Federal Court  Cour fédérale

Date: 20190102

Docket: T-1978-16

Citation: 2019 FC 5

Ottawa, Ontario, January 2, 2019

PRESENT: The Honourable Mr. Justice Lafrenière

BETWEEN:

ELANCO, A DIVISION OF ELI LILLY CANADA INC.

Applicant

and

ATTORNEY GENERAL OF CANADA AND MINISTER OF HEALTH

Respondents

JUDGMENT AND REASONS

[1] This is an application for judicial review by the Applicant, Elanco, a division of Eli Lilly Canada Inc. [Elanco], under section 18.1 of the *Federal Courts Act*, RSC 1985, c F-7, of a decision [the Decision] communicated by letter dated October 17, 2016 on behalf of the Respondent, the Minister of Health [the Minister], refusing to list Canadian Patent No. 2,812,704 [the '704 Patent] on the Patent Register maintained pursuant to the *Patented Medicines (Notice*

of Compliance) Regulations, SOR/93-133, [the *NOC Regulations*] and the *Food and Drug Regulations*, CRC, c 870, [the *FD Regulations*].

[2] The ‘704 Patent was submitted in a patent list filed in accordance with the *NOC Regulations* and *FD Regulations* in respect of a 15 mg subcutaneous solution of Elanco’s pegbovigrastim veterinary drug product, IMRESTOR [the IMRESTOR Product].

[3] The Minister refuses to list the ‘704 Patent on the Patent Register because she takes the position that the date of filing of Elanco’s new drug submission precedes the filing date of the application for the patent, contrary to the timing requirements of subsection 4(6) of the *NOC Regulations*. The issue to be determined in this application is whether the Minister erred in considering Elanco’s new drug submission to be effectively filed upon receipt by Health Canada, notwithstanding that it did not contain any substantive information and material to enable the Minister to assess the safety and effectiveness of the new drug.

[4] Elanco seeks (a) an order declaring that the ‘704 Patent is eligible for listing on the Patent Register in respect of the IMRESTOR Product; (b) an order quashing the Minister’s Decision; (c) an order directing the Minister to add the ‘704 Patent to the Patent Register in respect of the IMRESTOR Product, effective as of the day that the Patent List [Form IV] was submitted, or alternatively as of the date received or, in the further alternative, as of an appropriate date determined by this Court.

[5] For the reasons that follow, I find no reason to intervene in the Minister's Decision to refuse to list Elanco's patent. The application is accordingly dismissed, with costs.

I. The Regulatory Framework

[6] Non-biological veterinary drug submissions are approved by way of a notice of compliance [NOC] pursuant to subsection C.08.002(1) of the *FD Regulations*. C.08.002(1) mandates that no person shall sell a new drug unless the manufacturer has filed with the Minister a new drug submission [NDS] relating to the new drug that is satisfactory to the Minister and that a NOC is issued to the manufacturer:

C.08.002 (1) No person shall sell or advertise a new drug unless	C.08.002 (1) Il est interdit de vendre ou d'annoncer une drogue nouvelle, à moins que les conditions suivantes ne soient réunies :
(a) the manufacturer of the new drug has filed with the Minister a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission or an abbreviated extraordinary use new drug submission relating to the new drug that is satisfactory to the Minister;	a) le fabricant de la drogue nouvelle a, relativement à celle-ci, déposé auprès du ministre une présentation de drogue nouvelle, une présentation de drogue nouvelle pour usage exceptionnel, une présentation abrégée de drogue nouvelle ou une présentation abrégée de drogue nouvelle pour usage exceptionnel que celui-ci juge acceptable;
(b) the Minister has issued, under section C.08.004 or C.08.004.01, a notice of compliance to the manufacturer of the new drug in respect of the submission; and	b) le ministre a délivré au fabricant de la drogue nouvelle, en application des articles C.08.004 ou C.08.004.01, un avis de conformité relativement à la présentation;

(c) the notice of compliance in respect of the submission has not been suspended under section C.08.006.	c) l'avis de conformité relatif à la présentation n'a pas été suspendu aux termes de l'article C.08.006.

