not occur naturally". TWC accordingly amended its notice of application for judicial review to include the August 2007 notice of refusal.

[8] Beginning in August 2007 until January 2012, TWC embarked on a reconsideration process during which it provided the NHPD with written submissions, additional scientific data and expert analysis regarding its conclusions relating to the classification, safety and efficacy of RESOLVE. A number of decisions were issued by Health Canada officials throughout,

culminating in a letter by the NHPD stating in January 2012 that it maintained its position on both classification and efficacy.

[9] The application for judicial review was heard over two (2) days in November 2015 by Justice James Russell. In his decision issued on April 6, 2016, he quashed both notices of refusal dated July 19, 2007 and August 21, 2007, together with all of the subsequent reconsideration decisions. After finding that government officials involved in the regulatory review process were biased and that there had been multiple breaches of procedural fairness, Justice Russell issued an order of *mandamus* compelling the Minister of Health to issue a Natural Product Licence to TWC. He also granted costs of the application to TWC on a full indemnity basis.

[10] The Respondent and the Minister of Health appealed Justice Russell's judgment to the Federal Court of Appeal [FCA]. Their principal ground of appeal was that Justice Russell erred in law in issuing an order of *mandamus* and in so doing, usurped a duty vested in the Minister of Health under the Regulations. The Respondent and the Minister of Health had conceded at the outset of the hearing that the licensing decision and reconsideration process under the Regulations had not been reached in accordance with procedural fairness.

[11] In a decision dated May 15, 2017, the FCA allowed the appeal in part, finding that Justice Russell had erred in directing the Minister of Health to issue a Natural Product Licence in respect to RESOLVE. Despite the significant and damaging findings made by Justice Russell relating to the behaviour of senior Health Canada officials, the FCA determined that the proper remedy was to remit TWC's licence application back to the Minister of Health for redetermination in

accordance with its reasons. The FCA further ordered that the redetermination be completed within 90 days of the date of the decision, unless extended on consent. Despite the divided success, the FCA awarded TWC costs of the appeal on a solicitor-client basis due to Health Canada's conduct throughout the process.

[12] By letter dated May 19, 2017, Health Canada advised TWC that efficacy had been established such that the scope of the redetermination would be limited to determine whether RESOLVE is a NHP, and specifically, whether the Active Ingredient fell within Schedule 1 of the Regulations. Health Canada informed TWC that the redetermination process would consist of two (2) parts: a) scientific testing of the passion-flower – said by TWC to be a natural source of the Active Ingredient – to be conducted by three (3) independent laboratories for the presence of the Active Ingredient in whichever form and/or part of the passion-flower TWC chooses; b) a panel process that provides TWC a right to be heard and results in a recommendation to a Health Canada decision-maker. TWC was asked to confirm which of two (2) panel options it preferred: a) an external panel which would require an extension of fifty (50) days to the ninety (90) days outlined in the FCA decision; or b) an internal process.

[13] By way of this application for judicial review, TWC challenges the use of laboratory testing as part of the redetermination process. In essence, TWC submits that: (1) Health Canada does not have the authority to include independent laboratory testing as a component of the redetermination process following the FCA's decision; (2) a reasonable apprehension of bias arose out of the conduct of Health Canada when it decided to gather its own evidence by conducting laboratory testing as part of the redetermination process; (3) Health Canada is

motivated by a desire to "bootstrap its previous decisions to refuse the PLA or to shore up the reasons for its previous denials" and is therefore acting for an improper purpose; (4) Health Canada created a legitimate expectation that the redetermination process would follow the standard procedures established by Health Canada, namely that it would be a passive recipient of information and would not gather its own evidence or conduct its own testing of the product.

[14] In its response, the Respondent submits that in order to fulfill the regulatory obligation to issue a licence in accordance with the Regulations and to avoid risks to the health and safety of consumers, the Minister of Health has a duty to assess the strength of the claims by an applicant. This includes consulting other sources of information, including scientific journals and publications like the DNP. Also, section 15 of the Regulations permits the Minister of Health to request samples of an applicant's product before determining if a licence should be issued. It was therefore Parliament's intent that Health Canada's review of a PLA could include testing. The Respondent further argues that while Health Canada does not typically accept new materials for review, in the unique circumstances of this case, independent laboratory testing of passion-flower is an appropriate component of the redetermination process. These circumstances include: (a) the legitimacy and significance of a scientific debate regarding the nature of the Active Ingredient, exemplified in part by the contradictory evidence filed in support of the PLA; and (b) the concerns raised by both Justice Russell and the FCA as to the lack of laboratory testing conducted by Health Canada, and the need for objective, scientific evidence.

