Federal Court  Cour fédérale

Date: 20200117

Docket: T-2092-17

Citation: 2019 FC 1455

Ottawa, Ontario, January 17, 2020

PRESENT: Madam Justice McDonald

BETWEEN:

ELANCO CANADA LIMITED

Applicant

and

CANADA (MINISTER OF HEALTH)

Respondent

JUDGMENT AND REASONS

(Confidential Judgment and Reasons issued November 19, 2019)

[1] In this Section 44 *Access to Information Act*, RSC, 1985, c A-1 [*ATIA*] judicial review application, Elanco Canada Limited (Elanco) seeks an Order prohibiting Health Canada from disclosing information about their Fortekor veterinary medication. As much of the information at issue is confidential, the hearing was held in-camera. I agreed to provide the parties with a

Confidential version of the Judgment and Reasons, with a Public version to be issued once the parties identify any information to be redacted.

[2] For the reasons that follow, I agree with Elanco that the records they seek to protect should not be disclosed. Health Canada largely challenged Elanco's position by arguing that the information relating to Fortekor is in the public domain. However, I am satisfied that the public domain information relied upon by Health Canada is for different pharmaceutical formulations in different regulatory jurisdictions.

[3] In the circumstances, I accept Elanco's evidence and therefore grant their judicial review application. Additionally, Elanco is entitled to costs.

Relevant Background

[4] Elanco, a division of Eli Lilly, is a pharmaceutical company engaged in the development, distribution, sale, and marketing of animal health products in Canada. The records requested by an unknown third party relate to Elanco's submissions to Health Canada for approval of the veterinary medication Fortekor Flavour Tabs in the 2.5 mg, 5 mg, and 20 mg concentrations (Fortekor) (the Records).

[5] Fortekor is an enzyme inhibitor used to slow the progression of chronic heart failure in dogs and to treat chronic kidney disease in cats. The active pharmaceutical ingredient in Fortekor is Benazepril hydrochloride (Benazepril), which in its native form is bitter tasting and unpleasant for animals to consume.

[redacted].

[6] According to Elanco, Fortekor's palatability and taste-masking is the essential selling feature of the drug, as it distinguishes it from competing products. This, says Elanco, has been achieved through extensive investment in research and development.

[7] In the fall of 2017, Health Canada received an online Access to Information (ATI) request for information on the Drug Identification Numbers (DIN) for the Fortekor Flavor Tabs. On November 6, 2017, Health Canada advised Elanco of the request. Health Canada forwarded Elanco copies of the records they determined were responsive to the request. These records consist of the submissions Elanco made for the approval of Fortekor as held by the Proprietary and Scientific Information Assessment (PSIA) and the Health Products and Food Branch (HPFB) of Health Canada.

[8] On November 28, 2017, Elanco advised Health Canada that it opposed disclosure of certain information contained in these records pursuant to Section 20(1) of the *Act*. This information falls into eight categories:

- Concentration Information
- [redacted] Acceptance Criteria
- Solubility [redacted] Information
- Identity of Suppliers and Contractual Agreements

- Packaging and Storage Information
- Stability Information
- Fortekor Acceptance Criteria
- [redacted] Information

[9] While Health Canada conceded that certain portions of the Solubility Information, Packaging and Storage Information, and the [redacted] were exempt from disclosure, it took the position that the balance of the records were subject to disclosure. On December 7, 2017, Health Canada informed Elanco that it would disclose portions of the records.

[10] Following Elanco filing this Application for judicial review, Health Canada changed its position on the information subject to disclosure. It insists the information it had previously agreed to withhold, should now be disclosed. The change to Health Canada's position on disclosure is driven by its view that much of the information Elanco seeks to protect is already in the public domain.

[11] In response, Elanco says that in addition to the information in the categories outlined above, it also objects to the disclosure of information in the following categories:

- Fortekor Manufacturing Information
- Fortekor Palatability Information
- [redacted] Manufacturing Information
- [redacted] Manufacturing Information

[12] The records at issue here total 166 pages. On a confidential basis, Elanco provided the Court with a complete copy of the records with highlighting to indicate the portions of the record at issue. As noted above, the parties have identified the information in the records by categories rather than by page and paragraph number. I will refer to the information by the categories used by the parties.