[7] To obtain a NOC, a manufacturer must file a drug submission pursuant to Part C, Division 8 of the *FD Regulations* and, in certain cases, satisfy the requirements of the *NOC Regulations*. Subsection C.08.002(2) sets out the information and material that must be contained in a submission as follows:

C.08.002 (2) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:	C.08.002 (2) La présentation de drogue nouvelle doit contenir suffisamment de renseignements et de matériel pour permettre au ministre d'évaluer l'innocuité et l'efficacité de la drogue nouvelle, notamment :
(a) a description of the new drug and a statement of its proper name or its common name if there is no proper name;	a) une description de la drogue nouvelle et une mention de son nom propre ou, à défaut, de son nom usuel;
(b) a statement of the brand name of the new drug or the identifying name or code proposed for the new drug;	b) une mention de la marque nominative de la drogue nouvelle ou du nom ou code d'identification projeté pour celle-ci;
(c) a list of the ingredients of the new drug, stated quantitatively, and the specifications for each of those ingredients;	c) la liste quantitative des ingrédients de la drogue nouvelle et les spécifications relatives à chaque ingrédient;
(d) a description of the plant and equipment to be used in the manufacture, preparation and packaging of the new drug;	d) la description des installations et de l'équipement à utiliser pour la fabrication, la préparation et l'emballage de la drogue nouvelle;

(e) details of the method of manufacture and the controls to be used in the manufacture, preparation and packaging of the new drug;

e) des précisions sur la méthode de fabrication et les mécanismes de contrôle à appliquer pour la fabrication, la préparation et l'emballage de la drogue nouvelle;

(f) details of the tests to be applied to control the potency, purity, stability and safety of the new drug;

f) le détail des épreuves qui doivent être effectuées pour contrôler l'activité, la pureté, la stabilité et l'innocuité de la drogue nouvelle;

(g) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended;

g) les rapports détaillés des épreuves effectuées en vue d'établir l'innocuité de la drogue nouvelle, aux fins et selon le mode d'emploi recommandés;

(h) substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended;

h) des preuves substantielles de l'efficacité clinique de la drogue nouvelle aux fins et selon le mode d'emploi recommandés;

(i) a statement of the names and qualifications of all the investigators to whom the new drug has been sold;

i) la déclaration des noms et titres professionnels de tous les chercheurs à qui la drogue nouvelle a été vendue;

(j) in the case of a new drug for veterinary use, a draft of every label to be used in connection with the new drug, including any package insert and any document that is provided on request and that sets out supplementary information on the use of the new drug;

j) dans le cas d'une drogue nouvelle pour usage vétérinaire, une esquisse de toute étiquette à utiliser relativement à la drogue nouvelle, y compris tout dépliant d'accompagnement et toute documentation supplémentaire sur l'emploi de la drogue nouvelle qui est fournie sur demande;

(j.1) in the case of a new drug for human use…

j.1) dans le cas d'une drogue nouvelle pour usage humain…

(k) a statement of all the

k) la déclaration de toutes les

representations to be made for the promotion of the new drug respecting

(i) the recommended route of administration of the new drug,

(ii) the proposed dosage of the new drug,

(iii) the claims to be made for the new drug, and

(iv) the contra-indications and side effects of the new drug;

recommandations qui doivent être faites dans la réclame pour la drogue nouvelle, au sujet

(i) de la voie d'administration recommandée pour la drogue nouvelle,

(ii) de la posologie proposée pour la drogue nouvelle,

(iii) des propriétés attribuées à la drogue nouvelle,

(iv) des contre-indications et les effets secondaires de la drogue nouvelle;

(l) a description of the dosage form in which it is proposed that the new drug be sold;

l) la description de la forme posologique proposée pour la vente de la drogue nouvelle;

(m) evidence that all test batches of the new drug used in any studies conducted in connection with the submission were manufactured and controlled in a manner that is representative of market production

m) les éléments de preuve établissant que les lots d'essai de la drogue nouvelle ayant servi aux études menées dans le cadre de la présentation ont été fabriqués et contrôlés d'une manière représentative de la production destinée au commerce;

(n) in the case of a new drug intended for administration to food-producing animals, the withdrawal period of the new drug; and

n) dans le cas d'une drogue nouvelle destinée à être administrée à des animaux producteurs de denrées alimentaires, le délai d'attente applicable;

(o) in the case of a new drug for human use…

o) dans le cas d'une drogue nouvelle pour usage humain…

[8] A submission usually contains a significant volume of information that forms the basis upon which a drug is initially approved for sale in the Canadian market. In addition to filing a NDS, a manufacturer will typically continue to file information about a drug. Significant changes made to the drug itself, or the information regarding the drug contained in the NDS, are made by filing a supplemental NDS pursuant to section C.08.003 of the *FD Regulations*.

[9] Section C.08.004 of the *FD Regulations* stipulates that, subject to section C.08.004.1, the Minister shall, after completing an examination of a NDS, an abbreviated NDS, or a supplement to either submission, issue a NOC if the submission or supplement complies with sections C.08.002, C.08.002.1, or C.08.003. If the submission or supplement does not comply, the Minister shall notify the manufacturer of such.

