Federal Court  Cour fédérale

Date: 20220310

Docket: T-1047-21

Reference: 2022 FC 292

Ottawa, Ontario, March 10, 2022

PRESENT: The Honourable Madam Justice St-Louis

BETWEEN:

CATALYST PHARMACEUTICALS, INC.
AND KYE PHARMACEUTICALS INC.

Applicants

and

ATTORNEY GENERAL OF CANADA
AND MÉDUNIK CANADA

Respondents

JUDGMENT AND REASONS

I. Introduction

[1] The Applicants, Catalyst Pharmaceuticals, Inc. [Catalyst] and KYE Pharmaceuticals Inc. [KYE] seek judicial review of the Minister of Health [the Minister]'s June 24, 2021 decision to issue Médunik Canada [Médunik] a Notice of Compliance [NOC] in respect of its New Drug Submission [NDS] for its RUZURGI 10 mg tablet [the Minister's Decision].

[2] The Applicants challenge the Minister's Decision as contrary to the data protection provisions of the *Food and Drug Regulations*, CRC, c 870 [the *Food and Drug Regulations*], and in particular, to its paragraph C.08.004.1(3)(b). They generally submit that the Minister's Decision is unreasonable because the Minister (1) misinterpreted the *timing* requirement; and (2) wrongly decided that, as a matter of fact, Médunik and the Minister did not *rely* on Catalyst's amifampridine phosphate product, i.e., FIRDAPSE's data, and therefore there was no comparison.

[3] The Attorney General of Canada [the AGC] and Médunik oppose the application and respond, essentially, that the Minister's interpretation of the data protection provisions, as well as his application to the matter at hand, are reasonable. They submit that the Minister reasonably interpreted and applied subsection C.08.004.1(3) of the *Food and Drug Regulations,* acted reasonably in accepting the explanations of the basis of its safety and efficacy approval of RUZURGI and that there is no basis for the Applicants' new complaint about the "published articles".

[4] The AGC and Médunik particularly caution the Court against assessing the Minister's interpretation of the data protection provisions against the Court's own favorable interpretation. They stress that the standard of reasonableness commands the Court to assess whether the Minister's interpretation is a reasonable one.

[5] I am mindful that, under the standard of reasonableness, my role is not to decide the issue myself according to my own yardstick or determine what the correct decision would have been.

As the Federal Court of Appeal reminded us again recently in *Burlacu v Canada (Attorney general)*, 2022 FCA 10 at paragraph 18, the role of the Court is to approach the reasons provided by the Minister with "respectful attention", with a view to understanding the chain of analysis and ensuring that the decision falls within a range of possible, acceptable outcomes that are defensible in respect of the facts and the law that constrain the Minister.

[6] However, and for the reasons exposed below, I conclude that the Minister's Decision does not fall within a range of possible, acceptable outcomes that are defensible in respect of the facts and the law that constrain the Minister.

[7] First, I find the Minister's interpretation of the data protection provisions in regards to the *timing* issue unreasonable. I find that the Minister's interpretation is contrary to the text of subsection C.08.004.1(3) of the *Food and Drug Regulations*, and that it ignores the purpose and context of the data protection regime. Read in context and in its grammatical and ordinary sense, the data protection provisions of the *Food and Drug Regulations* cannot reasonably be interpreted as the Minister suggests.

[8] Second, I find the Minister's application of the *reliance* issue unreasonable as he (1) does not actually apply the test he puts forth; and (2) unreasonably relies on only one set of explanations of Health Canada's basis for the approval of RUZURGI, ignoring contradictory evidence.

[9] I will thus grant the Applicants' application for judicial review.

[10] In their Memorandum of Fact and Law, the Applicants request an order (1) quashing Médunik's NOC for RUZURGI dated June 24, 2021; (2) ordering the Minister not to issue a NOC to RUZURGI before (i) the end of a period of eight years after the day on which FIRDAPSE received its NOC (i.e., August 1, 2028); or (ii) in the alternative until Médunik files its own carcinogenicity and reproductive and developmental toxicity data; and (3) granting them costs, on a solicitor-client basis or on an elevated scale.

[11] The Respondents oppose these remedies, and suggest that, if the Court is to grant the application, it should, as usual, set the decision aside and send it back for a new determination.

[12] I have not been convinced that the situation warrants departure from the usual remedy. I will consequently set aside the decision and send it to the Minister for a new determination in light of these reasons.

II. Context

[13] Amifampridine treats an ultra-rare and debilitating autoimmune disorder called Lambert-Eaton myasthenic syndrome [LEMS]. Currently, some 200 Canadians suffer from LEMS. Until the approval of FIRDAPSE in July 2020, amifampridine was not commercially available in Canada. It was only available through Health Canada's Special Access Program [SAP], which provides access to certain drugs that cannot otherwise be sold or distributed in Canada. Drugs accessed via the SAP are supplied directly by manufacturers to practitioners prescribing the drug, usually physicians. Amifampridine was supplied through the SAP by Jacobus Pharmaceuticals

Co, the New Jersey based pharmaceutical company that ultimately licensed RUZURGI to Médunik.

[14] Catalyst is a Florida-based biopharmaceutical company and KYE is a Canadian company founded and incorporated in July of 2019. KYE's first commercially launched product is FIRDAPSE, as a result of an agreement with Catalyst. Médunik is a manufacturer and supplier of pharmaceutical products based in Blainville, Québec.

[15] In 2019, both Catalyst and Médunik submitted a NDS in regards to an amifampridine drug. Catalyst's drug, a phosphate salt, is marketed under the name FIRDAPSE by KYE in Canada, while Médunik's drug, a free base, is marketed under the name RUZURGI. Health Canada granted both Catalyst and Médunik's NDS priority review status and found both eligible for the innovative drug status. The first approved drug would thus be recognized as an innovative drug and benefit from the data protection provision of subsection C.08.004.1(3) of the *Food and Drug Regulations.*

[16] Subsection C.08.004.1(3) states that:

(3) If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug,	**(3)** Lorsque le fabricant demande la délivrance d'un avis de conformité pour une drogue nouvelle sur la base d'une comparaison directe ou indirecte entre celle-ci et la drogue innovante :
(a) the manufacturer may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a	**a)** le fabricant ne peut déposer pour cette drogue nouvelle de présentation de drogue nouvelle, de présentation abrégée de drogue nouvelle

supplement to an abbreviated new drug submission in respect of the new drug before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug; and	ou de supplément à l'une de ces présentations avant l'expiration d'un délai de six ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante;
(b) the Minister shall not approve that submission or supplement and shall not issue a notice of compliance in respect of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.	**b)** le ministre ne peut approuver une telle présentation ou un tel supplément et ne peut délivrer d'avis de conformité pour cette nouvelle drogue avant l'expiration d'un délai de huit ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante.

[17] Drugs determined to be "innovative drugs" are listed on the Register of Innovative Drugs [the Register], which the Minister is required to maintain pursuant to subsection C.08.004.1(9) of the *Food and Drug Regulations*. The Register confirms that data protection is granted from the date the drug's NOC is issued.

[18] Within Health Canada, the Office of Submissions and Intellectual Property [the OSIP] is responsible for applying the data protection provisions. The Office of Patented Medicines and Liaison [the OPML] is part of the OSIP and is tasked with conducting the final review.

[19] On the other hand, within Health Canada, the Therapeutic Product Directorate [the TPD] is responsible for assessing the NDS's safety and efficacy profile. It is divided into sections, among which two played a role in the RUZURGI NDS: the Bureau of Cardiology, Allergy and

Neurological Sciences [the BCANS] and the Central Nervous System Division of the BCANS [the CNSD].

[20] Notably, in its RUZURGI NDS, Médunik included an Original Annotated Product Monograph [Product Monograph] for RUZURGI. In the part of the document dedicated to scientific information, under the heading related to non-clinical toxicology, Médunik addresses, *inter alia*, carcinogenicity and reproductive and developmental toxicity (Certified Tribunal Record [CTR]; Applicants Record [AR] at 302).

[21] Under the carcinogenicity heading, Médunik indicates that carcinogenicity studies of amifampridine have not been conducted. However, it adds information about (1) a 104-week carcinogenicity study conducted with the phosphate salt form of amifampridine, including a parenthetical reference to FIRDAPSE USPI 2018; and (2) a 2-year study rat dietary carcinogenicity study. Both descriptions are actually referring to the same study (Miller affidavit at para 39; AR at 1005-1006).

