Federal Court of Appeal | Cour d'appel fédérale

Date: 20211102

Docket: A-179-20

Citation: 2021 FCA 213

CORAM: **RENNIE J.A.**
LASKIN J.A.
MACTAVISH J.A.

BETWEEN:

CANADA RNA BIOCHEMICAL INC.

Appellant

and

CANADA (MINISTER OF HEALTH)
and THE ATTORNEY GENERAL OF CANADA

Respondents

Heard by online video conference hosted by the Registry on October 20, 2021.

Judgment delivered at Ottawa, Ontario, on November 2, 2021.

REASONS FOR JUDGMENT BY: RENNIE J.A.

CONCURRED IN BY: LASKIN J.A.
MACTAVISH J.A.

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REASONS FOR JUDGMENT

RENNIE J.A.

I. Overview

[1] The appellant appeals from the judgment of the Federal Court (2020 FC 668, *per* McHaffie J.) dismissing an application for judicial review. The appellant sought to set aside the decision of the respondent Minister of Health (Minister) refusing to grant a Natural Health

Product (NHP) licence under the *Natural Health Products Regulations*, S.O.R./2003-196 (*NHP Regulations*). For the reasons that follow, I would dismiss the appeal.

[2] Canada RNA Biochemical Inc. (C-RNA) sought a licence for oral lumbrokinase capsules, branded Boluoke. Boluoke has a single medicinal ingredient, lumbrokinase, an enzyme derived from earthworms. Lumbrokinase has "fibrinolytic" properties, meaning that it enhances the breakdown of blood clots or prevents them from forming. In its product licence application, C-RNA emphasized Boluoke's fibrinolytic properties and its ability to "reduce blood viscosity" and "improve circulation".

[3] It is not necessary for the purposes of this appeal to track C-RNA's progress through the regulatory review process. It is fully described in the reasons of the Federal Court; rather it is sufficient to note that at the end of the review of the appellant's NHP licence submission, the Minister concluded that the evidence submitted was insufficient to support the safe use of lumbrokinase. The application was rejected as C-RNA's evidence was "insufficient to support the safe use of this product in the target subpopulation" (FC reasons at para. 62).

[4] C-RNA asked for reconsideration of the decision, a recourse mechanism provided for under the *NHP Regulations.* After reviewing the submission in support of the request for reconsideration, Health Canada upheld its original decision not to issue a product licence and notified C-RNA accordingly. The notice emphasized that the risk of internal bleeding could not be properly monitored in circumstances where the product was sold over the counter.

[5] The Federal Court concluded that the refusal to grant an NHP licence for Boluoke was reasonable (FC reasons at para. 4). The Federal Court found that the decision was consistent with the text, context and purpose of the regulations, and reflected a consistent and reasoned view on the adequacy of the evidence pertaining to the safety of the product. The Federal Court also dismissed the challenges based on asserted breaches of procedural fairness.

II. Standard of review

[6] An appeal from a judicial review decision requires an appellate court to determine whether the correct standard of review was identified and properly applied by the reviewing court (*Northern Regional Health Authority v. Horrocks*, 2021 SCC 42 at para. 12; *Agraira v. Canada (Public Safety and Emergency Preparedness*), 2013 SCC 36, [2013] 2 S.C.R. 559 at para. 46).

[7] This does not mean that this Court should ignore reasons given by the Federal Court in rejecting the application (*Bank of Montreal v. Canada (Attorney General)*, 2021 FCA 189 (*BMO*)). Where the Federal Court appears to have given a complete answer to the argument advanced on judicial review, an appellant bears a tactical burden to show that the Federal Court's reasoning is flawed (*BMO* at para. 4). That burden has not been met. The appellant has not identified any reviewable error in either the decision to refuse a licence to the appellant or in the manner by which that decision was reached. Nor has the appellant demonstrated any error in the Federal Court's reasoning.

[8] Before turning to the specific grounds of appeal raised by the appellant, I will deal with a new argument raised by the appellant at the hearing of the appeal, one to which the respondent did not object. The appellant argues that the Minister was "confused" about whether the product in question was to be considered a drug or an NHP. This argument fails, as it is based on a misunderstanding of the legislative and regulatory scheme.

III. The legislative scheme

[9] The *NHP Regulations* fall under the *Food and Drugs Act*, R.S.C., 1985, c. F-27 (FDA). The purpose of the NHP regulatory framework is to provide Canadians with access to safe, effective and high quality NHPs, and to regulate these products in a manner commensurate with their level of risk.