[10] A manufacturer who files a NDS or supplemental NDS may also submit to the Minister a patent for listing on Health Canada's Patent Register, an alphabetical listing maintained by the Minister of medicinal ingredients and their associated patents, the patent expiry dates, and other related information, by filing a Form IV: Patent List in accordance with the requirements of section 4 of the *NOC Regulations*.

[11] Subsection 4(5) of the *NOC Regulations* states that subject to subsection 4(6), a first person who submits a patent list must do so at the time the person files the NDS or the supplemental NDS to which the patent list relates. Where the filing date of the NDS occurs between the date of filing of the patent application and issuance of the patent, subsection 4(6) provides that a first person may submit a patent list for inclusion in the Patent Register within

thirty days after the issuance of the patent, as long as the patent application has a filing date in Canada that is before the date of filing of the NDS or supplemental NDS. Subsection 4(6) provides as follows:

4 (6) A first person may, after the date of filing of a new drug submission or a supplement to a new drug submission, and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date in Canada that precedes the date of filing of the submission or supplement, submit a patent list, including the information referred to in subsection (4), in relation to the submission or supplement.	4 (6) La première personne peut, après la date de dépôt de la présentation de drogue nouvelle ou du supplément à une présentation de drogue nouvelle et dans les trente jours suivant la délivrance d'un brevet faite au titre d'une demande de brevet dont la date de dépôt au Canada est antérieure à celle de la présentation ou du supplément, présenter une liste de brevets, à l'égard de cette présentation ou de ce supplément, qui contient les renseignements visés au paragraphe (4).

[12] The rationale for the timing requirement is stated in the Regulatory Impact Analysis Statement [RIAS] that accompanied the October 5, 2006 amendments to the *NOC Regulations*:

> By stipulating that the application filing date of the patent precede the date of the corresponding drug submission, the timing requirement promotes a temporal connection between the invention sought to be protected and the product sought to be approved. This ensures that patents for inventions discovered after the existence of a product do not pre-empt generic competition on that product…

[13] In assessing compliance with the timing requirements in section 4 of the *NOC Regulations*, the Office of Patented Medicines and Liaison [OPML] relies on the date upon which a patent application was filed in Canada, as stated in section 3.2.1 of Health Canada's

guidance document entitled *Guidance Document: Patented Medicines (Notice of Compliance) Regulations* (Revised date 2010/03/01):

> Date of filing the submission or supplement: Refers to the date allocated to the submission upon receipt by Health Canada provided that the submission is found to be administratively complete [(i.e.) once all submission criteria and forms required for processing are completed and submitted to Health Canada]. In the event that the submission is found to be administratively incomplete, the date of filing will be the date on which these deficiencies are corrected. Therefore, the date of filing may differ from the date of original receipt should the submission be considered administratively incomplete.

[14] If a patent is found to meet the eligibility requirements set out in section 4 of the *NOC Regulations*, it will be added to the Patent Register upon issuance of the NOC for the corresponding submission. In cases when a NOC has already been issued, patents added to the Patent Register will be added as of the date of the final decision of eligibility.

[15] A "second person", typically a generic drug manufacturer, who seeks a NOC on the basis of a submission that directly or indirectly compares with, or makes reference to, a first person's drug must address the patents listed on the Patent Register for that drug in accordance with section 5 of the *NOC Regulations* before a NOC can issue.

II. Facts

[16] The facts underlying this proceeding are, for the most part, not in dispute.

A. *The IMRESTOR Product*

[17] The IMRESTOR Product is currently marketed with an indication for a reduction in the incidence of clinical mastitis in the first 30 days of lactation in dairy cows and replacement heifers. The product is a subcutaneous solution containing pegbovigrastim (PEGylated Bovine Granulocyte Colony Stimulating Factor) to be used by veterinarians as an immune restorative particularly during the critical time around calving when a dairy cow's immune system is suppressed. It helps to restore the function and increase the number of bacteria-fighting neutrophils, significantly reducing the incidence of clinical mastitis.

B. *The '704 Patent*

[18] The '704 Patent contains claims to a formulation that contains pegbovigrastim and claims for use of the formulation. These claims relate to the formulation and use as approved in the IMRESTOR pegbovigrastim NDS.

C. *Chronology of Events Leading to the Decision*

[19] At a meeting with the Veterinary Drugs Directorate [VDD] in March 2011, it was agreed that Elanco could partake in a rolling or phased submission process to enable simultaneous reviews of its product by Health Canada and the United States Food and Drug Administration [FDA], as a part of the Canada-United States Regulatory Cooperation Council [RCC] Initiative. The proposed timeline for submitting the data was to align with the submission of information to the FDA's Center for Veterinary Medicines. The VDD accepted Elanco's proposal.