[22] Under the reproductive and development toxicity heading, Médunik again confirms that animal studies to assess the potential adverse effects of amifampridine on fertility and embryofetal development have not been conducted. However, again it adds information about animal studies conducted with the phosphate salt form of amifampridine on rats, again including a parenthetical reference to FIRDAPSE USPI 2018. The animal studies with amifampridine phosphate described in these excerpts are descriptions of Catalyst's Development and Reproductive Toxicology study data (Miller affidavit at para 43; AR at 1007).

[23] Dr. Miller, the Chief Operating Officer and Chief Scientific Officer of Catalyst, affirms that these studies were part of the non-clinical development program required for FIRDAPSE to gain regulatory approval, and that they were submitted confidentially as part of the New Drug Application of FIRDAPSE in the United States and as part of its Canadian NDS (Miller affidavit at paras 17 and 22; AR at 1001-1002). The source of the information, i.e., FIRDAPSE USPI 2018, is the United States prescribing information approved by the US Food and Drug Administration in respect of the US market authorization for FIRDAPSE.

[24] I will refer to the two non-clinical FIRDAPSE studies Médunik included in its Product Monograph as the "Impugned Information".

[25] Before this Court, Catalyst indicates having found, in July 2021, that Médunik also included information about some FIRDAPSE clinical efficacy studies in its NDS. These are the LMS-002, LMS-003, Haroldsen and DAPSEL studies referred to in the Miller and Zimmerman affidavits (AR at 4245ff). The Applicants accessed this information in July 2021 when Health Canada responded to their request for Access to Information, and informed them that the information was available on Heath Canada's website. I tend to agree with the arguments outlined at paragraphs 81 and 82 of the Minister's Memorandum of Fact and Law. However, in any event, given my conclusion on the Minister's interpretation, I need not examine this argument.

[26] In 2019, as there were then no amifampridine innovative drug on the Register when Catalyst's NDS and Médunik's NDS were submitted, both were filed and accepted for review by

Health Canada. As there were no amifampridine innovative drug on the Register at the time of filing, the OSIP did not examine if a manufacturer was seeking a NOC based on a direct or indirect comparison.

[27] On July 31, 2020, the Minister issued the FIRDAPSE NOC, recognized it as an innovative drug, placed FIRDAPSE on the Register and granted it the data protection found at subsection C.08.004.1(3) of the *Food and Drug Regulations*. The Register indicates the data protection to be effective as of July 31, 2020 (AR at 186), hence on the day of the FIRDAPSE NOC issuance. There is no indication that the protection was pending or dependant of FIRDAPSE having to be *marketed* in Canada, or as to what marketing means in this context, or again that anybody at Health Canada verified if FIRDAPSE was *marketed* prior to placing it on the Register.

[28] As we will see below, prior to the approval of the FIRDAPSE NOC, Médunik, the TPD and the OSIP communicated amongst themselves. They discussed the removal and subsequent reinstatement of the Impugned Information in the RUZURGI Product Monograph, as well as the impact of said reinstatement on the data protection.

[29] On July 31, 2020, the Director of the BCANS sent the Pharmaceutical Submission Executive Summary of RUZURGI [the Executive Summary] to the Director General of the TPD. I note that there are in fact two signed RUZURGI Executive Summaries, one dated July 31, 2020 and one dated August 5, 2020. I understand that the one dated July 31, 2020 was included in the NOC package and that the two bear no difference, save for their date. I will refer to the one dated

July 31, 2020. On August 5, 2020, the RUZURGI Product Monograph containing the reinstated Impugned Information was approved. On August 10, 2020, a NOC was issued to Médunik for its RUZURGI amifampridine product, in oral, tablet, 10 mg form (AR at 3271).

[30] On August 17, 2020, the OPML issued its Data Protection Eligibility Assessment for RUZURGI. It identified the assessment as "preliminary" and recommended RUZURGI as being not eligible for data protection. On September 10, 2020, the OPML informed Médunik that RUZURGI was not an innovative drug.

[31] The Applicants challenged the Minister's decision to issue the RUZURGI NOC by way of an application for judicial review before this Court. On May, 31, 2021, this Court granted the application, set aside the Minister's decision to issue Médunik a NOC for its RUZURGI drug, and sent back the file to the Minister for a new determination (*Catalyst Pharmaceuticals Inc v Canada (Attorney General)*, 2021 FC 505 [*Catalyst 2021*] in the T-984-20).

[32] On June 3, 2021, the OSIP wrote to Médunik and KYE. The OSIP indicated that, on behalf of the Minister, the OSIP will make a new determination as to whether, in consideration of the Minister's determination in August 2020 that NDS No. 234655 for RUZURGI meets the regulatory requirement for safety and efficacy, it would contravene paragraph C.08.004.1(3)(b) to issue a NOC. The OSIP provided KYE and Médunik the opportunity to make submissions while indicating that it would also be considering the detailed submissions that were filed by the parties in the Applicants' first challenge that led to the *Catalyst 2021* decision.

[33] On June 9, 2021, Médunik filed its submissions with the OSIP. While arguing that it did not seek approval of its RUZURGI NDS on the basis of a comparison to FIRDAPSE, Médunik indicated, at page 8 of its submissions, that "[i]nformation pertaining to non-clinical studies using amifampridine phosphate (i.e., the impugned information) was added to the RUZURGI product monograph during the labelling review process at Health Canada's request to ensure that it contains 'publicly available' and 'known information'" (AR at 402).

[34] On June 10, 2021, KYE filed its submissions with the OSIP, arguing essentially that (1) the amendment check is flawed and should not be followed on this redetermination, referring to paragraphs 81 to 87 of the Memorandum of Fact and Law it filed in the Court file T-984-20; (2) Médunik is seeking a NOC on the basis of a direct or indirect comparison with FIRDAPSE; (3) the marketing exception does not apply; and (4) the public nature of data is irrelevant.

[35] On June 21, 2021, prompted by Médunik's aforementioned statement that the Impugned Information was added at the request of Health Canada, the OSIP asked the Director of the BCANS for clarification.

[36] On June 23, 2021, the Director of the BCANS responded to the OSIP. He referred to the Impugned Information as the "publicly available safety information", and indicated that (1) the publicly available safety information related to amifampridine phosphate (i.e. FIRDAPSE) was included in the original RUZURGI Product Monograph; (2) on June 16, 2020, the CNSD sent a clarification request to Médunik and requested that this information, originally proposed by Médunik, be removed; (3) on July 16, 2020, the CNSD sent a further clarification request to

Médunik, requesting that the information be reinstated; and (4) on July 27, 2020, the information was reinstated to the originally proposed wording in the Product Monograph. The Director of the BCANS added that the rationale [the Rationale] for the request was previously set out in the Summary Basis for Decision [SBD] and Regulatory Decision Summary [RDS], both published after the August 10, 2020 RUZURGI NOC approval, and that it will be set out in his upcoming Addendum to the Executive Summary for the RUZURGI NDS dated June 23, 2021 [the Addendum].

[37] This Rationale, revealed initially in October 2020 in the SBD and in the RDS, reads like this:

> While not essential for market authorization, publicly available safety information for the phosphate salt of amifampridine is included on the Product Monograph to ensure that it contains known information relevant to the optimal, safe, and effective use of Ruzurgi.

[38] According to the Director of the BCANS, this explains why, in July 2020, the BCANS requested Médunik to reinstate the FIRDAPSE carcinogenicity and reproductive toxicity studies in its RUZURGI Product Monograph.

[39] On June 23, 2021, the Director of the BCANS sent the Addendum to the Director General of the TPD and the Director of the OSIP. The Addendum indicates that it was prepared for litigation purposes. The Director of the BCANS indicates that said Addendum is prepared to clarify certain elements of the Executive Summary for the RUZURGI NDS in light of the Court's decision of May 31, 2021, i.e., *Catalyst 2021*.

[40] In the Addendum, the Director of the BCANS outlines, *inter alia*, that the RUZURGI NDS was a stand-alone submission, including all the data required for review, with the exception of carcinogenicity, reproductive and developmental toxicity data. He cites an extract of the RUZURGI Executive Summary, and based on said statement, he concludes that it is clear that the approval of FIRDAPSE had no bearing on the recommendation for approval of RUZURGI. He adds that "[h]owever, some information related to carcinogenicity and reproductive and developmental toxicity was considered important safety information worth adding to the Product Monograph of RUZURGI. This safety information was publicly available from the US Prescribing Information for the US marketed FIRDAPSE product. It is often the case that known safety information, whether it be for individual active pharmaceutical ingredients or for classes of products, is included for awareness for the prescribers".