The Evidence

[13] Elanco relies upon the Affidavit evidence of Anthony Kahama who is their Regulatory Affairs Team Lead. Mr. Kahama has been in this role with Elanco since 2015 and previously worked as its Senior Principle Scientist & Team Lead in Analytical Development from 2012-2015.

[14] Mr. Kahama provided the following Affidavit evidence:

a) Affidavit of Anthony Kahama, sworn March 29, 2018 [Kahama Affidavit].

b) Reply Affidavit of Anthony Kahama, sworn September 14, 2018 [Kahama Reply Affidavit].

c) Further Reply Affidavit of Anthony Kahama, sworn November 16, 2018.

[15] Health Canada relies upon the following Affidavit evidence:

a) Affidavit of Janet Sewell McPherson sworn to April 27, 2018, who is the Manager with the Access to Information and Privacy (ATIP) division of Health Canada.

b) Affidavit of MacKenzie Milton sworn April 27, 2018, who is the Regulatory Affairs Officer with PSIA within HPFB.

c) Affidavit of Vicky Nadon sworn October 15, 2018, who is a team leader with the ATIP division of Health Canada.

Relevant Statutory Provisions

[16] Section 20(1) of the *ATIA* provides as follows:

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;
(b.1) information that is supplied in confidence to a government institution by a third party for the preparation, maintenance, testing or implementation by the government institution of emergency management plans within	**b.1)** des renseignements qui, d'une part, sont fournis à titre confidentiel à une institution fédérale par un tiers en vue de l'élaboration, de la mise à jour, de la mise à l'essai ou de la mise en oeuvre par celle-ci de plans de gestion

the meaning of section 2 of the *Emergency Management Act* and that concerns the vulnerability of the third party's buildings or other structures, its networks or systems, including its computer or communications networks or systems, or the methods used to protect any of those buildings, structures, networks or systems;	des urgences au sens de l'article 2 de la *Loi sur la gestion des urgences* et, d'autre part, portent sur la vulnérabilité des bâtiments ou autres ouvrages de ce tiers, ou de ses réseaux ou systèmes, y compris ses réseaux ou systèmes informatiques ou de communication, ou sur les méthodes employées pour leur protection;
(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.

Issue

[17] Is the record, or parts thereof, exempt from disclosure pursuant to section 20(1) of the *ATIA*?

Standard of Review

[18] The parties agree that the standard of review is correctness as stated in *Merck Frosst Canada Ltd v Canada (Health)*, 2012 SCC 3 [*Merck*] at para 53:

> There are no discretionary decisions by the institutional head at issue in this case. Under s. 51 of the Act, the judge on review is to determine whether "the head of a government institution is required to refuse to disclose a record" and, if so, the judge must order the head not to disclose it. It follows that when a third party…requests a "review" under s. 44 of the Act by the Federal Court of a decision by a head of a government institution to disclose all or part of a record, the Federal Court judge is to determine whether the institutional head has correctly applied the exemptions to the records in issue…This review has sometimes been referred to as *de novo* assessment of whether the record is exempt from disclosure…The term "*de novo*" may not, strictly speaking, be apt; there is, however, no disagreement in the cases that the role of the judge on review in these types of cases is to determine whether the exemptions have been applied correctly to the contested records. [Citations omitted]

Burden and Standard of Proof

[19] Elanco has the burden to demonstrate that the statutory exemptions in s. 20(1) of the *Act* apply to the records (*Merck* at para 92). The standard of proof is the balance of probabilities (*Merck* at para 94).

[20] If Elanco can establish, on a balance of probabilities, that a record falls under one or more of the exemptions listed under section 20 of the *Act*, the record must be withheld from disclosure (*Merck* at para 98).

Analysis

Section 20(1)(a) - Trade Secrets

[21] Section 20(1)(a) of the *Act* exempts "trade secret" information from disclosure. A trade secret is defined as a "plan or process, tool, mechanism, or compound" that possesses the following four characteristics (see *Merck* at para 109):

> The information must be secret in an absolute or relative sense (i.e. is known only by one or a relatively small number of persons);
>
> The possessor of the information must demonstrate that s/he acted with the intention to treat the information as secret;
>
> The information must be capable of industrial and commercial application; and
>
> The possessor must have an interest (e.g., an economic interest) worthy of legal protection).