[20] On June 21, 2011, Elanco submitted a veterinary NDS for the approval of a 15 mg subcutaneous solution of pegbovigrastim under the trade name IMRESTOR, which consisted of three (3) forms (Drug Submission Application form, Submission Certifications and Veterinary Drug Submission Fee Application form) including the Manufacturer/Sponsor name, medicinal ingredient, the strength, the dosage form and route of administration of the drug, as well as some initial human food safety data that had been submitted to the FDA. It is common ground that some substantive information required to meet the requirements of subsection C.08.002(2) of the *FD Regulations* was not provided at that time, and more particularly, efficacy data, animal safety data, chemistry and manufacturing information.

[21] VDD received Elanco's original information and material on June 24, 2011, determined that the submission was "administratively complete" and assigned a filing date on the same day. Elanco was provided with an "Acknowledgement and Certification of Receipt of Information and Material" from the VDD indicating that the "New Drug Submission (NDS) Rolling Sub" was received on June 24, 2011 and allocated Drug Submission Tracking System #: 148171.

[22] On September 22, 2011, Elanco filed an application for the '704 Patent.

[23] Elanco provided information for its product, as required by subsection C.08.002(2) of the *FD Regulations*, in phases, which it characterizes as the "four key pillars" of its NDS:

i. human safety on March 6, 2012;

ii. clinical efficacy on March 6, 2012;

iii. chemistry and manufacturing on February 11, 2013; and

iv. animal safety on March 27, 2013.

[24] On March 9, 2016, the NOC for the IMRESTOR Product was issued by Health Canada.

[25] The ‘704 Patent was issued on March 15, 2016.

[26] On March 23, 2016, Elanco submitted a Form IV to list the ‘704 Patent on the Patent Register, which was received by Health Canada on March 29, 2016.

[27] On April 4, 2016, Health Canada notified Elanco that its patent list had been reviewed and was not eligible for listing on the Patent Register on the grounds that the ‘704 Patent did not meet the timing requirements set out in subsection 4(6) of the *NOC Regulations*.

[28] By letter dated April 15, 2016, Health Canada reiterated its preliminary view that the ‘704 Patent was not eligible to be added to the Patent Register and invited Elanco to make representations as to its eligibility, failing which the letter would be considered a final decision.

[29] On July 8, 2016, Elanco submitted a detailed response, taking issue with Health Canada’s preliminary decision. The arguments made by Elanco are essentially the same ones advanced in this application.

D. *The Decision*

[30] A final decision was communicated in a letter dated October 17, 2016, signed by the Minister's Delegate, Anne Bowes, Director of the OPML.

[31] Ms. Bowes sets out in the Decision a chronology of dates relevant to the '704 patent and Elanco's NDS and addresses each of the arguments advanced by Elanco. She confirms that the requirement in subsection 4(6) of the *NOC Regulations* that the patent list be filed within 30 days after the issuance of a patent was complied with by Elanco, as the patent list was filed on March 29, 2016, which was within the 30 days of its issuance date of March 15, 2016, but observes that subsection 4(6) also requires that the patent application filing date *precede* the date of filing of the submission.

[32] Ms. Bowes explains that the VDD has two main stages in its review process, which progress chronologically in the following order: screening and review. Processing is the first step of screening during which the filing date is established. A filing date is the date established by the VDD when a submission is considered to be "administratively complete", as explained in the VDD guidance document entitled *"Guidance for Industry: Management of Regulatory Submissions"* (Effective July 1, 2005). This occurs when a drug manufacturer files a Drug Submission Application form, Submission Certifications, a Veterinary Drug Submission Fee Application form, and includes in the submission the Manufacturer/Sponsor name, medicinal ingredient, the strength, the dosage form and route of administration of a drug.

[33] Ms. Bowes states that the filing date established for a NDS is permanent and is not affected by subsequent screening or review activities. As all applicable forms required by VDD for establishing a filing date for Elanco's NDS were received by Health Canada on June 24, 2011, the submission was considered administratively complete. Therefore, the filing date of the NDS was established as June 24, 2011.

[34] Ms. Bowes concludes that the '704 patent does not meet the timing requirements of subsection 4(6) of the *NOC Regulations* because the patent was issued on the basis of an application with a filing date in Canada that does not precede the date of filing of the NDS. Accordingly, pursuant to subsection 3(2) of the *NOC Regulations*, the Minister refused to add the '704 Patent to the Patent Register in respect of the drug submission for the IMRESTOR Product.

III. Issues

[35] The issues to be determined are the following:

a) What is the proper standard of review of the Minister's Decision?

b) Having regard to the proper standard of review, whether the Minister committed a reviewable error by refusing to list the '704 Patent on the Patent Register?