[41] Notably, the Addendum makes no mention (1) of the information the BCANS had outlined in its June 23, 2021 email to the OSIP, hence that (i) on June 16, 2020, the CNSD had asked Médunik to remove the Impugned Information it had included in its original Product Monograph; (ii) on July 16, 2020, the CNSD requested Médunik reinstated the Impugned Information; and (iii) on July 27, 2020, it was reinstated; and (2) the fact that the Executive Summary submitted to the Director General of the TPD in July 2020 made no mention of this Rationale and that only the SBD and the RDS, published after the RUZURGI NOC was approved, added the Rationale.

[42] On June 24, 2021, the OSIP issued its reasons [the OSIP Reasons] and the Minister issued the RUZURGI NOC. Relevant to the understanding of this context, paragraph 73 of the

OSIP Reasons includes a footnote pertaining to the statement that Médunik included in its June 2021 written submissions to the OSIP. Again, as a reminder, this statement outlined that the "Impugned Information" had been reinstated at the request of Health Canada.

[43] On July 5, 2021, the Applicants filed their Notice of Application challenging the Minister's Decision before the Court.

[44] On July 28, 2021, the Applicants received a response to the Access to Information request they had filed for "all documents related to Médunik's new drug submission No. 234655 created or amended on or after August 10, 2020". The Applicants were informed that a portion of the record responsive to their request (Module 5 (Clinical)) had been proactively released and was available online. They accessed these documents and realized that the RUZURGI NDS also included clinical information pertaining to FIRDAPSE. I have addressed this information already.

[45] On July 21, 2021, the Director of the OSIP certified the CTR, and objected to producing some of the documents requested by the Applicants as part of the CTR.

[46] On August 11, 2021, the AGC provided 25 additional documents to the Applicants in response to a document request set out in their Notice of Application. These documents had not been previously released. They were tendered into evidence in this application, introduced by Ms. Diane Zimmerman (exhibits O1 to O25). These documents outline communications between

Médunik, the BCANS and the OSIP in regards to the Impugned Information, and its impact on the data protection provisions.

[47] On August 27, 2021, the Applicants filed their Amended Notice of Application. Each parties successively filed their record and, from December 13 to 15, 2021, they presented their arguments to the Court.

III. The Minister's Decision

[48] At the heart of this application, and of the Minister's Decision, are the OSIP Reasons and OSIP's determination that paragraph C.08.004.1(3)(b) of the *Food and Drug Regulations* does not prohibit the issuance of a NOC for RUZURGI because Médunik was not seeking a NOC on the basis of a direct or indirect comparison to FIRDAPSE as approved and marketed in Canada.

[49] RUZURGI's safety and efficacy is not at play.

[50] The OSIP Reasons are contained in a 35-page document divided in the following five sections: (I) Regulatory Framework; (II) Points of interpretation of the data protection provisions particularly relevant for this new determination; (III) The RUZURGI NDS and the FIRDAPSE NDS; (IV) The RUZURGI NDS does not engage paragraph C.08.004.1(3)(b); and (V) Other comments.

[51] The OSIP divides the first section, Regulatory Framework, in four subsections. The OSIP examines (1) Drug submissions for New Drugs; (2) Product Monographs; (3) Data Protection for Innovative Drugs; and (4) the data protection provisions implement certain treaty obligations.

[52] Notably, the OSIP outlines the situation of subsequent entry drugs and subsequent entry manufacturers, and discusses the seemingly unrelated abbreviated new drug submission [ANDS], generics, bioequivalent or biosimilar drugs. It stresses that reference to subsequent entry drugs may be any drug whose approval is being sought through an NDS based on a comparison to a drug as approved in Canada.

[53] The OSIP explains inter alia that "[a]s part of the drug review process for either an NDS or ANDS, Health Canada reviews a product monograph" (OSIP Reasons at para 14; AR at 20). The OSIP asserts that it is normal for monographs to include safety information on the drug class or other similar drugs and that "[t]he inclusion of this safety information in the product monograph is not intended to be comparative information providing the basis of approval, but rather is part of the regulatory responsibility of a manufacturer and Health Canada to inform patients and health professionals about potentially relevant information" (OSIP Reasons at para 15; AR at 20).

[54] The OSIP adds that, after determining that the submission requirements are met, the Minister must issue a NOC pursuant to paragraphs C.08.004(1)(a) or C.08.004(3)(a). In short, "[…] where the Minister of Health determines that the data protection provisions are not engaged, the Minister does not have discretion to withhold an NOC if the other submission

requirements are met" (OSIP Reasons at para 16). The OSIP cites the data protection provisions for innovative drug, namely paragraphs C.08.004.1(3)(a) and C.08.004.1(3)(b), and identified two points of regulatory interpretation, which are the meaning of "on the basis of" in the chapeau of the subsection and the connection and interaction between the two paragraphs. The chapeau of subsection C.08.004.1(3) refers to its first part, i.e., "If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug".

[55] The OSIP cites subsection C.08.004.1(2) of the *Food and Drug Regulations* setting out that the purpose of the data protection provisions is to implement certain treaty obligations undertaken by Canada, namely article 20.48 of the *Canada-United States-Mexico Agreement* (CUSMA), paragraph 39(3) of the *Agreement on Trade-related Aspects of Intellectual Property Rights* (TRIPS) and article 20.29 of the *Comprehensive Economic and Trade Agreement* (CETA). The OSIP cites the *Regulatory Impact Analysis Statement* [2006 RIAS] that accompanied the 2006 amendments to the data protection provisions.

[56] In regards to the second section of the OSIP Reasons, i.e., Points of interpretation of the data protection provisions particularly relevant for this new determination, the OSIP identifies two particularly relevant points, the first relates to the *timing* of the drug submission and the second, to the *reliance* on a comparison to an innovative drug.

[57] The first of the OSIP's points of interpretation relates to *timing* – the information is assessed as of the time it is provided to Health Canada to determine whether the manufacturer is

seeking approval on the basis of a comparison with an innovative drug, whether in an initial filing of a drug submission or in an amendment to a submission. OSIP's position is that the data protection provisions must be interpreted, having regard to its wording, context and purpose of the provisions, to operate in a forward-looking manner in the sense that the manufacturer's conduct needs to be evaluated *when it occurs.*

[58] The OSIP divides its timing interpretation analysis in five subsections.

[59] First, the OSIP states that only comparisons made when an innovative drug is approved and marketed in Canada can trigger the data protection provisions. This refers to the conditions contained in the chapeau of subsection C.08.004.1(3), as well as to the marketing requirement stated in subsection C.08.004.1(5).

[60] Per the OSIP's timing interpretation, when the conditions of the chapeau are met, and subject to the marketing requirement, the provision becomes engaged and paragraph C.08.004.1(3)(a) provides the filing prohibition. If there is no innovative drug on the Register, paragraph C.08.004.1(3)(a) cannot be engaged and the manufacturer is allowed to file its NDS.

[61] The OSIP goes on to address the specific provision actually at issue in this new determination, which is paragraph C.08.004.1(3)(b) of the *Food and Drug Regulations*, and refers to it as the "prohibition to NOC issuance". The OSIP outlines that paragraph (b) is likewise subject to the conditions in the chapeau and to the marketing requirement, but adds that

it is subject to an additional condition, which is that paragraph (b) can be engaged only when and if the filing prohibition found at paragraph (a) was first engaged.

[62] Per the OSIP interpretation, paragraphs (a) and (b) are linked and work together so that paragraph (b) is engaged only if a manufacturer, initially prohibited from filing its NDS, becomes allowed to file a NDS after the 6-year no-filing period has elapsed. In such a case, the paragraph (b) "NOC issuance" prohibition becomes engaged until the total 8-year period (since the NOC issued) has elapsed.

[63] At the hearing, the AGC confirmed this aforementioned interpretation of paragraphs 41 and 42 of the OSIP Reasons to be the proper one.

[64] The OSIP justifies the link and dependence between paragraphs (a) and (b) by the legislator's use of the term "that" before the expression "submission or supplement" in paragraph (b), which the OSIP asserts, can only refer to the submission or supplement found in paragraph (a). The OSIP adds that support for this explanation are contained in the 2006 RIAS.

[65] Notably, and as I will discuss later, the OSIP makes no mention of the fact that paragraph (b) clearly creates two prohibitions, not one. The first prohibition is that the Minister s*hall not approve <u>that submission</u> or supplement* (i.e., the "approval prohibition"), while the second prohibition is that the Minister *shall not issue a notice of compliance <u>in respect of the new drug</u>*, (i.e., the "NOC issuance prohibition").