[10] There is an inter-relationship between the *NHP Regulations* and the *Food and Drug Regulations*, C.R.C., c. 870 (*Food and Drug Regulations*). The definition of "natural health product" under the *NHP Regulations* explicitly excludes drugs described in Schedules C and D of the FDA, and subsection 2(2) of the *NHP Regulations* prevents substances from being considered NHPs if they are required to be sold by prescription (FC reasons at para. 17). Similarly, if a drug is included on the Prescription Drug List, it presumptively falls outside the scope of the *NHP Regulations* (FC reasons at para. 18; *Food and Drug Regulations*, s. C.01.040.3).

[11] Apart from these legislative demarcations or distinctions, the regulatory evaluation and analysis conducted under each scheme are "legally and operationally discrete" from one another

(*Canada (Health) v. The Winning Combination Inc.*, 2017 FCA 101, 413 D.L.R. (4th) 362 at para. 8 (*Winning Combination*)).

[12] An NHP is defined to include naturally-occurring substances (or synthetic duplicates) identified in Schedule 1 of the *NHP Regulations* which are manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease or disorder (*NHP Regulations*, s. 1). Schedule 1 includes animal products or products that are derived from animals. NHPs are intended for self-directed over the counter use by consumers, with no or limited practitioner oversight and monitoring. NHPs are thus necessarily sold without a prescription; as noted, any substance requiring a prescription is regulated pursuant to the *Food and Drug Regulations*.

[13] There is, therefore, no basis for the argument that the Minister was confused as to which regulatory regime governed the application for Boluoke. Lumbrokinase is an enzyme derived from an animal and falls squarely within Schedule 1 of the *NHP Regulations* and the review process for NHPs.

IV. Onus

[14] Many of the appellant's submissions appear to be grounded on the understanding that it is incumbent on the Minister to prove that a substance is not safe or efficacious. This misunderstands the legislative scheme. The onus is on the licence applicant to demonstrate to the satisfaction of the Minister that the product is both safe and efficacious.

[15] The *NHP Regulations* place the onus on a licence applicant to satisfy the Minister that the proposed product is safe and efficacious and that it would be so in the circumstances or conditions under which it would be used or made available, in this case, over the counter. The existence of some evidence demonstrating the safety and efficacy of the product does not require the grant of a licence; there must be evidence which demonstrates, to the satisfaction of the Minister, that the product is safe and efficacious. Even in the face of contradictory or competing evidence as to safety and efficacy, there is no obligation on the Minister to decide in favour of an applicant. This is subject to the important caveat that the reasons for the refusal are rationally supported by the scientific analysis, regulatory criteria and relevant policies (compare *Winning Combination*).

[16] The operation of the scheme, its purposes and objectives, the stages of the decision process and the reconsideration mechanism provided by the *NHP Regulations* were described in detail by this Court in *Winning Combination* and set forth by the Federal Court.

[17] Section 5 of the *NHP Regulations* prescribes the mandatory content of an application for a product licence. At the time of C-RNA's application for a product license, subsection 5(g) required that information be submitted that "supports" the safety and efficacy of the product.

[18] It was subsequently amended to align with the French version of the NHP Regulations (*Regulations Amending Certain Department of Health Regulations (Miscellaneous Program)*, S.O.R./2018-69, Canada Gazette Part II, Vol. 152, No. 8, p. 775 at 779). The French version consistently uses the word "montrer" in subsections 5(g), 11(2)(c), 17(1)(b) and 17(2)(a). Prior to

2018, subsection 5(g) was the only one of these subsections to use the word “supports”, whereas the three other subsections used the word “demonstrates”. This change thus created congruity across both versions of the *NHP Regulations*.

[19] As outlined in subsection 5(g), this includes information that demonstrates the safety and efficacy of the product:

Licence Application	**Demande**
5 An application for a product licence shall be submitted to the Minister and shall contain the following information and documents: … (g) information that demonstrates the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use.	5 La demande de licence de mise en marché est présentée au ministre et comporte les renseignements et documents suivants : […] g) les renseignements montrant l’innocuité et l’efficacité du produit lorsqu’il est utilisé selon les conditions d’utilisation recommandées.