II. Analysis

[15] Prior to the hearing and after considering the written submissions of the parties, I issued a direction whereby I invited both parties to provide additional submissions with respect to whether the letter dated May 19, 2017 constitutes a reviewable decision under section 18.1 of the *Federal Courts Act*, RSC 1985, c F-7 and whether the application for judicial review was premature in light of the principles enunciated in *Canada (Border Services Agency) v CB Powell Limited*, 2010 FCA 61 [*CB Powell Limited*].

[16] After considering the additional submissions of both parties, I am of the view that the determinative issue in this matter is the prematurity of the application for judicial review.

[17] The general rule is that absent exceptional circumstances, the courts will not interfere with interlocutory decisions until the ongoing administrative processes have been completed and until all other available effective remedies have been exhausted. This rule has been described in a number of ways, including the doctrine of exhaustion, the doctrine of adequate alternative remedies, the doctrine against fragmentation or bifurcation of administrative proceedings, the rule against interlocutory judicial reviews and the objection against premature judicial reviews (*CB Powell Limited* at paras 30-32). The underlying purpose of this rule is to prevent fragmentation of the administrative process and to reduce the large costs and delays associated with premature court challenges, particularly where the party may ultimately be successful at the conclusion of the administrative process (*CB Powell Limited* at para 32).

[18] While there are "exceptional circumstances" where the courts will entertain an application for judicial review before the completion of administrative proceedings, very few circumstances qualify as exceptional and the threshold for exceptionality is high (*CB Powell Limited* at para 33).

[19] These principles were reiterated by the Supreme Court of Canada in *Halifax (Regional Municipality) v Nova Scotia (Human Rights Commission)*, 2012 SCC 10 at paragraphs 35 to 38 and in subsequent decisions of both the FCA and this Court (*Alexion Pharmaceuticals Inc v Canada (Attorney General)*, 2017 FCA 241 at paras 47-50, 53; *Forner v Professional Institute of the Public Service of Canada*, 2016 FCA 35 at paras 13-16; *Wilson v Atomic Energy of Canada Limited*, 2015 FCA 17 at paras 28-34; *Whalen v Fort McMurray No 468 First Nation*, 2019 FC 732 at paras 16-18; *Girouard v Inquiry Committee Constituted Under the Procedures for Dealing With Complaints Made to the Canadian Judicial Council About Federally Appointed Judges*, 2014 FC 1175 at paras 18-19; *Douglas v Canada (Attorney General)*, 2014 FC 299 at para 128; *Fairmont Hotels Inc v Canada (Corporations)*, 2007 FC 95 at paras 9-10).

[20] TWC acknowledges the high threshold for exceptionality. However, TWC contends that the long history of the proceedings between the parties justifies the early intervention of the Court. In particular, TWC argues that the grounds underlying its application for judicial review go to the jurisdiction of Health Canada and would result in TWC being denied the benefit of a fair redetermination process. Relying on the factors identified in *Air Canada v Lorenz* (1999), [2000] 1 FC 494 at paragraphs 19 to 27 and 33 to 35 [*Lorenz*], TWC submits that the application

for judicial review should be allowed to proceed since significant hardship, waste and delays will follow if the parties are required to go through the flawed redetermination process.

[21] The Respondent also supports the early determination of whether Health Canada has the authority to conduct independent laboratory testing during the redetermination process.

[22] After considering the submissions of both parties, I am not persuaded that the circumstances of this case constitute "exceptional circumstances" that warrant an exception to the general rule.

[23] In *CB Powell Limited*, the FCA clearly stated that "the fact that all parties have consented to early recourse to the courts [is] not [an] exceptional circumstanc[e] allowing parties to bypass an administrative process, as long as that process allows the issues to be raised and an effective remedy to be granted" (*CB Powell Limited* at para 33). The consent of the parties is therefore not binding on this Court.

[24] During oral argument, counsel for the Respondent indicated that one of the reasons Health Canada did not raise a prematurity objection was because it did not want to be seen as being obstructive in any way during the redetermination process and in the context of this application for judicial review, given the particularly strong rebuke of Health Canada officials by Justice Russell and the FCA in the prior proceedings. While understandable, the Respondent's concerns do not justify early intervention by this Court.

