Federal Court Cour fédérale

Date: 20220629

Docket: T-6-20

Citation: 2022 FC 971

Ottawa, Ontario, June 29, 2022

PRESENT: The Honourable Mr. Justice Fothergill

BETWEEN:

ACTIAL FARMACEUTICA S.R.L.

Applicant

and

THE MINISTER OF HEALTH

Respondent

PUBLIC JUDGMENT AND REASONS

I. Overview

[1] VSL#3® [VSL] is a probiotic that is said to promote gut health. The website of Ferring Inc [Ferring], the former distributor and vendor of VSL in Canada, described VSL as a "food supplement, containing 450 billion live bacteria in eight different strains per sachet, which colonizes the gut and benefits from a unique formulation".

[2] According to media articles and press releases filed in this proceeding, VSL was invented by Dr. Claudio De Simone. It was initially distributed under a commercial agreement between Dr. De Simone and VSL Pharmaceuticals Inc. However, the relationship soured, and Dr. De Simone subsequently accused his former partners of making a counterfeit copy of his original formulation and selling it using the same VSL#3® brand name. This resulted in a protracted international dispute.

[3] On November 9, 2018, a request was made to the Minister of Health [Minister] under the *Access to Information Act*, RSC 1985, c A-1 [ATIA] for "any information pertaining to a recall, stop sale or any compliance and enforcement related activities involving NPN 80037590 and NPN 80042116 licensed to Ferring Inc." from January 1, 2018 to the date of the request. NPN 80037590 [NPN 590] and NPN 80042116 [NPN 116] are the licences granted by Health Canada to Ferring for the distribution and sale of VSL in Canada.

[4] Health Canada's Regulatory Operations and Regions Branch provided the records to the Access to Information and Privacy [ATIP] Division, noting that many of them had been supplied to Health Canada by Ferring.

[5] The ATIP Division notified Ferring of the access request on October 1, 2019, and provided it with an opportunity to make written submissions regarding the application of s 20(1) of the ATIA. This provision requires the head of a government institution to refuse disclosure of any record that will reveal trade secrets of a third party; information supplied by the third party

in confidence; and information that could reasonably be expected to cause financial harm to, or interfere with contractual or other negotiations of, the third party if disclosed.

[6] Unbeknownst to Health Canada, Ferring forwarded the October 1, 2019 letter to Actial Farmaceutica Srl [Actial], a company based in Rome, Italy. Actial is the parent company of VSL Pharmaceuticals Inc, the supplier of the VSL marketed by Ferring in Canada.

[7] Between October and December 2019, the ATIP Division communicated with Ferring about the access request. Ferring asked that a number of redactions be applied to the information to be disclosed, citing trade secrets and commercial sensitivity.

[8] On December 16, 2019, the ATIP Division provided Ferring with notice of its decision under s 28 of the ATIA, together with 140 pages of records to be disclosed [Disclosure Package]. Most, but not all, of the redactions requested by Ferring were applied to the Disclosure Package.

[9] Actial seeks judicial review of the decision of the Minister to disclose some information contained in the Disclosure Package. The disputed information is contained in two documents: a [redacted], and a letter on Actial letterhead dated July 30, 2018 titled "Cover Letter [redacted]" [Cover Letter]. Actial asks that these documents be withheld in their entirety or, in the alternative, that further portions be redacted on the grounds that they reveal trade secrets or commercially sensitive information.

[10] For the reasons that follow, I am not persuaded that Actial is a “third party” for the purposes of bringing an application pursuant to s 44(1) of the ATIA. In any event, the application for judicial review must be dismissed because Actial has not met its burden of demonstrating that the information in issue should be exempt from disclosure.

II. Background

[11] On November 19, 2012, the Minister granted Ferring a licence to market VSL in Canada under the brand name VSL#3®. VSL was given the licence NPN 590. The product was supplied by VSL Pharmaceuticals Inc, and was manufactured by Danisco USA Inc [Danisco].

[12] On May 7, 2013, Ferring was granted a second licence for a natural health product also marketed under the brand name VSL#3®. The second product was given the licence NPN 116.

[13] In February 2015, Danisco informed Health Canada’s Natural and Non-Prescription Health Products Directorate [NNHPD] that VSL Pharmaceuticals was no longer authorized to purchase VSL, and the exclusive purchasing rights had been transferred to Exegi Pharma, LLC. However, the underlying scientific evidence respecting VSL was not withdrawn.