[22] *Merck,* at paras 110-111, acknowledges that the chemical compounds of a product and the manufacturing process are unquestionably "trade secrets" provided the other criteria are satisfied.

Elanco's Position

[23] [redacted]

[24] Elanco explains that it supplied the information in the Records to Health Canada based on the understanding that Health Canada would maintain confidentiality. Health Canada expressly advised Elanco that all information submitted through the veterinary drug submission process would be treated as proprietary and confidential ([redacted]).

[25] According to Elanco, it is self-evident that the trade secret information is capable of industrial and commercial application and that it has a strong economic interest worthy of protection in relation to this information. Elanco states that it treats this information as confidential through the use of confidentiality agreements that employees and others who may have access to such information are required to sign. Elanco also states that it has safeguards in place to prevent any unauthorized disclosure or use of the information ([redacted]).

[26] This confidentiality of trade secret information extends to Elanco's suppliers, such that the [redacted] Manufacturing Information and the [redacted] Manufacturing Information are protected by contractual provisions.

[27] Elanco argues that Health Canada has applied the wrong legal test to the trade secrets category of information. Health Canada relies upon foreign documentation to argue that one can "reasonably infer" much of the information that Elanco seeks to protect. [redacted]:

[redacted]

[redacted].

[28] [redacted].

Health Canada's Position

[29] Health Canada does not consider Fortekor Manufacturing Information to be secret, as this information includes [redacted]

[redacted] information in the public domain. On the public domain arguments, Health Canada [redacted] argue that this information can be deduced by independent observation.

[30] On the Fortekor Palatability Information, which includes the description of the drug product, manufacturing information, and drug composition, Health Canada argues that this information is in the public domain [redacted]. Health Canada also says this information can be deduced from guidelines or by independent observation.

[31] Regarding [redacted] Manufacturing Information, Health Canada says this category of information can also be found in the public domain. Health Canada concedes that the manufacturing details supplied by Elanco, [redacted], is information that is scientific, technical information that is confidential and has agreed it should not be disclosed. However, Health Canada states that the balance of the [redacted] Manufacturing Information is not trade secret, as more than a few individuals know it and manufacturing methods [redacted] are discussed at length in the public domain.

[32] Similarly, it is Health Canada's position that the [redacted] Manufacturing Information is also not a trade secret because it would also be known to more than a few individuals.

[33] Health Canada argues that the Concentration Information does not qualify as a trade secret [redacted].

[34] Further, Health Canada argues that the [redacted] Acceptance Criteria does not constitute a formula, method, or technique of process. Health Canada asserts that the specification and acceptance criteria are merely a physical description of the drug product and therefore does not provide specific, technical description of the product.

[35] Health Canada agrees to a records redaction regarding some of the [redacted] Information that is not readily found in the public domain [redacted]. However, Health Canada takes the position that the other references to Fortekor tablets containing [redacted] in its formulation cannot be considered to constitute trade secrets or confidential information. Health Canada is of the view that an individual could reasonably infer, or come to the conclusion, [redacted] examining documents in the public domain as the documents are identical.

Analysis Section 20(1)(a)

[36] Health Canada relies upon foreign information for different products and medications to argue that Elanco's information about Fortekor tablets is already in the public domain. However, as Elanco points out, the information for the [redacted] is not for the same medication; [redacted]. I therefore agree with Elanco

that it is not appropriate to conclude that the [redacted] put the Fortekor formulation in the public domain.

[37] Further, the patent information that Health Canada relies upon [redacted]. [redacted] can also not be assumed to be the same formulation as the medications at issue here. The information about the [redacted] patent refers to an invention that has nothing to do with how the medication at issue is formulated.

[38] Additionally, I would note that any foreign veterinary medications would be subject to approval processes for their domestic markets that may or may not be the same approval process in Canada. Although I recognize that Health Canada does not have the burden of proof, their assertions should nonetheless be based upon reliable evidence. In my view, the position taken by Health Canada regarding information being in the public domain is misleading.

[39] Further, there is no evidence that Elanco relied upon any of this "public domain" information when it sought approval to bring Fortekor to market in Canada.