IV. Analysis

A. *What is the proper standard of review of the Minister's Decision?*

[36] The Supreme Court of Canada held in *Dunsmuir v New Brunswick*, 2008 SCC 9 at paragraph 57 [*Dunsmuir*], that an exhaustive analysis is not required in every case to determine the proper standard of review. A court deciding an application for judicial review must engage in a two-step process to identify the proper standard of review. First, it must consider whether the level of deference to be accorded with regard to the type of question raised in the application has been established satisfactorily in the jurisprudence. Where the standard of review applicable to a particular question is well-settled, the reviewing court may adopt that standard of review. The second inquiry becomes relevant if the first is unfruitful or if the relevant precedents appear to be inconsistent with recent developments in the common law principles of judicial review. At this second stage, the court performs a full analysis in order to determine the applicable standard (see *Agraira v Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36 at paragraph 48).

[37] Elanco devotes little time in its written submissions on the standard of review to be applied by the Court, notwithstanding its importance. It submits that the Federal Court of Appeal has repeatedly held that the interpretation of section 4 of the *NOC Regulations* by the Minister is a question of law that is reviewable on a standard of correctness, whereas the determination by the Minister as to whether the eligibility requirements for listing a patent on the Patent Register have been met is to be reviewed on a standard of reasonableness as it requires the application of section 4 to the specific facts of the case: *Gilead Sciences Canada Inc v Canada (Health)*, 2012 FCA 254 at para 12 [*Gilead*] and *Eli Lilly Canada Inc v Canada (Attorney General)*, 2015 FCA 166 at para 47 [*Lilly*]. According to Elanco, since subsection 4(6) of the *NOC Regulations* is at issue, a correctness standard should be applied.

[38] The two decisions cited by Elanco are of little assistance in determining the appropriate standard of review in the present case as they both involve judicial reviews of a decision made by the Minister under subsection 4(2) of the *NOC Regulations*, the interpretation of which was found by the Federal Court of Appeal to attract a correctness standard. No jurisprudence has been cited by either party which addresses the standard of review to be applied to a decision of the Minister that is based, at least in part, on the application of subsection 4(6).

[39] Guidance on the question of the applicable standard of review can be found in the decision of the Federal Court of Appeal in *Teva Canada Limited v Pfizer Canada Inc*, 2016 FCA 248 [*Teva Canada*]. The decision relates to two separate judicial reviews before the Federal Court, both brought by innovator pharmaceutical companies, of the Minister's decision to grant NOCs to generic companies for drugs containing active ingredients patented by the innovator companies. The issue was whether it was reasonable for the Minister to issue a NOC to Teva without triggering the notice requirement found in section 5 of the *NOC Regulations* because the Minister concluded that Teva's generic drug submissions did not engage the section.

[40] The Federal Court of Appeal determined that the prior jurisprudence had not satisfactorily determined the standard of review to be applied and began the second step analysis as set forward by *Dunsmuir*. At this second stage, the Federal Court of Appeal found that the contextual analysis of the case did not rebut the presumption of reasonableness. Indeed, the presumption of reasonableness applies when an administrative decision-maker is interpreting not just its home statute, but also "statutes closely connected to its function" (*Dunsmuir* at paragraph 54). Further, the Federal Court of Appeal added that the interpretation of unclear language in an

administrative decision-maker's home statute (or regulation) is usually best left to the administrative decision-maker and that there is no evidence that Parliament's intention was for the decisions of the Minister interpreting the *NOC Regulations* to be reviewed on a less deferential standard of review.

[41] The Federal Court of Appeal held that a decision of the Minister involving the determination that a generic drug submission is administrative in nature and does not trigger the notice requirement found in section 5 of the *NOC Regulations* should be reviewed on a reasonableness standard based on the Minister's expertise and the nature of the question. As the Minister was interpreting a statute closely connected to her function, the presumption that the decision was subject to reasonableness applied. The Federal Court of Appeal further found that the question was one of mixed fact and law, which the jurisprudence firmly establishes as subject to the reasonableness standard.

[42] Although the decision under review in this case involves the interpretation and application of subsection 4(6) of the *NOC Regulations* rather than section 5, similar considerations apply. A parallel can be drawn from *Teva Canada* because the nature of the Minister's decision in *Teva Canada* is similar to the Minister's Decision to exclude the '704 Patent from the Patent Register based on the filing date of the NDS, pursuant to subsection 4(6) of the *NOC Regulations.* In applying subsection 4(6), the Minister is required to determine if the temporal linkage has been made between the date of filing of a NDS and the filing date of a patent. Similarly to *Teva Canada*, the Minister's Decision is of an administrative nature and the

question of whether the eligibility requirements for listing a patent on the Register have been met is a question of mixed fact and law.