[14] On June 16, 2015, Visbiome, the probiotic blend originally sold as VSL#3®, was authorized for sale in Canada. Visbiome is said to contain the proprietary formulation of Dr. De Simone. The product licence holder is Exegi Pharma, LLC, and the manufacturing process is

considered by Health Canada to be the same as that of Danisco. On March 31, 2021, Visbiome Extra Strength was approved in a similar manner.

[15] On June 20, 2016, Ferring was again authorized to market VSL under the licence NPN 116 using the same processes and organisms that were disclosed in the initial scientific supporting evidence. Alternative designations for VSL were submitted, and assessed to be identical in accordance with standard quality review practices. The supporting evidence included a certificate of deposit from the Belgian Co-ordinated Collections of Micro-organisms, and attestations from VSL Pharmaceuticals Inc and Ferring that there were no significant compositional differences between the two batches of products.

[16] In May 2017 and February 2018, Health Canada received three complaints about VSL, alleging that the product was no longer what it claimed to be. The complaints alleged that the change in bacterial strains between the “original” and the “new” VSL resulted in misleading therapeutic claims. The “original” VSL was manufactured in the USA by Danisco, while the “new” VSL was manufactured in Italy by CSL/Nutrilinea.

[17] [redacted]

[18] By letter dated May 11, 2018, Ferring authorized Actial to communicate jointly with Health Canada in respect of the [redacted]

[19] The NNHPD required Ferring to provide additional information and suggested four options to address the [redacted] In its responding Cover Letter, Actial confirmed that it had commissioned [redacted]

[20] Because Actial's study did not include a comparison between [redacted]

[21] On November 5, 2018, Ferring informed NNHPD of its intention to discontinue the product licence for NPN 116 as of November 15, 2018.

[22] In a letter dated November 5, 2019, [redacted]

[23] On December 23, 2019, Actial submitted a licence transfer notification to the NNHPD in respect of the two licences held by Ferring. The submission included a joint letter of authorization dated March 22, 2019 and signed by representatives of Ferring and Actial. Actial says that the transfer request was not made sooner due to the need to secure a Canadian representative and address for correspondence with Health Canada.

[24] Actial commenced this application for judicial review on January 3, 2020.

[25] On February 11, 2020, the NNHPD confirmed that ownership of NPN 590 had been transferred from Ferring to Actial. Ownership of NPN 116 was not transferred, because the product was “inactive”.

III. Issues

[26] This application for judicial review raises the following issues:

A. Does Actial have standing to bring this application?

B. Is the information exempt from disclosure?

IV. Analysis

A. *Does Actial have standing to bring this application?*

[27] On August 6, 2020, the Minister moved to strike this application on the ground that Actial was not a “third party” for the purposes of s 44 of the ATIA, and therefore lacked standing. In an Order dated January 4, 2021, Prothonotary Angela Furlanetto (as she then was) dismissed the motion without prejudice to the Court’s further consideration of the issue based on additional evidence to be provided by Actial.

[28] Actial concedes that Health Canada communicated exclusively with Ferring in determining the release of documents in response to the ATIP Request. However, Actial

maintains that Ferring sought the company's input and provided it with regular updates because the records pertained to confidential information belonging to Actial.

[29] Actial says it reached an agreement with Ferring to transfer ownership of VSL before the ATIP Division issued its notice to Ferring under s 27(1) of ATIA on October 1, 2019. Actial relies on the common law principle that ownership of property, such as a natural health products licence, and any corresponding rights and obligations, may be freely conveyed from one party to another.

[30] Although NPN 116 is inactive, Actial says it has post-market obligations arising from the licence. Actial says that Health Canada has identified no legal basis for its contention that ownership of an inactive NPN cannot be transferred.

[31] According to the Minister, s 44 of the ATIA provides only a "third party" with the right to apply to this Court for review of a decision respecting disclosure. The third party must be the one to whom the head of a government institution provided notice of a decision pursuant to s 28(1)(b) of the ATIA, and to whom notice was given pursuant to s 27(1).

[32] There is no dispute that Ferring was the party that received notice pursuant to s 27(1) of the ATIA, and the party with which Health Canada corresponded regarding the disclosure of records under s 28. Ferring was the only party that was given notice of the Minister's decision under s 28(1)(b).