[40] Therefore, I accept Elanco's first-hand evidence over the foreign evidence relied upon by Health Canada. The "evidence" relied upon by Health Canada consists of foreign information which has not been verified by anyone who can confirm it is the same information Elanco seeks to protect. Elanco's evidence contradicts Health Canada's evidence by demonstrating that this information is not the same, and that the comparisons Health Canada attempts to make are not

tenable. In fact, other than the use of the same name, some of the comparisons with the other products are entirely irrelevant.

[41] I accept Elanco's evidence over Health Canada's and conclude that the balance of the evidence weighs in favour of Elanco with regard to the information it seeks to protect under s. 20(1)(a).

Section 20(1)(b) - Confidential Information

[42] The test under s. 20(1)(b) is outlined in *Air Atonabee Ltd v Canada (Minister of Transport)*, [1989] 27 FTR 194 (FC) [*Air Atonabee*]. It provides that information does not have to have an independent market value in order to be financial, commercial, scientific or technical information within the meaning of s. 20(1)(b). Rather, it is sufficient that it pertain to finance, commerce, science or technical matters as those terms are commonly understood (*Air Atonabee* at para 36).

[43] Whether information is confidential depends on its contents, its purposes, and the circumstances in which it is compiled and communicated. As described in paras 43-45 of *Air Atonabee*, the requirements are:

> (a) that the content of the record be such that the information it contains is not available from sources otherwise accessible by the public or that could not be obtained by observation or independent study by a member of the public acting on his own,
>
> (b) that the information originate and be communicated in a reasonable expectation of confidence that it will not be disclosed, and

> (c) that the information be communicated, whether required by law or supplied gratuitously, in a relationship between government and the party supplying it that is either a fiduciary relationship or one that is not contrary to the public interest, and which relationship will be fostered for public benefit by confidential communication.

[44] *Merck,* at para 146, states that to be confidential the information "must not be available from sources otherwise accessible by the public or obtainable by observation or independent study by a member of the public…"

Elanco's Position

[45] Elanco argues that the confidentiality in the drug submissions scenario is a cornerstone principle. Elanco has identified nine categories of information it asserts are confidential financial, commercial, scientific, or technical information within the meaning of s. 20(1)(b) of the *Act*. Those categories are:

- Concentration information
- [redacted] Acceptance Criteria
- Solubility Information
- Supplier Information
- Packaging and Storage Information
- Stability Information
- Fortekor Acceptance Criteria
- [redacted] Information
- Additional Manufacturing Information

[46] Elanco argues that the Concentration Information reveals important details about the process used to manufacture Fortekor and is essential to its commercial success [redacted]. Accordingly, the Concentration Information is concerned with scientific methods and principles that relate to techniques used by Elanco to manufacture Fortekor and has clear commercial application.

[47] Elanco also argues that the [redacted] Acceptance Criteria qualifies as scientific and technical information [redacted].

[48] The Supplier Information details information on Elanco's confidential commercial relationships with its suppliers and would disclose information regarding the cost of production. Therefore, within the ordinary sense of the term, the information is commercial and treated confidentially by Elanco and reinforced by contractual provisions in agreements with suppliers.

[49] The Packaging and Storage Information has a scientific character as it relates to Elanco's techniques for distributing Fortekor, the scientific and technical nature of which has been acknowledged by Health Canada. Additionally, portions of the Packaging and Storage Information are the intellectual property of Elanco's suppliers [redacted], and are subject to obligations of confidentiality in the commercial agreements with these suppliers. Therefore, this information is also commercial in nature. It is confidential information and treated as such by Elanco.

[50] The Stability Information, or shelf life information, is addressed at various parts of the records and Elanco argues that it is commercial, scientific, and technical in nature because it reveals the shelf life of Fortekor. It would also disclose the scientific methods and techniques used by Elanco to test and store Fortekor.

[51] The information Health Canada relies upon to suggest that the Stability Information has been publicly disclosed relates to medications in [redacted]. Elanco argues that information from other jurisdictions with different requirements cannot be assumed to be the same as that for Canada. They argue that this information would have to be assessed independently by health authorities in each jurisdiction, and that each jurisdiction's assessment of this information will vary.

[52] The Fortekor Acceptance criteria [redacted] relates to scientific methods and principles and techniques used by Elanco to produce Fortekor.