[20] Section 7 of the *NHP Regulations* outlines when the Minister is required to issue a product licence:

Issuance and Amendment	**Délivrance et modification**
7 The Minister shall issue or amend a product licence if (a) the applicant submits an application to the Minister that is in accordance with section 5 or subsection 11(2), as the case may be;	7 Le ministre délivre ou modifie la licence de mise en marché si les conditions suivantes sont réunies : a) le demandeur présente au ministre une demande conforme à l’article 5 ou au paragraphe 11(2), selon le cas;

(b) the applicant submits to the Minister all additional information or samples requested under section 15;	b) le demandeur fournit au ministre les renseignements complémentaires ou les échantillons demandés en vertu de l'article 15;
(c) the applicant does not make a false or misleading statement in the application; and	c) le demandeur ne fait pas de déclaration fausse ou trompeuse dans sa demande;
(d) the issuance or amendment of the licence, as the case may be, is not likely to result in injury to the health of a purchaser or consumer.	d) la délivrance ou la modification de la licence ne risque pas de causer un préjudice à la santé de l'acheteur ou du consommateur.

[21] Subsection 7(a) requires an application be made "in accordance with section 5" for a product license to be issued. Thus, to satisfy subsection 7(a), the applicant must also comply with section 5 – namely, the Minister must be satisfied that the applicant has not just filed information on safety and efficacy, but that the evidence supports that the product is safe and effective when used in accordance with its recommended conditions of use.

[22] I do not read the word "supports" to authorize the grant of an NHP licence on a lesser standard than required by the word "demonstrates". While the word is suggestive of a different standard, neither the context nor the purpose supports the conclusion that the Governor in Council intended to authorize licencing of natural products intended for human consumption on a lesser standard of safety. Such a conclusion would offend both the context and the purpose of the regulatory scheme.

[23] Further, statutes are to be read harmoniously, such that like meaning is given to like terms in like circumstances unless a different intention is indicated (*Canada Trust Mortgage Co.*

v. Canada, 2005 SCC 54, [2005] 2 S.C.R. 601 at para. 10). The subsequent amendment of the word to align with the other provisions in the *NHP Regulations* confirms this interpretation.

[24] The interaction between subsections 7(a) and 7(d) is similarly relevant for new product licensees in that the product must not only be effective, but it must also not be likely to cause injury to health. As the Federal Court observed, safety and efficacy considerations are joined in subsection 5(g) as part of the risk-benefit analysis, whereas subsection 7(d) confirms that even if this risk-benefit analysis favours licensing, a product license will not be granted if it is likely to cause injury. In sum, an applicant must not only show that their product is not likely to cause injury to health (subsection 7(d)), but also that it is safe when used under the recommended conditions of use (subsections 5(g) and 7(a)).

[25] As the scheme indicates, the decision whether to issue a product licence is contingent on the Minister being satisfied that the product is safe and efficacious when used in accordance with its intended conditions of use. Here, with respect to the appellant's product, the Minister was not satisfied that that was the case. That decision was grounded in an ample evidentiary record and the appellant has not identified any aspect of the regulatory review process that could be considered unreasonable.

V. Procedural fairness

[26] The appellant contends that the Federal Court erred in applying a reasonableness standard of review to questions of procedural fairness. Were that the case, it would be a reviewable error, but this is not what the Federal Court did. The Federal Court noted that many of the arguments

advanced by the appellant as breaches of procedural fairness were mischaracterized; they were, in fact, challenges to the substantive decision itself and were to be assessed on a reasonableness basis (para. 94). The judge understood the distinction between the standard of review applicable to the decision, and the obligation of the court to be satisfied that that that decision had been reached in a procedurally fair manner.

[27] After considering the *Baker* factors (*Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817, 1999 CanLII 699 (SCC)), the Federal Court determined the degree of procedural fairness owed to the appellant was in the "low to medium range" and then considered whether the appellant had been accorded procedural fairness. Here, the Federal Court expressly followed the guidance of this Court in *Canadian Pacific Railway Company v. Canada (Attorney General)*, 2018 FCA 69, [2019] 1 F.C.R. 121, that "[a] court assessing a procedural fairness argument is required to ask whether the procedure was fair having regard to all the circumstances" and that "[a]ttempting to shoehorn the question of procedural fairness into a standard of review analysis is … an unprofitable exercise" (at paras. 54-55; *Demitor v. Westcoast Energy Inc. (Spectra Energy Transmission)*, 2019 FCA 114, 305 A.C.W.S. (3d) 146 at para. 26).