[25] The FCA also clearly stated in *CB Powell Limited* that concerns about procedural fairness or bias or the presence of "so-called jurisdictional issues" do not constitute exceptional circumstances justifying early recourse to the courts (*CB Powell Limited* at paras 33, 39-40, 45). This is particularly relevant since TWC has raised the issue of Health Canada's jurisdiction to order further scientific testing as well as the issue of a reasonable apprehension of bias arising from the decision to do so.

[26] TWC submits that the long and complicated history between the parties constitutes "exceptional circumstances" warranting judicial intervention at an early stage. While I agree that the parties have a long and complicated history, I am not persuaded that the history between them rises to the level of "exceptional circumstances" as contemplated by the FCA in *CB Powell Limited*. I am concerned, however, that this application for judicial review is an attempt to indirectly challenge some of the findings made by the FCA in *TWC FCA.*

[27] In determining whether the issuance of a *mandamus* order was warranted in the circumstances of this case, the FCA considered TWC's argument regarding the excessive delay in processing the application. The FCA noted that the definition of what constitutes a NHP can, in some cases, be a matter of legitimate scientific debate. It acknowledged that such a debate existed in this case and determined that it would best be addressed by the Minister of Health through an expedited redetermination, not a directed verdict. Cognizant of the long and complicated history between the parties and despite the admitted denial of procedural fairness by Health Canada officials, the FCA nevertheless explicitly granted discretion to the Minister of Health to devise a process by which the regulatory decision-making responsibilities in respect of

TWC's application could be discharged in a manner consistent with its reasons. It also refused to limit the scope of the redetermination to only those matters TWC would put in issue, as TWC had requested. TWC had argued that the Minister of Health could only reconsider the issues of safety and efficacy and not classification. Finally, the FCA rejected TWC's post-hearing motion asking that the FCA reconsider its judgment to provide specific parameters for how Health Canada should conduct the redetermination. The FCA dismissed the motion, confirming its decision that it was Health Canada's responsibility to devise a fair redetermination process.

[28] Even if it is not TWC's intention to relitigate the FCA's conclusion regarding Health Canada's authority to devise the process for redetermination, I am not persuaded that the history between the parties constitutes "exceptional circumstances" that meet the "clear and obvious" standard discussed in *Lorenz* at paragraph 32 and in *Almrei v Canada (Citizenship and Immigration)*, 2014 FC 1002 at paragraph 35. I fail to understand how the inclusion of independent laboratory testing as a component of the redetermination process gives rise to a reasonable apprehension of bias or to an unfair process, particularly in the context of the findings made by both Justice Russell and the FCA in the prior judicial review application. Also, I note that pursuant to section 15 of the Regulations, the Minister of Health may request samples of an applicant's product before determining if a licence should be issued, and that one of the concerns of Justice Russell was the fact that Health Canada had not conducted its own laboratory testing before making its decision. The FCA also noted the importance of objective, scientific considerations in the Minister of Health's exercise of discretion.

[29] The process currently designed by Health Canada will ultimately result in a decision to grant or deny TWC's PLA. The inclusion of testing in the process is not dispositive of TWC's substantive rights. If the PLA is granted by Health Canada, no dispute will be left. If TWC is not granted the PLA, TWC can then raise arguments regarding the process that was followed, including those relating to jurisdiction and procedural fairness. However, if I were to grant the judicial review, this Court risks being seized of the matter again if TWC remains unsatisfied with the process designed by Health Canada. There would be no limit to the number of times TWC could challenge Health Canada's decisions regarding the process to be followed. The prevention of piecemeal court proceedings clearly justifies this Court's non-interference in the underlying administrative process.

[30] For these reasons, the application for judicial review is dismissed on the basis of prematurity, without prejudice to TWC raising the same arguments upon any future judicial review after Health Canada has rendered its final decision regarding the PLA.

[31] Given the basis upon which I am dismissing the application for judicial review, there will be no award of costs as per the request of the parties.

[32] On a final note, counsel for the parties agreed that the proper Respondent in these proceedings is the Attorney General of Canada. Thus, the style of cause shall be amended to remove the Minister of Health as a Respondent.

JUDGMENT in T-1866-18

THIS COURT'S JUDGMENT is that:

1. The application for judicial review is dismissed on the basis of prematurity;

2. The style of cause is amended to remove the Minister of Health as a Respondent.

3. No costs are awarded.

"Sylvie E. Roussel"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1866-18
STYLE OF CAUSE:	THE WINNING COMBINATION INC. v THE ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	WINNIPEG, MANITOBA
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