[53] Elanco says that the [redacted] Information [redacted] has clear industrial applications and relates to scientific methods, principles, and techniques used by Elanco to produce Fortekor. The [redacted] Information is kept confidential by Elanco and has not been disclosed.

[54] The Additional Manufacturing Information is said to be essential to Fortekor's commercial success and profitability. This is because Fortekor's manufacturing process and formulation, [redacted] is commercial in nature and kept strictly confidential by Elanco.

Health Canada's Position

[55] Generally, Health Canada argues that the Concentration Information, [redacted] Acceptance Criteria, and [redacted] Information are all in the public domain.

[56] Health Canada argues that because Elanco has only provided redacted versions of the confidentiality agreements, it cannot rely upon them to establish that it has such agreements with its suppliers. [redacted]. [redacted] Health Canada says, Elanco cannot avoid the suggestion of a business link between Fortekor and [redacted] is in the public domain and also found in publicly available labelling information.

[57] In any event, Health Canada's position is that the agreements cannot supersede the right of access under the *Act*, and that Health Canada is not bound by commercial agreements such that they would prevent disclosure of otherwise accessible information.

[58] Health Canada agreed to redact certain packaging information, but takes the positon that information relating to batch number and date of manufacture is not scientific or technical in

nature, but instead, administrative information that does not reveal confidential information regarding manufacturing process.

[59] Health Canada also admits that the information relating to Storage Conditions [redacted] are scientific and technical in nature, but that with additional context from information available in the public domain, and with the non-redacted information in the Records, some of this information is not confidential.

[60] Health Canada argues that the Stability Information for Fortekor can be reasonably inferred and tested objectively, so the Stability Information according to Health Canada is not confidential.

[61] Although Elanco agreed to the disclosure of its Fortekor Acceptance Criteria for the physical appearance of Fortekor tablets, it still objects to the disclosure of the acceptance criteria relating to [redacted] the Fortekor tablets. Health Canada argues that the acceptance criteria [redacted] information that can be obtained through independent observation or study, and information much of which can be found non-redacted throughout the Records.

[62] Health Canada argues that the Additional Manufacturing Information is generally in the public domain and refers to administrative information that cannot be exempted.

Analysis Section 20(1)(b)

[63] Again, with respect to the Records under this paragraph, Health Canada's main argument is that the information is in the public domain. However, the only public domain information referenced by Health Canada is information for other jurisdictions and for other formulations. The fact that a word or a phrase can be located in public domain information does not necessarily equate to Elanco's information being in the public domain.

[64] In the circumstances, I am not satisfied that the public domain information is reliable nor am I satisfied that it is comparable information to that contained in the Records. Health Canada did not offer any evidence to confirm that the information from these foreign jurisdictions is comparable and applicable to the veterinary medication at issue here.

[65] To be satisfied that this same information is in the public domain requires more than a simple word match. A more in-depth analysis was required on Health Canada's part if it purports to rely upon this information to support its position that the information in the Records is the same and therefore should be disclosed.

[66] I acknowledge that Health Canada was entitled to change its position with respect to disclosure of the Records. In the course of this litigation, Health Canada significantly changed its position. This change of position regarding disclosure was not the result of an internal reassessment of the Records by Health Canada, but rather, was the result of information obtained through Internet search of terms found in the Records. This is confirmed in the affidavit of McKenzie Milton. Without more analysis of this information in relation to Fortekor, I do not find this evidence persuasive or reliable.

[67] In my opinion, the fact that a word, [redacted], appears in the public domain does not equate to proof of Elanco's use of the product in relation to Fortekor. Despite its position, Health Canada has not established that the information on Fortekor is in the public domain. [redacted]. In the circumstances, more is needed to establish that this public domain information is the same information Elanco seeks to protect from disclosure.

[68] Furthermore, Health Canada cites no authority for their argument that the confidentiality agreements filed by Elanco cannot supersede the provisions of the *Act*. This is irreconcilable with the provision of the *Act* that specifically protects confidential information provided the evidence meets the criteria outlined in s. 20(1)(b).

Section 20(1)(c) –Competitive Position

[69] Section 20(1)(c) of the *Act* provides:

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 :
…	…
(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;	**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;

[70] According to *Merck*, at para 206, a third party relying on this exemption is not required to establish that harm or prejudice will in fact result from the disclosure, only that there is a reasonable expectation of probable harm.