[66] Once it establishes that paragraphs (a) and (b) are linked, the OSIP goes on to indicate that this interpretation suffers an exception whereby paragraphs (a) and (b) actually become independent and no longer work together. The OSIP argues that this exception occurs only if the manufacturer, initially allowed to file its NDS, subsequently amends it, and becomes considered as seeking a NOC on the basis of a direct or indirect comparison to an innovative drug. In that precise case, and only in that precise case, the OSIP considers that the same paragraphs (a) and (b) no longer work together. In fact, the OSIP considers first, that the prohibition to file of paragraph (a) no longer applies, despite the conditions in the chapeau being met, and second, that despite the fact that the amendment has been accepted for filing from the onset (not after 6 years), the NOC issuance prohibition applies.

[67] Second, the OSIP asserts that previous Federal Court jurisprudence is consistent with the OSIP's interpretation of the data protection provisions. The OSIP acknowledges that the wording of subsection C.08.004.1(3) does not specifically address the situation of amendments made to a submission after it is first accepted for filing. It cites the Federal Court's decision in *Hospira Healthcare Corporation v Canada Health*, 2015 FC 1205 [*Hospira*] to support its interpretation that amendments to submissions can trigger subsection C.08.004.1(3) as the additional information filed is also subject to the data protection provisions.

[68] Third, the OSIP asserts that its interpretation is consistent with the treaty obligations. It stresses that it is inherent in the idea of preventing subsequent entry manufacturer from engaging in "unfair commercial use" of protected data that the fairness of conduct needs to be assessed at the time the conduct occurs and not at a subsequent date after an innovative drug is approved in

Canada. The OSIP thus asserts that, independent from the actual wording of the provision, the treaties are intended to be forward looking and not to prohibit the use of information submitted before the marketing approval of the new pharmaceutical product whose data is being protected, and its actual marketing.

[69] Fourth, the OSIP asserts that its interpretation is consistent with Health Canada's Data Protection Guidance Document.

[70] Fifth and finally, the OSIP asserts that its interpretation also reflects the reality of preparing a typical subsequent entry submission for filing in Canada.

[71] The second of OSIP's points of interpretation relates to the reliance on a comparison to an innovative drug.

[72] The OSIP outlines that the obligations to protect data only exist where a subsequent entry manufacturer relies on the data of the pharmaceutical product eligible for protection, as the objective of the treaty is not to provide a monopoly. The OSIP stresses that protection is not against competing drugs from other innovators. Another innovative company may thus decide at any time to conduct trials, file a submission and thereby provide access to a drug to Canadians. In summary, the OSIP asserts that only submissions for subsequent entry products relying on the safety and efficacy data filed to obtain approval of the innovative reference product will meet these criteria.

[73] The OSIP refers again to the chapeau of subsection C.08.004.1(3) which, the OSIP indicates, clearly sets out that the protection is only available where *a manufacturer* seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug. Notably, in this section, it is clear that the OSIP does not require the Minister to be relying on the protected information for approval. The sole mention of the Minister's reliance on an innovator's data is contained in the 2006 RIAS citation, which relates to the regime applicable to a generic.

[74] The OSIP indicates that the types of "comparison" intended to be captured by the provisions are those akin to where a generic manufacturer seeks to copy an innovative drug. It adds that only submissions for subsequent entry products are intended to be captured by the prohibitions as those are the products that are relying on comparisons to reference products and can therefore be copies of the innovative drug.

[75] In regards to the third section, i.e., The RUZURGI NDS and the FIRDAPSE NDS, the OSIP examines both NDS.

[76] In regards to the RUZURGI NDS, the OSIP confirms having conducted an initial intellectual property check at the time it received the NDS in order to determine whether the six-year no-filing period under paragraph C.08.004.1(3)(a) applied and whether the submission could thus be filed. As there was no approved innovative drug on the Register, there could be no comparison of any kind with an innovative drug and the data protection provisions could not be triggered. The RUZURGI NDS was forwarded into screening.

[77] The OSIP specifies that it had noted, presumably when the RUZURGI NDS was filed, that Médunik had included safety information regarding the phosphate salt version of the medicinal ingredient (which is the medicinal ingredient in the drug FIRDAPSE). It adds that "[…] Health Canada expects drug manufacturers applying for approval of a drug to provide available safety information about similar drugs" (OSIP Reasons at para 72).

[78] The OSIP goes on to describe the safety information on the phosphate salt of amifampridine contained in Médunik's NDS as essentially, "[s]ummaries of publicly available safety data on the phosphate salt of amifampridine under the headings Carcinogenicity and Reproductive and Developmental Toxicity in the original draft annotated and final versions of the product monograph for RUZURGI. The information in these summaries was drawn from information in the published United States Prescribing Information and other published documents from the *United States Food and Drug Administration* for FIRDAPSE, as approved in the United States" (OSIP Reasons at para 73).

[79] The OSIP inserts a footnote in this description and refers to the statement made by Médunik, in its June 2021 submissions to the OSIP (see paragraph 73 of the OSIP Reasons). The OSIP clarifies that the information on the phosphate salt was initially submitted by Médunik in its Product Monograph, that it was removed at the request of Health Canada on June 16, 2020, but subsequently reinstated after the CNSD requested it on July 16, 2020. The OSIP notes that the rationale for including the information in the Product Monograph was explained in the SBD and the RDS and is now also explained in the Addendum of June 23, 2021.

[80] The OSIP indicates that the review of the RUZURGI was completed shortly after the FIRDAPSE NOC was issued and FIRDAPSE approved as an innovative drug. The OSIP confirms it was aware, when approving RUZURGI, that FIRDAPSE had been approved and recognised as an innovative drug. The OSIP determined then that the RUZURGI NDS did not engage paragraph C.08.004.1(3)(b) of the *Food and Drug Regulations* because its approval was not based on a direct or indirect comparison to FIRDAPSE as approved in Canada. The OSIP specifies having identified whether Médunik had made any amendments to its NDS since the time the FIDAPSE NOC was issued, confirmed it had not made any such amendments and thus concluded that the RUZURGI NDS did not engage paragraph C.08.004.1(3)(b), and that the provisions did not prohibit the issuance of a NOC.

[81] The OSIP outlines that the SBD and the RDS both contain the Rationale put forth to publicly explain why the FIRDAPSE studies are in the RUZURGI Product Monograph.

[82] In the fourth section of the OSIP Reasons, i.e., The RUZURGI NDS does not engage paragraph C.08.004.1(3)(b), the OSIP, as previously stated, asserts that the RUZURGI NDS does not engage paragraph C.08.004.1(3)(b) because of two reasons, which are based on the two specific points of interpretation described above: the timing and the reliance. The OSIP specifies that the "[…] two reasons are independent, and either reason is sufficient for the OSIP to conclude that paragraph C.08.004.1(3)(b) does not prohibit the issuance of a NOC for the RUZURGI NDS".

[83] The OSIP asserts that the timing of when the information on the phosphate salt was included in the RUZURGI NDS means that it does not engage paragraph C.08.004.1(3)(b) of the *Food and Drug Regulations*. The OSIP raises that (a) only comparisons made when an innovative drug is approved and marketed in Canada can trigger the protections of subsection C.08.004.1(3); (b) the OSIP's final intellectual property check is not flawed (citing *Hospira*); (c) Catalyst's and KYE's interpretation is unreasonable because it would require data protection to apply retroactively to information submitted before there was an innovative drug and transform an entirely proper NDS into one that engaged the data protection provisions; (d) the availability of data protection as an incentive to drug development does not equate to market exclusivity in all circumstances; (e) the OSIP's interpretation avoids unjustifiably undermining the public interest in encouraging drug manufacturers from seeking approval of safe and effective drugs so that they can be made available to Canadians; and (f) the OSIP does not treat the Register as frozen, but does apply the provisions in a forward-looking manner.

[84] The OSIP repeats its position that if a submission is filed when there is no innovative drug listed on the Register, paragraph C.08.004.1(3)(b) does not prohibit the issuance of a NOC, i.e., the NOC issuance prohibition, unless the submission is amended after filing and during the course or the review to seek approval on the basis of a comparison to an innovative drug as approved and marketed in Canada; the RUZURGI NDS was not amended.

[85] The OSIP states its position that paragraph C.08.004.1(3)(b) of the *Food and Drug Regulations* does not prohibit the issuance of a NOC for the RUZURGI NDS because “[…] the safety information on the phosphate salt of amifampridine was included in the NDS before

FIRDAPSE was approved and designated as an innovative drug" (OSIP Reasons at para 91). The OSIP concludes that, as such, i.e., because of the timing, the presence of the safety information could not have been to seek approval on the basis of a comparison to FIRDAPSE.

[86] I pause again to note that the OSIP makes somewhat of a circular conclusion. It does not actually determine if the use of the information constitute or not reliance, concluding instead that there was no such reliance because of the timing.