[33] The Minister acknowledges that companies may change ownership, and this may be accommodated in the ATIP consultation process. However, in this case there has been no change in company ownership. Ferring and Actial continue to exist as independent entities, notwithstanding the agreement to transfer the licences.

[34] The Minister also notes that NPN 116 was never transferred to Actial, and Actial therefore does not hold that licence. [redacted] was issued only in relation to NPN 116.

[35] I am not persuaded that Actial is a "third party" for the purposes of commencing this application. Health Canada reasonably identified Ferring as the appropriate third party under the ATIA. Ferring was the licence-holder with the statutory responsibility to respond to Health Canada's investigation, which was the focus of the ATIP request. Health Canada was not made aware of Ferring's agreement to transfer the licences to Actial until December 23, 2019, when the parties filed a licence transfer notification with the NNHPD.

[36] Despite being given the opportunity to adduce further evidence, Actial has not demonstrated that Ferring transferred the right to commence legal proceedings under s 44(1) of the ATIA in respect of the Disclosure Package. The affidavit of Lee Ferreira, General Manager of Ferring, confirms only that Ferring provided Actial with the Disclosure Package, and consented to Health Canada providing documents to Actial. The excerpts of contracts relied upon by Actial are heavily redacted, and do not establish that the information in issue is confidential or that it belongs to Actial.

[37] Clause 13.1(b)(v) of the Exclusive Supply and Distribution Agreement between Actial and Ferring dated February 14, 2017 obliges Ferring to defend against any disclosure that might be authorized by law. This provision survives the agreement pursuant to clause 14.3.1. The excerpts from the 2019 amendment of the agreement do not affect these provisions, suggesting that the right to bring legal proceedings in respect of the Disclosure Package remains with Ferring.

[38] In any event, the application for judicial review must be dismissed because Actial has not met its burden of demonstrating that the information in issue should be exempt from disclosure.

B. *Is the information exempt from disclosure?*

[39] Subsection 44(1) of the ATIA permits a third party who is given notice of a decision to apply for judicial review of the head of a government institution's decision respecting disclosure (ATIA, s 44(1)). The matter is to be heard and determined as a new proceeding and in a summary way (ATIA, ss 44.1, 45).

[40] A third party bears the burden of showing why disclosure should not be made (*Merck Frosst Canada Ltd v Canada (Health)*, 2012 SCC 3 [*Merck*] at para 92). The third party must establish that a statutory exemption applies on the balance of probabilities. The evidence required to meet that standard will be affected by the nature of the proposition the third party seeks to establish and the particular context of the case (*Merck* at para 94).

[41] Section 20 of the ATIA provides as follows:

Third party information	**Renseignements de tiers**
20 (1) Subject to this section, the head of a government institution shall refuse to disclose any record requested under this Part that contains	20 (1) Le responsable d'une institution fédérale est tenu, sous réserve des autres dispositions du présent article, de refuser la communication de documents contenant :
(a) trade secrets of a third party;	a) des secrets industriels de tiers;
(b) financial, commercial, scientific or technical information that is confidential information supplied to a government institution by a third party and is treated consistently in a confidential manner by the third party;	b) des renseignements financiers, commerciaux, scientifiques ou techniques fournis à une institution fédérale par un tiers, qui sont de nature confidentielle et qui sont traités comme tels de façon constante par ce tiers;
[…]	[…]
(c) information the disclosure of which could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, a third party; or	c) des renseignements dont la divulgation risquerait vraisemblablement de causer des pertes ou profits financiers appréciables à un tiers ou de nuire à sa compétitivité;
(d) information the disclosure of which could reasonably be expected to interfere with contractual or other negotiations of a third party.	d) des renseignements dont la divulgation risquerait vraisemblablement d'entraver des négociations menées par un tiers en vue de contrats ou à d'autres fins.

[42] When considering an application under s 44 of ATIA, the Court does not review the decision of the Minister *per se*, but makes an independent determination of whether the

exemptions from disclosure contained in s 20 of the ATIA are applicable (*Canada (Health) v Elanco Canada Limited*, 2021 FCA 191 at para 23).