[43] The *NOC Regulations* are closely connected with the Minister's functions. The Minister has great expertise in the application and interpretation of the *NOC Regulations* and has considerable knowledge in regard to the established procedure and requirements for timing and eligibility of listing a patent on the Patent Register set out in section 4 of the *NOC Regulations*.

[44] As the *NOC Regulations* do not define the "date of filing of a new drug submission", this determination is essentially a question of fact, requiring only the application of the clear legal requirements: either the patent application was filed before the NDS or it was not. As a result, findings of this nature should not be disturbed except if found to be unreasonable.

[45] The Decision also does not engage the Minister's scientific expertise, unlike the facts in *Gilead* and *Lilly*. It does not require a determination whether a direct or indirect comparison has been made between patent claims or drugs in relation to a patent on the Patent List and a NDS.

[46] Alternatively, on a standard of review analysis applying the contextual factors set in *Dunsmuir*, I would arrive at the same conclusion as to the applicable standard of review.

[47] The issue at hand does not involve categories of legal questions such as a constitutional question, a question of general importance to the legal system as a whole, a determination of the jurisdiction of two or more administrative decision-makers or a true question of *vires* (*Canadian*

National Railway Company v Canada (Attorney General), 2014 SCC 40). The *NOC Regulations* do not provide a privative clause nor do they contain a clear direction that the decision maker is not to be accorded deference by the courts.

[48] The issue in this judicial review is not whether the Minister properly interpreted subsection 4(6) of the *NOC Regulations*, rather, it is whether the material tendered by Elanco in its NDS satisfied the requirements to be considered administratively complete for processing and to be given a filing date, which was subsequently used to make the Decision pursuant to subsection 4(6). Determining whether the date of filing of Elanco's NDS satisfies the timing requirement for filing a patent on the Patent Register requires regulatory experience of the procedure of filing a NDS pursuant to the *FD Regulations* and the procedure of filing a patent on the Patent Register pursuant to the *NOC Regulations*, rather than knowledge of the law or legal principles. The Decision applying subsection 4(6) of the *NOC Regulations* cannot be dissociated with the facts of the case.

[49] As stated at paragraph 53 of the Respondent's memorandum of fact and law:

> The Minister's function is to maintain the Patent Register. In so doing, she must regularly interpret and apply the requirements for registration set out in section 4 of the *Regulations* regarding eligibility and timing. The conferral by Parliament of a decision-making function which requires the interpretation and application of a statute closely connected to decision-maker's function gives rise to the presumption of reasonableness. The Minister's interpretation of subsection 4(6) of the *PM(NOC) Regulations* is informed by her expertise and familiarity with the factual *content* and *context* of her own filing procedures.

[50] For the above reasons, I conclude that the presumption of a reasonableness standard has not been rebutted and that the Decision attracts considerable deference.

B. *Whether the Minister committed a reviewable error by refusing to list the '704 Patent on the Patent Register?*

[51] Elanco submits that the Minister's Decision, and more specifically the Minister's finding that the NDS was filed on June 24, 2011, is incorrect at law and unreasonable, as it is inconsistent with the applicable regulations, her own public policies and guidance documents, and the representations of her own officials. I will deal with the issues together as they are interrelated.

[52] Subsection 3(1) of the *NOC Regulations* defines "new drug submission" by incorporating the definition of that term in the *FD Regulations*. According to Elanco, the date of filing of a NDS cannot happen until the compulsory information and material required under the *FD Regulations* at paragraphs C.08.002(2)(a) to (o), has actually been filed.

[53] Elanco submits that subsection C.08.002(2) uses mandatory language that a NDS "shall" include each of the elements listed in paragraphs (a) to (o) and that the Minister therefore cannot interpret that the submission is complete before all components of subsection C.08.002(2) have been filed with Health Canada. To do so, Elanco says, is *ultra vires* the statutory authority conferred upon the Minister. According to Elanco, until all such submission criteria have been provided to the Minister, a submission is incomplete and thus cannot constitute a NDS that can be assigned a filing date.

[54] Elanco submits that its position is consistent with Health Canada's own guidance document that states that a submission is only considered "filed" once all elements of the NDS have been submitted to Health Canada. Elanco refers to Health Canada's Guidance for Industry document, "Management of Drug Submissions", which states as follows:

> Filing date refers to the final central registry (CR) file date allocated to the submission once it is deemed administratively complete by Health Canada (that is [i.e.] **once all elements** and forms required for processing are completed and submitted to Health Canada). This date may differ from the date of original filing should the submission be considered administratively incomplete at the time of receipt. [Emphasis added by Elanco]

[55] Reference is also made to Health Canada's Guidance document on the *NOC Regulations* which provides that:

> …the date allocated to the submission upon receipt by Health Canada provided that the submission is found to be administratively complete (i.e. **once all submission criteria and forms** required for processing are completed and submitted to Health Canada). In the event that the submission is found to be administratively incomplete, date of filing will be the date on which these deficiencies are corrected. Therefore, the date of filing may differ from the date of original receipt should the submission be considered administratively incomplete... [Emphasis added by Elanco]

[56] Elanco contends that until all elements are submitted to fulfill all requirements of subsection C.08.002(2) of the *FD Regulations*, a NDS cannot be considered to be "administratively complete" and thus cannot be considered filed. In light of the submission history for the IMRESTOR Product, the NDS should therefore have been afforded a filing date of March 27, 2013, when the last substantive requirements for efficacy, human food safety,

chemistry and manufacturing, and animal safety information under C.08.002(2) with respect to the IMRESTOR Product's NDS were received by Health Canada.

[57] Elanco maintains that the substantive portions of the NDS were filed well after the Canadian filing date for the '704 patent, that the timing requirements of subsection 4(6) of the *NOC Regulations* are accordingly met, and the patent should be listed on the Patent Register.

[58] While, at first blush, the text of subsection C.08.002(2) may appear to assist Elanco, a closer analysis reveals that it does not. Neither the *Patent Act*, the *NOC Regulations* or the *FD Regulations* define the term "date of filing" of a submission, nor do they establish rules for determining that date.

[59] Subsection C.08.002(2) simply speaks to the contents of a NDS and not to when a NDS may be considered filed. All the provision does is to set out the information that a first person is required to provide in order for a submission to be processed.

[60] Subsection C.08.002(2) begins with the general requirement to provide "sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug" before listing specific types of information that must be provided. Although couched in mandatory language, it is only addressed to the first person, and not to the VDD or the Minister herself. The provision does not prevent the VDD from waiving any requirement, as it did in this case by permitting a rolling submission.

[61] Subsection C.08.002(2) cannot be read in isolation. Subsection C.08.004(2) contemplates the possibility that a submission that does not comply with subsection C.08.002(2) may notwithstanding be accepted for filing:

C.08.004(2) Where a new drug submission or abbreviated new drug submission or a supplement to either submission does not comply with section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, the manufacturer who filed the submission or supplement may amend the submission or supplement by filing additional information or material.	Lorsqu'une présentation de drogue nouvelle, une présentation abrégée de drogue nouvelle ou un supplément à l'une de ces présentations n'est pas conforme aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, ou à l'article C.08.005.1, le fabricant qui l'a déposé peut le modifier en déposant des renseignements ou du matériel supplémentaires.
[Emphasis added.]	[Non souligné dans l'original.]

[62] This distinction is made explicit in section C.08.003.1, which provides that, in examining a NDS, "the Minister may examine any information or material filed with the Minister […] to establish the safety and effectiveness of the new drug for which the submission […] has been filed." This section contemplates that filing a submission is different from filing (i.e. providing) the information to support it. It reinforces the notion that filing a submission is a first and formal step that initiates the review process.

[63] In the absence of legislation or regulations defining "date of filing" or prescribing rules for determining said date for filing, it was open to the Minister, in the exercise of her authority, to administer the drug submission process, to establish procedures governing submissions and to allocate a filing date for submissions. Guided by these procedures and informed by the legislative objectives, the Minister (and more strictly speaking, the VDD, which dictated the

veterinary drug submission procedure) had the discretion to decide whether the tendered material contained in Elanco's NDS contained sufficient information to be considered administratively complete for processing, pursuant to the *FD Regulations*. Elanco has failed to establish any reviewable error in the Minister's reasoning.

[64] As stated in the guidance document *Guidance for Industry: Management of Drug Submissions*, cited in the Decision, the filing date of submissions is defined as "the final central registry (CR) file date allocated to the submission once it is deemed administratively complete by Health Canada". The Minister's affiant, May Ming Wu, stated that a submission is considered to be "administratively complete" when a drug manufacturer files a Drug Submission Application Form, Submission Certifications, a Veterinary Drug Submission Fee Application Form and includes in the submission, the Manufacturer/ Sponsor name, medicinal ingredient, the strength, dosage form and route of administration of a drug. This date is not affected by subsequent screening or review activities. These activities would include the receipt of new information specified in subsections C.08.002(2) and C.08.002(3).

[65] The *Guidance document: Patented Medicines (Notice of Compliance) Regulations* contains a similar definition of "filing date", i.e. the date allocated to the submission by Health Canada provided that the submission is found to be "administratively complete".

[66] The rationale for this allocation of a filing date is consistent with sound regulatory management and with the rationale for the temporal requirement in the *NOC Regulations* given

in the RIAS. The interpretation suggested by Elanco would introduce considerable uncertainty into the regulatory process.