[87] Secondly, the OSIP asserts that Médunik was not relying on information on the phosphate salt of amifampridine in seeking a NOC for the RUZURGI NDS. More specifically, "[t]he OSIP considers that the published safety information in the RUZURGI Product Monograph and NDS cannot be said to amount to Médunik seeking a notice of compliance on the basis of that information, because the information was included in the product monograph and NDS simply by virtue of being publically available safety information, and not because it formed part of the basis on which the RUZURGI NDS is being recommended for approval" [Emphasis added] (OSIP Reasons at para 107).

[88] To justify this position, the OSIP states that (a) RUZURGI is not a subsequent entry version of FIRDAPSE and could well have received its NOC first; (b) seeking a NOC on the basis of comparison requires relying on the comparison to obtain the NOC while the information here did not factor into the approval of the safety and efficacy of RUZURGI or was not necessary for approval; (c) Médunik is not seeking a NOC for the RUZURGI NDS on the basis of a direct or indirect comparison to FIRDAPSE as the recommendation for approval is not

based on the safety information for the phosphate salt of amifampridine; this is demonstrated by the information included in the SBD and the RSD; (d) mere mention of an innovative drug in a submission does not equate to an automatic comparison under subsection C.08.004.1(3) of the *Food and Drugs Regulations*; and (e) the interpretations advanced by Catalyst and KYE would undermine the integrity of the drug approval process.

[89] The OSIP seemingly conflates the manufacturer's reliance on the data to seek a NOC, and the Minister's reliance on the data to approve the submission and issue the NOC.

[90] Finally, in the fifth and last section of the OSIP Reasons, dedicated to Other comments, the OSIP also concludes that (a) Catalyst and KYE cannot rewrite the TPD's basis for approving the RUZURGI NDS nor can they attack the Minister's decision regarding safety and efficacy; and (b) the application of the data protection provisions is not limited to undisclosed information as the OSIP agrees that the data protection provisions can protect some disclosed information.

[91] Ultimately, the OSIP concludes that the designation of FIRDAPSE as an innovative drug as of July 31, 2020, the date the FIRDAPSE NOC was issued, does not prevent the RUZURGI NDS from receiving its NOC. More specifically, the OSIP concludes that paragraph C.08.004.1(3)(b) does not prohibit the issuance of the NOC for the RUZURGI NDS, because Médunik is not seeking a NOC on the basis of a direct or indirect comparison to FIRDAPSE as approved in Canada. FIRDAPSE was not approved in Canada when Médunik prepared its drug submission and submitted its data to Health Canada, therefore no comparison was possible.

IV. Issues before the Court

[92] In these proceedings, the Court must determine if the Minister's Decision, as it pertains to the two points of interpretation of the data protection provisions of the *Food and Drug Regulations* and/or their application, is reasonable, and if found to be unreasonable, what remedies are appropriate.

V. The standard of review

[93] I agree with the parties that the Minister's Decision must be reviewed under the reasonableness standard as established by the Supreme Court of Canada in *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 [*Vavilov*].

[94] Where the applicable standard of review is reasonableness, the role of a reviewing court is to examine the reasons given by the administrative decision-maker and determine whether the decision is based on "an internally coherent and rational chain of analysis" and is "justified in relation to the facts and law that constrain the decision-maker" (*Vavilov* at para 85; *Canada Post Corp v Canadian Union of Postal Workers*, 2019 SCC 67 at paras 2, 31). A reviewing court must therefore ask itself whether "[…] the decision bears the hallmarks of reasonableness—justification, transparency and intelligibility" (*Vavilov* at para 99 citing *Dunsmuir v New Brunswick*, 2008 SCC 9 at paras 47, 74).

[95] It is not enough for the decision to be justifiable. A reasonableness review is concerned with both the outcome of the decision and the reasoning process followed (*Vavilov* at para 87). A

reasonableness review must include a careful evaluation of administrative decisions. However, as part of its analysis of the reasonableness of a decision, a reviewing court must examine the reasons given with "respectful attention" and seek to understand the reasoning process followed by the decision-maker in reaching its conclusion (*Vavilov* at para 84). The reviewing court must exercise restraint and intervene only "[…] where it is truly necessary to do so in order to safeguard the legality, rationality and fairness of the administrative process" (*Vavilov* at para 13).

[96] Citing paragraph 83 of *Vavilov*, the Federal Court of Appeal recently reminded us the principles behind the reasonableness standard of review in *Canada (Public Safety and Emergency Preparedness) v Bafakih*, 2022 FCA 18 at paragraph 52 [*Bafakih*]. The Federal Court of Appeal stated that "[…] a reviewing court applying the standard of reasonableness must refrain from deciding itself the issues that were before the administrative decision-maker" (*Bafakih* at para 52). Also, the reviewing court should not take it upon itself to make a finding on an issue that the decision-maker had declined to entertain (*Bafakih* at para 53).

[97] As the AGC outlines, a court applying the reasonableness standard does not ask what decision it would have made in place of that of the administrative decision-maker, attempt to ascertain the range of possible conclusions that would have been open to the decision-maker, conduct a *de novo* analysis or seek to determine the correct solution to the problem (*Vavilov* at para 83). The reviewing court is not to conduct its own analysis and then measure the administrative interpretation against it; that is disguised correctness (*Vavilov* at paras 83, 116). The reviewing court must consider only whether the decision made by the administrative decision-maker was reasonable (*Vavilov* at paras 83, 116).

[98] The Respondent Médunik cites particularly four decisions of the Federal Court of Appeal. Firstly, Médunik cites *Canada (Heath) v GlaxoSmithKline Biologicals S.A.*, 2021 FCA 71, to state that the Federal Court of Appeal held that where there is more than one possible reasonable interpretation of a provision, it is not for reviewing courts to choose the one they prefer or that they find the most logical from their point of view. Secondly, Médunik submits that, in *Janssen Inc v Canada (Attorney General),* 2021 FCA 137, the Federal Court of Appeal refused to interfere with the Minister's interpretation of the legislative scheme because the Minister's reasons were clear and because there was judicial precedent on point. Thirdly, referring to *Canada RNA Biochemical Inc v Canada (Health)*, 2021 FCA 213, Médunik submits that the Federal Court of Appeal held that the appellant did not identify any aspect of the regulatory review process that could be considered unreasonable and deferred to the Minister's findings of fact. Finally, Médunik cites *Merck Canada Inc v Canada (Health)*, 2021 FCA 224 to underline the Federal Court of Appeal's reasoning that although the decision was not organized as presented by the party, the decision-maker considered all the submissions and the decision-maker's analysis was sufficient for the court not to lose confidence in the outcome.

[99] I agree with Médunik that the Court should be guided by the principle of judicial restraint explained in *Vavilov,* and should only intervene if it is truly necessary to do so in order to safeguard the legality, rationality and fairness of the administrative process.

[100] In the end, a reviewing court must ultimately be satisfied that the decision-maker's reasoning "adds up" (*Vavilov* at para 104).

[101] In this case, and for the reasons exposed below, I am convinced it is necessary for the Court to intervene. The Minister's interpretation is not one of the possible reasonable interpretations of the data protection provisions.

VI. The two points of interpretation

A. *First point of interpretation: the timing*

(1) The parties' positions

(a) *The Applicants*

[102] The Applicants assert that the Minister erred in his interpretation of the regulations in regards to the timing issue so as to render it unreasonable. The Applicants remind us that the Minister's timing argument turns on the interplay between paragraphs (a) and (b) of subsection C.08.004.1(3) of the *Food and Drug Regulations*. They outline that, according to the Minister, these two provisions are linked so that "[i]f a drug submission is filed when there is no corresponding innovative drug on the Register of innovative drugs (the Register) such that paragraph C.08.004.1(3)(a) has no application, paragraph C.08.004.1(3)(b) cannot prohibit the issuance of a NOC unless the submission is amended to compare to an innovative drug as approved and marketed in Canada" (OSIP Reasons at para 34). They also outline that the Minister's interpretation thus has two keys parts. First, the two independent prohibitions must be read together and second, there is an exception when a submission is amended, at which time the two prohibitions must be read separately.

[103] The Applicants argue that the timing interpretation is unreasonable for four main reasons.

[104] First, the Applicants submit the interpretation is contrary to the text of the regulations; by reading one word, the word “that”, in isolation, it ignores the ordinary meaning of the text. The Applicants add that (1) the text and structure of the regulations show paragraphs (a) and (b) are independent prohibitions, aimed at different actors and having different consequences; (2) the Minister’s interpretation makes paragraph (a) a prerequisite for paragraph (b), while each is triggered by the conditions set out in the chapeau; and (3) paragraph (b) is broader than paragraph (a). Hence, any possible linkage between the two would apply only to the part of (b) prohibiting the Minister to approve the NDS and would not apply to the prohibition to issue a NOC *in respect of the new drug*, which refers more widely to the wording of the chapeau.