[43] The term "trade secret" in s 20(1) of the ATIA is defined as a "plan or process, tool, mechanism or compound" that meets the following criteria: (i) the information must be secret in an absolute or relative sense; (ii) the possessor of the information must demonstrate that he has acted with the intention to treat the information as secret; (iii) the information must be capable of industrial or commercial application; and (iv) the possessor must have an interest (*e.g.*, an economic interest) worthy of legal protection (*Merck* at paras 109, 112)

[44] Actial says that VSL is a concentrated multi-strain probiotic product with a composition resembling a biologic drug. Actial therefore maintains that information about strain characteristics and manufacturing procedures is necessarily a closely-guarded trade secret. Actial notes that its employees and those of its associated companies, such as Ferring, must sign confidentiality agreements before gaining access to this proprietary information. Actial also maintains that the composition of VSL qualifies for exemption pursuant to ss 20(1)(b), (c) and (d) of the ATIA.

[45] Actial relies on the affidavit of Luca Aurelio Guarna, President of the Board of Directors of Actial. Mr. Guarna deposes that he is responsible for (i) overseeing Actial's finances, operations, sales and human resources; (ii) making decisions about new commercial opportunities; and (iii) managing legal issues. In cross-examination, Mr. Guarna described himself as a consultant involved in crisis management. He was hired in 2013 to help manage the

dispute between Actial and Dr. De Simone. Mr. Guarna has no formal qualifications in biology or pharmacology.

[46] Mr. Guarna states in his affidavit that the Disclosure Package contains trade secrets of Actial, but he does not identify the specific information that falls within this category. Instead, a general reference is made to the entire composition and production of VSL. Sylvie E. Cousineau, one of the Minister's affiants, deposes as follows:

> 47. From my review of the records, I have not found any information in the records that constitutes a plan or process, tool, mechanism or compound which could fall within the meaning of a trade secret for the purposes of paragraph 20(1)(a) of the ATIA.
>
> 48. The Guarna's affidavit states (paragraphs 36–38) that some of the information pertains to scientific or technical information associated with VSL#3® without identifying which specific information in the disclosure package falls within these categories. I cannot ascertain which specific information the Applicant is referring to that would qualify as scientific or technical information that is confidential under paragraph 20(1) (b) of the ATIA.
>
> 49. The evidence filed in the Guarna's affidavit (paragraphs 39 - 41) under "disclosure package will cause material financial loss and prejudice to the competitive position of Actial" can be summarised as (i) the VSL#3® NHP is difficult to copy (para 39); (ii) the disclosure of confidential material would represent a significant diminution of the value of their investment (para 40); and (iii) the disclosure would allow competitors insight into the sourcing, formulation and manufacture of the VSL#3® NHP (para 41) which would expose Actial to a serious risk of economic harm and financial loss, on re-entry into the Canadian market or world-wide where the product is still for sale.
>
> 50. The Visbiome the brand name for the probiotic blend which was originally sold as VSL#3®, is now available in Canada. The product license holder is Exegi Pharma, LLC. (see the paragraphs 34-35 of the NNHPD affidavit and information found in the public domain chart).

> 51. The consequences stated in the Guarna's affidavit are speculative in relation to a reasonable expectation of probable harm that would result from disclosure of any information to justify protection of any of the information found in the records under paragraph 20(1)(c) of the ATIA.
>
> 52. The evidence filed in the Guarna's affidavit (paragraphs 42-44) in support of the interference with contractual or other negotiations of Actial does not meet the requirements for any information found in the records to be exempted under paragraph 20(1)(d) of the ATIA.
>
> [*sic* throughout]

[47] Ms. Cousineau was not seriously challenged on any of these assertions in cross-examination.

[48] VSL has been marketed as containing the following strains:

> Bifidobacterium animalis subsp. Lactis SD-5219
>
> Bifidobacterium animalis subsp. Lactis SD-5220
>
> Bifidobacterium breve SD-5206
>
> Lactobacillus acidophilus SD-5212
>
> Lactobacillus delbrueckii subsp. bulgaricus SD-5210
>
> Lactobacillus paracasei SD-5218
>
> Lactobacillus plantarum SD-5209
>
> Streptococcus thermophilus SD-5207

[49] The Licenced Natural Health Products Database, which is publicly available, lists all of these species in the product information for NPN 116.