[71] The Federal Court in *AstraZeneca Canada Inc v Health Canada*, 2005 FC 1451 [*AstraZeneca*], at paras 44 to 45, explained that a determination of reasonable expectation of probable harm necessitates reasonable speculation and a flexible approach as evidenced by the plain word meaning of this section of the *Act*. Furthermore, the list of harms in s. 20(1)(c) is disjunctive such that disclosure of any one of (a) financial loss, (b) gain for a competitor, or (c) prejudice to the third party's competitive position could reasonably be expected to result (*AstraZeneca* at para 42-43). Therefore, the s. 20(1)(c) exemption applies if reasonable speculation leads the Court to believe that disclosure would result in harm to Elanco in the form of financial loss, gain to a competitor, or prejudice to Elanco's competitive position.

Elanco's Position

[72] Elanco argues that it would experience financial loss and competitors would have financial gain if the information in the Records is disclosed. Elanco states that the records contain information relating to the key elements of Elanco's confidential process for manufacturing Fortekor the disclosure of which would allow Elanco's competitors [redacted] an advantage. Elanco argues that disclosure of any of the following categories of information would reasonably lead to competitive harm: Concentration Information, the [redacted] Acceptance Criteria, the Solubility Information, the Supplier Information, the Packaging and Storage Information, the

Stability Information, the [redacted] Information, the Fortekor Palatability Information, the Fortekor Manufacturing Information, the [redacted] Manufacturing Information, and the [redacted] Manufacturing Information.

[73] Elanco's evidence is that it has invested significant time and resources into developing and refining its confidential and proprietary manufacturing process to produce Fortekor. [redacted]. As such, Elanco's competitors would enjoy a head start and material gain from the savings in research and development costs for the development of a competing product. This would also allow competitors to cut down on the time necessary to bring such a product to market.

[74] Elanco's position on the harm test is that the disclosure of the Records would allow competitors [redacted] better compete with Fortekor. [redacted].

[75] Elanco relies upon *Canada (Office of the Information Commissioner) v Calian Ltd.* 2017 FCA 135 at para 42:

> In my view, the Judge correctly applied the *Merck* framework and committed no reviewable error in concluding, on the basis of the evidence that was before him, that releasing Calian's detailed personnel rates would give its competitors a "free ride" and "tilt the level playing field" against Calian …. Contrary to the position taken by the Commissioner, the Judge did not merely rely on bald

> and unsupported assertions found in the affidavit of Calian's Vice President of Operations (Mr. Jerry Johnston). He came to the conclusion, based on his own assessment, that the personnel rates individually and in the aggregate were the most significant factor in the success of Calian's bid and were crucial to Calian's competitive position ... He also accepted Mr. Johnston's evidence that the development of the personnel rates was effected through the confidential and proprietary salary and other information that Calian directly obtained from, or negotiated with, the numerous potential providers of the required specialist labour services, in addition to its own business analyses of overhead, other costs, and profit … While the absence of cross-examination and of contradictory evidence is not conclusive one way or another, the Judge could certainly take these factors into consideration to determine whether Calian had met its burden of establishing a reasonable expectation of probable harm [Citations omitted].

Health Canada's Position

[76] Health Canada's position is that harm must be demonstrated. Health Canada asserts that the inherently speculative nature of proof of harm does not relieve Elanco from putting forward something more than internally held beliefs and fears (*AstraZeneca* at para 46).

[77] For example, Health Canada argues that Elanco has not filed any comparative [redacted] study or research to [redacted] with other commercial formulations [redacted] already on the market. Health Canada argues that, as such, Elanco's arguments [redacted] are unsupported and that Elanco has provided conclusions of probable harm rather than evidence of harm.

Analysis Section 20(1)(c)

[78] In the circumstances, I am satisfied based upon Mr. Kahama's evidence, that Elanco has established a reasonable expectation of harm if this information is disclosed. The evidence is that Elanco is an industry leader for this medication. Their investment in research and development is undoubtedly the reason. To allow the information be released, presumably to a competitor, would result in financial harm to Elanco.

[79] Contrary to the assertions of Health Canada, I do not read *AstraZeneca* and *Merck* as saying that Elanco must present expert evidence on this point. I am satisfied that Elanco has provided sufficient evidence through Mr. Kahama's affidavits to establish real risk of harm.