[105] Second, the Applicants submit that the Minister’s interpretation in this case is inconsistent with the one he took in *Hospira* when he argued that subsection C.08.004.1(3) established “[…] two prohibitions which run concurrently from the date the first NOC was first issued to the innovator” and that the second prohibition (against approval) was broader in scope that the first (against filing). The Applicants stress that the Minister’s explanation of this inconsistency is flawed as the Court in *Hospira* expressly declined to determine whether paragraph (b) applied independently of paragraph (a).

[106] Third, the Applicants argue that the amendment exception detracts from the coherence of the interpretation. The Applicants submit that nowhere do the regulations distinguish between a submission and an amendment. Also, the exception means that the two same paragraphs of the

data protection provision must sometimes be read together while they must be read separately at other times, which is impossible to justify.

[107] Forth and finally, the Applicants argue that the Minister's interpretation on the timing issue ignores the purpose of the regulations to protect and reward the innovators and prevent unfair commercial use of data generated for regulatory approval. They raise particularly that (1) it is contrary to the language of the treaties such as CUSMA and TRIPS; (2) it creates a loophole in the data protection scheme; (3) the Minister gave insufficient weight to purpose, ignoring the Applicants' investment, time effort and resources committed; (3) the Minister considered irrelevant factors such as the work done by Médunik; (4) Médunik's conduct is irrelevant and the fact it did nothing wrong when it filed its submission is irrelevant; and (5) the Applicants propose no retroactivity or retrospectivity, but submit that at approval, if there is an innovative drug on the Register, then paragraph (b) applies, prospectively, to prohibit the Minister from approving it.

(b) *The Respondent the Attorney General of Canada*

[108] The AGC responds that the OSIP reasonably concluded that subsection C.08.004.1(3) requires to consider, at the time a subsequent entry manufacturer makes or amends a drug submission, whether the manufacturer is seeking a NOC on the basis of a comparison between its drug and an innovative drug. The AGC adds that the OSIP reasonably justified its interpretation and conclusion based on the text of subsection C.08.004.1(3) and its context and purpose.

[109] Based on the text of subsection C.08.004.1.1(3), the AGC asserts that (1) the chapeau clearly requires the existence of an approved innovative drug; (2) the first prohibition is engaged only when there is an approved innovative drug against which comparison could be made, it was not engaged here and the Applicants do not take issue with this finding; and (3) the plain language of the second prohibition connects it to the first prohibition by the reference to "that submission or supplement". In regards to the Applicants' argument that paragraph (b) is wider that paragraph (a) and exposes two actions, approval of that submission and issuance of a NOC, the AGC asserts that these two actions are not distinct as the issuance of a NOC is the manifestation of the approval of a submission.

[110] As to context, the AGC asserts that the OSIP reasonably relied on the 2006 RIAS in finding that the two sub-paragraphs work in concert. The AGC adds that the purpose of the provisions to protect the innovator from subsequent entrants making unfair commercial use of its drug filing to obtain approval for other drugs and that the idea of preventing "unfair commercial use of data" by a manufacturer requires that the "fairness" of the manufacturer's conduct be considered as of the time of the conduct. The AGC stresses that it requires that the provisions be interpreted as the OSIP interpreted them to apply in a forward-looking manner.

[111] The AGC adds that the OSIP's interpretation is consistent with the Court's decision in *Hospira*, which is now incorporated in the OSIP's IP check process.

(c) *The Respondent Médunik*

[112] Médunik submits that the Applicants' allegations are without merit. The Minister interpreted the *Food and Drug Regulations* reasonably, and applied the law to the facts in a reasonable manner.

[113] Médunik responds that the Minister's Decision on the "timing" was reasonable. It adds that the Minister's legal interpretation respects the modern principles of statutory interpretation, which require legislative provisions to be read in accordance with their ordinary meaning and the legislative context in which they are adopted. Médunik asserts that the Minister responded specifically to each of the submission made by KYE on its submission on redetermination and his reasons reveal a "rational chain of analysis" as required by the *Vavilov* decision.

[114] Médunik submits that the Minister's interpretation of subsection C.08.004.1(3) is reasonable, as it gives meaning to every word in the provision and conforms to the jurisprudence such as the *Hospira* decision. Médunik qualifies the Applicants' argument that paragraph (b) is wider that (a) and that the "that submission" applies only to the "approval of the submission" as an acknowledgement that the section could be subject to more than one interpretation. It adds that it places the Applicants squarely within the circumstances cautioned by the Federal Court of Appeal in *Canada (Health) v Glaxosmithkline Biologicals S.A.*, 2021 FCA 71.

(2) Analysis and decision in regards to timing

[115] The Applicants, as it is their burden, have convinced me that the Minister's interpretation of subsection C.08.004.1(3) of the *Food and Drug Regulations* as it pertains to the timing issue is unreasonable given the text of the regulations, as well as the context and purpose of the data protection regime.

(a) *The Minister's interpretation is contrary to the text of subsection C.08.004.1(3)*

(i) The limited linkage between paragraphs (a) and (b)

[116] As a reminder, subsection C.08.004.1(1) confirms that the data protection regime was established to implement certain international treaties. Pursuant to such treaties, Canada agreed to protect drug manufacturers from the unfair commercial use of undisclosed test or other data that they are required to file with Health Canada to obtain marketing approval through a NOC for a drug that uses a new chemical entity.

[117] The data protection provisions apply only where a NOC has been issued to an "innovative drug". This term means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph (subsection C.08.004.1(1) of the *Food and Drug Regulations*). Drugs determined to be "innovative drugs" are listed on the Register, which the Minister is required to maintain pursuant to subsection C.08.004.1(9) of the *Food and Drug Regulations*.

[118] Where a NOC has been issued to an "innovative drug," subsection C.08.004.1(3) protects the data that was filed to obtain the NOC. Again, subsection C.08.004.1(3) states that:

(3) If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug,	**(3)** Lorsque le fabricant demande la délivrance d'un avis de conformité pour une drogue nouvelle sur la base d'une comparaison directe ou indirecte entre celle-ci et la drogue innovante :
(a) the manufacturer may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission in respect of the new drug before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug; and	**a)** le fabricant ne peut déposer pour cette drogue nouvelle de présentation de drogue nouvelle, de présentation abrégée de drogue nouvelle ou de supplément à l'une de ces présentations avant l'expiration d'un délai de six ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante;
(b) the Minister shall not approve that submission or supplement and shall not issue a notice of compliance in respect of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.	**b)** le ministre ne peut approuver une telle présentation ou un tel supplément et ne peut délivrer d'avis de conformité pour cette nouvelle drogue avant l'expiration d'un délai de huit ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante.

[119] Despite the AGC's argument that the Minister executes only one action, not two distinct actions, and that the regulations thus impose only one prohibition, the actual regulatory text states otherwise.

[120] Paragraph (b) contains two clear and distinct prohibitions. The first is that the Minister "shall not approve that submission" which I defined earlier as the *approval prohibition*, and the second is that the Minister "shall not issue a notice of compliance in respect of the new drug" which I defined earlier as the *NOC issuance prohibition*. The legislator used different language for each.

[121] Even if one accepts the Minister's interpretation that the reference to "that submission" links the two paragraphs, this can only apply to the approval prohibition. It cannot apply to the NOC issuance prohibition.

[122] The NOC issuance prohibition clearly refers to the language set out in the chapeau of subsection C.08.004.1(3), i.e., to "the new drug". It does not refer to "that submission". Per the argument of the AGC, the NOC issuance prohibition is therefore not dependant on paragraph (a) for its application. Had the legislator intended for the two prohibitions to be interpreted in the same manner, he would have used the same wording.

[123] In the OSIP Reasons, not only does the OSIP not attempt to reconcile its interpretation with the actual text of subsection C.08.004.1(3), it amalgamates the two prohibitions and specifically applies "that submission" to the NOC issuance prohibition, completely ignoring the actual regulatory text. The expression "that submission" is attached only to the approval prohibition.

[124] It is clear from the text of the regulations that, even if one accepts the OSIP's interpretation that paragraphs (a) and (b) are linked, this linkage can only apply to the approval prohibition.

[125] Subsection C.08.004.1(3), read with the relevant portion of its paragraph (b), thus states that "[i]f a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug, […] the Minister shall not issue a notice of compliance in respect of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug" [Emphasis added.]

[126] Given that the NOC issuance prohibition depends only on the chapeau of subsection C.08.004.1(3), and does not depend on its paragraph (a), it can take effect even if a manufacturer was initially allowed to file its NDS.