[50] In an article published in *Frontiers in Immunology* in 2017, the authors compare the VSL#3® formulation manufactured by Dupont/Danisco in the United States with the VSL#3® formulation manufactured by CSL/Nutrilinea in Italy. The article lists all of the strains contained in the VSL#3® manufactured by Dupont/Danisco, [redacted]

[51] The strains that comprise VSL#3® are also the subject of an article published in 2018 titled "Comparative genomic analysis of the multispecies probiotic-marketed product VSL#3®." According to the article, "several probiotic-marketed formulations available for the consumers contain live lactic acid bacteria and/or bifidobacteria. The multispecies product commercialized as VSL#3® has been used for treating various gastro-intestinal disorders."

[52] Health Canada says that VSL#3® is one of the most widely studied probiotics, with over 60 published human clinical studies. The exhibits attached to the affidavits tendered on behalf of the Minister identify numerous instances where the information Actial seeks to protect against disclosure is already in the public domain.

[53] Actial has not met its burden of establishing, on the balance of probabilities, that the disputed information in [redacted] or Cover Letter would reveal trade secrets or harm a third party's commercial interests if disclosed. Broad claims that "strain characteristics" and "manufacturing procedures" are closely-guarded trade secrets are insufficient (*Merck* at para 122).

[54] [redacted]

[55] The excerpts from Actial's confidentiality agreements are heavily redacted and sometimes unsigned. The documents do not permit the Court to reliably conclude anything about the nature and scope of Actial's proprietary information.

[56] With respect to s 20(1)(b) of the ATIA, Actial bears the burden of establishing the three-part confidentiality test adopted in *Merck*. The information must be (i) financial, commercial, scientific or technical; (ii) confidential and consistently treated in a confidential manner by the third party; and (iii) supplied to a government institution by a third party (*Merck* at para 133).

[57] In order to benefit from s 20(1)(c) of the ATIA, Actial must demonstrate that it "supplied" the information in issue. Here, some of the information concerning different strains appears in Health Canada's [redacted]

[58] The exemption for information that could cause a third party material financial gain or loss cannot be satisfied with evidence that merely affirms the harm flowing from disclosure. The evidence must establish that harmful outcomes are reasonably probable. Evidence of harm flowing from disclosure can only be determined on the basis of the specific records at issue. The assessment is fact-specific and turns on the circumstances of each case (*Samsung Electronics* at

para 113, citing *Canada (Office of the Information Commissioner) v Calian Ltd*, 2017 FCA 135 at para 44).

[59] Actial argues that disclosure will enable competitors to copy VSL, but no evidence has been provided to demonstrate how the information contained in the [redacted] or Cover Letter would facilitate copying. Furthermore, [redacted]

[60] In *Samsung Electronics*, Justice Alan Diner noted at paragraph 98 that numerous cases "have attenuated the expectation of confidentiality vis-à-vis information provided in regulatory contexts, particularly with respect to conclusions or reports prepared by the regulatory body." [redacted] was issued in the context of a statutory framework that is intended to protect the public interest by ensuring the safety of natural health products.

[61] Actial has offered no evidence to establish a reasonable expectation that the information Ferring provided to the regulator for oversight purposes would always remain confidential. Actial cannot demonstrate that maintaining confidentiality will foster a relationship conducive to the public interest (*Samsung Electronics* at paras 63, 107-109, citing *Air Atonabee Ltd v Canada (Minister of Transport)* (1989), 27 FTR 194). There is a strong public interest in disclosure, particularly considering that the purpose of [redacted] is to ensure licence holders comply with their regulatory obligations. These exist for the benefit of the public.

V. Conclusion

[62] The application for judicial review is dismissed.

[63] The awarding of costs is discretionary and will ordinarily follow the event, provided the proceeding does not raise an important new principle in relation to the statute (ATIA, s 53(1), (2)). No new principle has been raised in this proceeding, and accordingly costs are awarded to the Minister in accordance with the mid-range of Column III of Tariff B.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The application for judicial review is dismissed.

2. Costs are awarded to the Minister of Health in accordance with the mid-range of Column III of Tariff B.

3. The Reasons for Judgment shall remain confidential until the time in which to commence an appeal expires, unless Actial Farmaceutica Srl informs the Court that no appeal is contemplated.

4. If this Judgment is appealed, then the Reasons for Judgment shall remain confidential pending further direction, order or judgment of this Court or the Federal Court of Appeal.

"Simon Fothergill"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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