[67] Elanco conflates or confuses two separate matters: the date on which Elanco's forms, information and material were found by the VDD to be administratively complete and accepted for evaluation with the date on which all substantive components of the submission were provided for evaluation. The VDD assigned a filing date for Elanco's NDS on June 24, 2011 as the NDS included the information and documents required to be considered "administratively complete" and to establish a filing date. That decision was made years before the present application was commenced. The Minister's refusal to list the '704 Patent, based on VDD's earlier determination, is reasonable given that Elanco did not meet the temporal requirements of subsection 4(6) of the *NOC Regulations*.

[68] Elanco further contends that since its submission was filed as part of the RCC Initiative with the FDA, the Minister's assignment of a filing date should coincide with that of the FDA. The FDA's approach is that the filing date is not established until the application is complete. However, Health Canada's participation in the RCC Initiative to facilitate closer regulatory cooperation between Canada and the US does not imply that Health Canada's regulatory requirements are the same as the FDA's.

[69] In contrast to Health Canada, which assigns a filing date after a submission is "administratively complete", the FDA assigns a filing date after the submission is "sufficiently complete to permit a substantive review" or "technically complete". Once the determination has

been made, the date of filing will be the date 60 days after the date the FDA received submissions. Health Canada is governed by a different regulatory regime and legislation and has no obligation to follow the FDA's approach.

[70] Finally, Elanco relies on various statements, correspondence, acknowledgments and certifications of receipt from representatives of the Minister, suggesting that the Minister had conceded that Elanco's submission had not been filed because the submission was incomplete.

[71] On the record before me, I am not satisfied that any such concession was ever made, nor is there any evidence that Elanco was somehow misled. The Minister's affiant maintained consistently throughout her cross-examination that the elements listed in subsection C.08.002(2) of the *FD Regulations* are not relevant in determining whether a submission is "administratively complete" and assigning a filing date, and distinguished the different stages of the review process.

[72] Elanco also refers to correspondence between a Health Canada official and Elanco in November 2011, suggesting that the official acknowledged that the submission was incomplete and invited Elanco to submit a patent list. Elanco asks this Court to infer from this that Health Canada understood that the NDS was still in the process of being filed and a patent list could therefore be filed. In my view, Elanco places what was written by the official out of context. The brief email only advised Elanco to contact the OPML to inquire about the applicability of the Form IV. The official does not purport to come to any conclusion regarding the filing date of

Elanco's NDS. Moreover, there is no suggestion that the timing requirements for subsection 4(6) of the *(NOC) Regulations* were met.

V. Conclusion

[73] Where there is a discrete or special administrative regime in which the decision-maker has special expertise, that decision-maker is entitled to deference. Health Canada, and through it the Minister, are required on a regular basis to interpret section 4 of the *NOC Regulations* and assign filing dates. The Minister ought to be accorded deference in confirming that a filing date was properly allocated by VDD for Elanco's NDS.

[74] The *NOC Regulations* require the first person to file an application for the patent before filing the NDS for the drug product to which the patent relates. This ensures that patents for inventions discovered after the existence of a drug product do not pre-empt generic competition with that product.

[75] In this case, the Minister found as a fact that Elanco had filed its patent application after it filed its NDS for the related drug product. The Minister therefore refused to list the '704 Patent on the Patent Register. In so doing, the Minister reasonably determined that the filing date of the NDS was the date on which it was found by the VDD to be administratively complete and accepted for evaluation rather than the date on which all substantive components of the submission were provided for evaluation.

[76] By suggesting alternative filing dates in its submissions, Elanco acknowledges that determining a date of filing is fact specific. It was open for the Minister to set a filing date for Elanco's NDS according to her own public policies and guidance documents. In the absence of finding that the Decision is outside the range of reasonable outcomes, the Decision should not be disturbed.

[77] This application shall accordingly be dismissed. Costs of the application are hereby fixed in the amount of $4,500.00, inclusive of disbursements and taxes, as agreed by the parties at the hearing, to be paid by Elanco.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The application for judicial review is dismissed.

2. Costs of the application, hereby fixed in the amount of $4500.00, inclusive of disbursements and taxes, shall be paid by the Applicant to the Respondent.

"Roger R. Lafrenière"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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APPEARANCES:

Mr. Jay Zakaib Ms. Jennifer Wilkie Mr. Adam Heckman	FOR THE APPLICANT
Mr. J. Sanderson Graham Mr. Adrian Bieniasiewicz	FOR THE RESPONDENT

SOLICITORS OF RECORD:

Gowling WLG (Canada) LLP Barristers and Solicitors Ottawa, Ontario	FOR THE APPLICANT
Attorney General of Canada Ottawa, Ontario	FOR THE RESPONDENT