[127] Therefore, if a manufacturer's innovative drug is placed on the Register after another manufacturer's NDS is filed, but before its NOC is issued, and if this other manufacturer seeks its NOC on the basis of a direct or indirect comparison with the innovative drug, the regulatory text prohibits the Minister from issuing a NOC.

(ii) Subsection C.08.004.1(3) makes no mention of a distinct regime for amendments

[128] First, the Court in *Hospira* did not condone the OSIP's amendment check or exception. As previously stated, in *Hospira*, the Court expressly declined to determine whether paragraph (b) applies independently of paragraph (a). The Court simply decided that post-filing amendments are included in a NDS.

[129] Second, the OSIP's amendment check does not accord with the actual text of the regulations. Per paragraph (a), if a manufacturer were to amend its NDS to seek a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug, he should first be prohibited from *filing* its amendment. This discrepancy was not addressed by the Court in *Hospira*, was ignored by the OSIP in the OSIP Reasons and remained unexplained by the Respondents.

[130] Third, subsection C.08.004.1(3) of the *Food and Drug Regulations* does not distinguish between a submission and an amendment. On the contrary, in *Hospira*, the Court held that any subsequent amendments formed part of the NDS. Hence, there is simply no basis in the text and no logic for the OSIP to link paragraphs (a) and (b) and make them dependant on each other at the time of an NDS filing while reading them separately, no longer dependant of each other, at the time an amendment is made. The OSIP's interpretation strays beyond the limits set by the statutory language such that it is impossible to justify.

[131] Fourth, it seems quite unlikely that a manufacturer would amend its NDS so to precisely seek a NOC on the basis of a direct or indirect comparison with an innovative drug, save the particular situation outlined in *Hospira.* I doubt the same situation will arise again.

[132] I note that the present situation does not concern any amendment, and that the Applicants and Médunik are not directly concerned by the OSIP's amendment check. However, it was nonetheless addressed in the OSIP Reasons and by the parties.

[133] Paragraph 108 of *Vavilov* states "[t]hat administrative decision-makers play a role, along with courts, in elaborating the precise content of the administrative schemes they administer should not be taken to mean that administrative decision-makers are permitted to disregard or rewrite the law as enacted by Parliament and the provincial legislatures". Although the *Food and Drug Regulations* provide discretion to the Minister to interpret the regulations and reach a decision, the Minister cannot depart from the precise language chosen by the legislator. The Minister's interpretation of the amendment scheme is not supported by the language of the regulations themselves.

[134] What matters to the Court is whether "[…] the decision-maker has properly justified its interpretation of the statute in light of the surrounding context" (*Vavilov* at para 110). The Court cannot find that the Minister justified its interpretation nor that he has interpreted the regulations reasonably.

(iii) The time of the conduct

[135] The regulations do not indicate that the evaluation of a possible comparison with an innovative drug must be assessed strictly at the time of filing. On the contrary, the vocabulary used by the legislator – *if a manufacturer seeks a notice of compliance* – suggests a continuous verification during all the seeking-process, i.e., until the notice of compliance is issued.

[136] Again, the Minister's interpretation is not supported by the actual text of the regulations.

(b) *The Minister's interpretation ignores the purpose of the regulations*

[137] The *Vavilov* decision states that "[a] court interpreting a statutory provision does so by applying the 'modern principle' of statutory interpretation" and that "[…] legislative intent can be understood only by reading the language chosen by the legislature in light of the purpose of the provision and the entire relevant context" (*Vavilov* at paras 117-118). This Court and the Minister must consider the purpose of the regulations.

[138] In this regard, I agree with the Applicants who assert that the Minister's interpretation on the timing issue ignores the purpose of the regulations to protect and reward the innovators and prevent unfair commercial use of data generated for regulatory approval. I agree that the Minister's interpretation (1) is contrary to the language of the treaties such as CUSMA and TRIPS; (2) creates a loophole in the data protection scheme; (3) gives insufficient weight to purpose, by ignoring the Applicants' investment, time effort and resources committed while overly considering the work done by Médunik; (4) that Médunik's conduct is irrelevant and the

fact it did nothing wrong when it filed its submission is irrelevant; and (5) that the Applicants propose no retroactivity or retrospectivity, but submit that at approval, if there is an innovative drug on the Register, then paragraph (b) applies, prospectively, to prohibit the Minister from approving it.

[139] In fact, my decision does not turn on this, but I note that the OSIP seemingly finds inconceivable that the data protection regime would apply outside the innovator-generic paradigm, to two innovative drugs. This permeates through the OSIP Reasons, for instance at paragraphs 61 to 64.

B. *The second point of interpretation: the reliance*

(1) The parties' positions

(a) *The Applicants*

[140] The Applicants submit that the Minister's decision on the comparison, i.e., the *reliance* issue, is unreasonable. They submit that (1) the Minister assessed Médunik's reliance through the wrong lens; (2) Médunik did in fact rely on the FIRDAPSE data; and (3) whether the new drug is a generic or subsequent entry is irrelevant.

[141] First, the Applicants submit that the Minister assessed Médunik's reliance through the wrong lens. Even though the OSIP admits that the relevant question is whether Médunik relied on the data, it answers the question not by looking at the NDS, but by looking only at post-review documents drafted by the TPD. The Applicants stress that (a) the Minister's assessment

of comparison lead to inconsistent interpretations as the OSIP would only examine the manufacturer's NDS under paragraph (a) while it ignored the actual NDS and solely examined what the TPD drafted under paragraph (b); (b) the process lacks transparency, and it is foreign to the text; (c) assessing whether there is a comparison by reference to documents that are drafted after review introduces discretion and the potential for arbitrariness; and (d) Médunik did not "merely mention" FIRDAPSE and unreasonably makes a comparison to contraindication or combination therapy as it ignores the facts.

[142] Second, the Applicants submit that Médunik did in fact rely on the FIRDAPSE data. Consequently, even if the test is whether the TPD required the FIRDAPSE data for RUZURGI's approval, the decision is unreasonable because the OSIP failed to take the evidentiary record and the general factual matrix that bears on its decision. The Applicants asserts that (a) the OSIP blinded itself to the factual matrix by reviewing only a subset of documents and ignoring even its own office's assessment as shown by the correspondence of June 2020; and (b) the TPD required the FIRDAPSE data for RUZURGI's approval and would not approve the RUZURGI NDS when the FIRDAPSE data was absent. Per the Applicants' submissions, the record shows the topic of data protection was expressly discussed between Médunik and the Minister's delegates and establishes that the TPD did require the data, and that data protection was excluded solely based on the timing of the NDS.

[143] Third, the Applicants submit that whether the new drug is a generic or subsequent entry is irrelevant and that allowing that paradigm to play a role in its decision, the OSIP impermissibly based its decision on "unfounded generalizations" irrelevant to the statutory scheme that *Vavilov*

warned against. The Applicants stress that (a) FIRDAPSE and RUZURGI are not different drugs as it is the same medicinal ingredient; (b) the use of the term “subsequent entry” leads to circular reasoning; and (c) Canadian reference products are irrelevant (the Applicants’ Memorandum of Fact and Law citing *Natco Pharma (Canada) Inc v Canada (Health)*, 2020 FC 788).

(b) *The Respondent the Attorney General of Canada*

[144] The AGC responds that the OSIP (1) reasonably interpreted the data protection provision as also requiring that the information at issue had to be necessary to the approval of RUZURGI; and (2) acted reasonably in accepting the TPD’s explanations of the basis of its safety and efficacy approval of RUZURGI.

[145] First, the AGC asserts that the text of the provision, on a plain meaning, requires that the information in respect of the innovative drug must be necessary for the issuance of a NOC, and that the distinction between whether Médunik or the Minister relied on the data is not a meaningful one and that the Minister must decide if a manufacturer is seeking approval of a drug on the basis of a comparison. The AGC cites the treaties and the 2006 RIAS for the proposition, essentially, that references to available information that is not necessary for approval does not involve “unfair commercial use”. Finally, the AGC submits that the Applicants previously shared the OSIP’s understanding in regards to reference to published articles.

[146] Second, the AGC responds that the OSIP acted reasonably in accepting and relying upon the TPD’s explanations of the basis of its safety and efficacy approval of RUZURGI as disclosed in the Executive Summary, the SBD, the RDS and the Addendum. The AGC alleges that these

documents are clear that the Impugned Information was not necessary to the approval of RUZURGI and that the Impugned Information was include in the RUZURGI Product Monograph because it was public safety information potentially relevant to RUZURGI.

[147] The AGC qualifies the June 2020 communications as not relevant and adds that, in any event, the communications do not contradict the TPD documents on which the OSIP reasonably relied as setting out the "basis of" RUZURGI's approval. The AGC namely cites Dr. Anne Decrouy's email stating that the RUZURGI Product Monograph was being reinserted because it was publicly available information.