[28] The Federal Court did not apply a reasonableness standard to the assessment of whether the appellant was accorded procedural fairness.

VI. Failure to invite submissions

[29] The application was argued in the Federal Court prior to the Supreme Court of Canada's decision in *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, 441

D.L.R. (4th) 1 (*Vavilov*). The Federal Court therefore relied on the *Dunsmuir* framework in considering the standard of review (*Dunsmuir v. New Brunswick*, 2008 SCC 9, [2008] 1 S.C.R. 190 (*Dunsmuir*)). The appellant argues that the Federal Court erred in not allowing the parties to make submissions on the effect of *Vavilov* on its judicial review application.

[30] In *Canada Post Corp. v. Canadian Union of Postal Workers*, 2019 SCC 67, 441 D.L.R. (4th) 269 (*Canada Post*), Rowe J. applied *Vavilov* in determining the standard of review even though the parties had made submissions under *Dunsmuir*. Rowe J. held that no unfairness arises where, applying *Vavilov*, the outcome would have been the same under *Dunsmuir* (*Canada Post* at para. 24).

[31] That is the case in this appeal. The appellant has not even suggested, let alone demonstrated, that applying *Vavilov* would generate a different standard of review than that arrived at under *Dunsmuir*. We also note that if the appellant felt that *Vavilov* was pertinent, it could have communicated that fact to the Court via the Registry, which it did not.

VII. The specific breaches of procedural fairness

[32] The appellant points to a decision by Health Canada to consult an external hematologist regarding a potential post-market monitoring plan for lumbrokinase as a breach of its right to procedural fairness. The hematologist concluded that it was impractical for practitioners to monitor whether excessive fibrinolytic activity in users would contribute to a bleeding risk. The argument that this constituted a breach of procedural fairness has no merit.

[33] The hematologist's findings were shared with the appellant in an August 13, 2014 Information Request Notice. The Information Request Notice outlined the hematologist's concerns regarding product safety and efficacy, the impediments to practitioner oversight and the need for additional clinical evidence. The Notice invited the appellant to submit additional clinical trial evidence to support lumbrokinase's safety and efficacy and requested that C-RNA make submissions on these points.

[34] C-RNA responded in October 2014. It asserted that the hematologist's assumption that lumbrokinase caused hyperfibrinolysis was unfounded and unfair and that this opinion was contrary to other expert opinions. It submitted four expert opinions to rebut the hematologist's conclusions. Health Canada considered, but ultimately rejected, the new evidence and gave reasons in the 2015 Notice of Refusal for so doing; the unavailability of this testing in Canada and/or the lack of an appropriate reference range to predict bleeding that could inform dosing and discontinuation decisions for the product (Notice of Refusal (23 June 2015), Appeal Book at pp. 1355-1356).

[35] I turn to the appellant's second asserted breach of procedural fairness.

[36] Following the initial Notice of Refusal in 2013, Health Canada and C-RNA discussed the possibility of approving Boluoke under a "professional use" designation. Health Canada posited this as a potential avenue by which safety concerns could be mitigated (Information Request Notice (13 August 2014), Appeal Book at pp. 736-739).

[37] The professional use option would allow temporary market access to a product under the supervision and monitoring of a healthcare practitioner. The objective is to ensure the protection of the health of consumers while providing an opportunity to collect further safety evidence to support moving the product to over the counter distribution. If, following the professional use term, the evidence does not support safety without the oversight of a health professional, it is removed from the market and licensing is required under the *Food and Drug Regulations*, via a prescription. The professional use option has no foundation in either the regulations or policy guidelines governing the licencing of NHPs; it is a potential option suggested in the discretion of officials at Health Canada.

[38] There is no evidence Health Canada led the appellant astray in recommending and then rejecting, this option. The Federal Court found that Health Canada genuinely examined the option of restricting the sale of lumbrokinase to health care professionals for a limited period of time to compile additional safety data and engaged the external hematologist to develop a post-market monitoring plan that involved practitioner oversight to manage the risks. There is no indication the appellant was misled, intentionally or otherwise, into filing a new application for Boluoke that had no reasonable chance of success (Information Request Notice (13 August 2014), Appeal Book at pp. 736-737). The argument that the appellant had some form of legitimate expectation that this route would lead to licencing has no merit.

[39] I would therefore dismiss the appeal with costs.

"Donald J. Rennie"
J.A.

"I agree.
J.B. Laskin J.A."

"I agree.
Anne L. Mactavish J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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