Section 20(1)(d)

[80] Section 20(1)(d) protects from disclosure information "which could reasonably be expected to interfere with contractual or other negotiations of a third party."

[81] Section 20(1)(d) is a mandatory exemption based on an injury test that applies to contractual situations not covered under paragraph (c). As explained in *Société Gamma Inc. v. Canada (Secretary of State)*, [1994] 79 FTR 42 (FC) at para 10:

> I take it that this ground must be distinguishable from prejudice to the competitive position of a third party such as the applicant, a matter which is dealt with in para. (c). That is, when para. 20(1)(d) refers to disclosure which could "interfere" with contractual negotiations it must refer to an obstruction to those negotiations and not merely the heightening of competition for the third party which might flow from disclosure. ...

[82] The case law indicates that evidence of the possible effect of disclosure on other contracts is generally held to be insufficient to qualify under this exemption. Evidence about the effect on actual contractual negotiations is required (see *Canadian Broadcasting Corp v Canada (National Capital Commission)*, [1998] 147 FTR 264 at para 29; also *Brookfield Lepage Johnson Controls Facility Management Services v Canada (Minister of Public Works and Government Services)*, 2004 FCA 214 at paras 8-10).

Elanco's Position

[83] Elanco says its supplier gives it confidential information relating to Fortekor that falls into four categories: the Supplier Information; the Packaging and Supplier Information; the [redacted] manufacturing Information; and the [redacted] Manufacturing Information (supplier information).

[84] According to Mr. Kahama, supplier information is protected by contractual agreements and confidentiality provisions ([redacted]). This prohibits Elanco from disclosing the existence and details of Elanco's relationship with these suppliers. As a result, says Elanco there could be serious commercial consequences and financial harm regarding disclosure of the Confidential Supplier Information.

Health Canada's Position

[85] Health Canada's position is that the Applicant failed to provide such evidence and, accordingly, the information and Records in question do not meet the requirements of this exemption.

Analysis Section 20(1)(d)

[86] Elanco's position and their evidence of contractual terms requiring that they maintain their contractual relationships in confidence needs to be considered in the context of the competitive veterinary pharmaceutical industry. Elanco has filed evidence showing that it is bound to maintain the confidential nature of its relationships with other suppliers ([redacted]). In the circumstances, and recognizing that "proof" of harm is not necessary, I am satisfied that Elanco has produced all the evidence that is possible to produce in the circumstances.

[87] I am therefore satisfied that this information is entitled to protection under s. 20(1)(d).

Summary

[88] Overall, my conclusions regarding the application of the provisions of the *Act* to the Records is based upon an assessment of the evidence offered by the parties. Elanco has provided first-hand evidence from an employee, whereas Health Canada largely relies upon unsubstantiated information contained in documents in the public domain. Health Canada also makes unsupported blanket assertions.

[89] When the “public domain information” relied upon by Health Canada is scrutinized, it does not support Health Canada’s claims that this information is synonyms with the Fortekor information. This public domain information relates to different medications with different compounds in different jurisdictions. Overall, I do not find the so-called public domain information to be reliable.

[90] In the circumstances, and after weighing the evidence submitted by the parties in reviewing the Records, I agree with Elanco and their proposed redactions from the Records. I therefore declare that Health Canada’s decision to disclose the Records is invalid.

[91] Elanco is entitled to costs.

[92] If the parties are unable to agree on costs, they may exchange and file submissions with the Court within 20 days of the release to them on a confidential basis of the Judgment and Reasons.

JUDGMENT in T-2092-17

THIS COURT'S JUDGMENT is that the judicial review is allowed and I declare that Health Canada's decision to disclose the Records is invalid. Elanco is entitled to costs.

"Ann Marie McDonald"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-2092-17
STYLE OF CAUSE:	ELANCO CANADA LIMITED v CANADA (MINISTER OF HEALTH)
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	AUGUST 20, 2019
JUDGMENT AND REASONS:	MCDONALD J.
CONFIDENTIAL JUDGMENT AND REASONS ISSUED:	NOVEMBER 19, 2019
PUBLIC JUDGMENT AND REASONS ISSUED	JANUARY 17, 2020

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