(c) *The Respondent Médunik*

[148] Médunik responds that the OSIP's decision on the "comparison" issue is reasonable.

[149] Médunik first confirms that the OSIP held that the reliance must be that "[i]f the information is included in a submission, but not relied on for seeking approval, subsection C.08.004.1(3) of the *Food and Drug Regulations* is not engaged" (OSIP Reasons at para 66). The manufacturer is the one seeking approval and Médunik thus seemingly asserts that the OSIP required the manufacturer to rely, not the TPD (see Memorandum of Fact and Law of Médunik at paras 36(b), 61).

[150] Médunik submits that the OSIP Reasons reveal a rational chain of analysis and the outcome of the interpretative process follows from the analysis undertaken, as required by *Vavilov*. Médunik goes on to submit that the OSIP's interpretation of the term "on the basis of"

and the “comparison” requirements is reasonable. Finally, Médunik asserts that it is clear from the record that it did not seek or obtain approval for the RUZURGI NOC on the basis of any comparison to the Impugned Information and that the Applicants have not identified a single document in which the Minister said that it would not issue the RUZURGI NOC without the Impugned Information.

(2) Analysis and decision in regards to reliance

[151] The OSIP’s interpretation that the manufacturer must rely on an innovative drug data accords with the plain meaning of the regulatory text. This part of the OSIP Reasons is reasonable.

[152] However, after having set the principle, the OSIP fails to apply its own interpretation to the RUZURGI NDS, imposing, *de facto*, the reliance requirement not to the manufacturer, but to the Minister. This incoherence between its interpretation of the regulatory provision and its actual application to the facts remains largely unexplained.

[153] The AGC submits that the distinction between reliance by the manufacturer who seeks approval and reliance by the Minister in approving the NDS is not meaningful (Memorandum of Fact and Law of the AGC at para 67). Assuming this in indeed the case, I find the OSIP unreasonably relied solely on the TPD’s post-review documents (i.e., the SBD, the RDS, and the Addendum) to assert the Minister’s and/or Médunik’s reliance on the FIRDAPSE non-clinical studies, while ignoring the content of the exchanges between OSIP, Médunik and the TPD from April to July 2020. The evidentiary record paints a picture different than the one exposed in the

Rationale found in the SBD, the RDS and the Addendum, and which the OSIP adopted. Some evidence, ignored by the OSIP, shows on the contrary that the Impugned Information was essential for market authorization. It shows that both Médunik and the Minister actually relied on the FIRDAPSE studies.

[154] First, I disagree with the AGC and find the communications relevant. It is worth detailing what they entail.

[155] As mentioned previously, in this application, the AGC disclosed documents that were not disclosed in the T-984-20 application. These documents reveal communications between the BCANS, including the CNSD, Médunik and the OSIP, in regards precisely to the carcinogenicity and reproductive toxicity FIRDAPSE studies, i.e., the Impugned Information prior to the RUZURGI NOC being approved.

[156] In brief, the parties to the exchange discuss the absence of carcinogenicity and reproductive toxicity studies in the RUZURGI NDS, question whether the non-clinical information relating to the phosphate salt must or must not be included in the RUZURGI Product Monograph, and whether such inclusion will have an impact on the RUZURGI NDS in view of the *Food and Drug Regulations* data protection provisions.

[157] These communications clearly undermine the Rationale that was published in the SBD, the RDS and the Addendum, and on which the OSIP relied in the OSIP Reasons. I will not detail

all 25 new documents, but I consider it useful to outline some that are particularly informative in relation to the issues at play in these proceedings.

[158] Per these new documents, on April 22, 2020, the CNSD, as part of the BCANS, wrote to Médunik in regards to "missing studies" (AR at 5271). The CNSD indicated that the proposed Product Monograph for RUZURGI contained text relating to carcinogenicity findings that raised concerns which need to be considered in evaluating the benefit-harm-uncertainty profile of RUZURGI. It noted that carcinogenicity studies of RUZURGI had not been conducted and that per the ICH Guideline SIA, these studies should be conducted. The CNSD stated essentially the same in regards to the reproductive toxicity studies, and in both cases, asked Médunik to provide concise and clear rationale for not conducting these studies with RUZURGI and for failing to provide supportive documentation for the studies described in the Product Monograph. The CNSD then underlined that "[…] these groups of toxicity studies (carcinogenicity, reproductive and juvenile) are key in the assessment of the Benefit-Harm-Uncertainty of a product" (AR at 5272-5273).

[159] It therefore appears that the CNSD initially required non-clinical data on carcinogenicity and reproductive toxicity as part of the RUZURGI NDS, to evaluate its safety (Benefit-Harm-Uncertainty).

[160] On May 6, 2020, Médunik responded to the CNSD. It outlined the Jacobus Pharmaceutical Company, Inc. formulation's extensive use in the United States and in Canada with 25 years and 24 years of clinical experience and the agreement reached with the US Food

and Drug Administration [FDA] to conduct post approval studies. Médunik submitted for each question on the missing studies on the carcinogenicity and the reproductive toxicity that "[it] believe[s] that the available nonclinical data, and the extensive clinical experience in an ultra-rare disease population, are adequate to support the safe and effective use of this drug" (AR at 5283) [Emphasis added.] The only available non-clinical data consists in the aforementioned studies in regards to FIRDAPSE that RUZURGI included in its Product Monograph.

[161] It appears that Médunik indeed "relied" on the FIRDAPSE non-clinical data in seeking its NOC.

[162] Between May 28, 2020 and June 12, 2020, the BCANS and Médunik exchanged on the content of the RUZURGI Product Monograph.

[163] On June 16, 2020, the CNSD indicated that "per previous discussion/Clarimail response" and requested the references to the FIRDAPSE studies be removed from the RUZURGI Product Monograph. However, on July 16, 2020, the CNSD changed its mind and asked Médunik to reinstate the originally proposed wording in the Product Monograph. On July 21, 2020, the BCANS sent an email to Médunik providing it with the most recent version of the wording to include in its RUZURGI Product Monograph in regards to carcinogenicity and reproductive and development toxicity, citing the FIRDAPSE studies (AR at 5626), but omitting the parenthetical reference to FIRDAPSE USPI 2018. The BCANS indicated then that the request to reinstate the Impugned Information was "[…] due to the fact that there may be a significant delay before the

results of carcinogenicity and juvenile and reproductive toxicity studies for RUZURGI become available [...]" (AR at 5521).

[164] This email from the BCANS to Médunik dated July 21, 2020 appears to confirm that the FIRDAPSE studies are meant to compensate for the lack of RUZURGI studies, pending such studies. Another such indication is found in the July 22, 2020 email from the BCANS to the OSIP found at page 5647 of the AR and another yet in a July 22, 2020 email found at page 5652 of the AR.

[165] This is stated as well in an email dated July 20, 2020 from Dr. Decrouy to Mr. Siushansian confirming the information, i.e., the FIRDAPSE studies need to be added as it is safety information. It indicates further that it may or may not put Médunik "off the hook" in regards to the need for their own studies on carcinogenicity and reproductive toxicity. On July, 22, 2020, after a somewhat confusing exchange about the RUZURGI USPI, the data protection, its impact and possible arrival of generics, Dr. Decrouy confirmed what she suggests the sponsor be told, i.e., that the reasons to reinstate the Impugned Information are "[…] because of the safety signal that was seen in the carcinogenicity study and described in the USPI and that HC cannot ignore such signal exists" (AR at 5653). I have found no mention, by Dr. Decrouy, of the need for the public, or the prescribers, to be made aware of publicly available safety information.

[166] On the same day, July 22, 2020, Mr. Siushansian indicated that "describing studies of another similar product" in a Product Monograph is different than disclosing the risks associated with drugs of the same class: it is "going a step further". He indicated not recalling having done

that before and assumed it is similar to when generics of a product cite information in the product monograph of the Canadian reference product (AR at 5652).

[167] This seemingly (1) contradicts the TPD's position that this type of disclosure is almost routine as disclosure of publicly available information; and (2) undermines the conclusion that the inclusion is not a *comparison*, even if the subsequent entry manufacturer paradigm comes into play. The CNSD itself considered this akin to what a generic would do.

[168] On July 27, Médunik reinstated the Impugned Information, and on August 5, 2020, the RUZURGI Product Monograph containing the uncited FIRDAPSE studies was approved (AR at 334).

[169] From the date of the BCANS' request to Médunik to reinstate the Impugned Information until it was reinstated, the BCANS, Médunik and the OSIP exchanged on the impact, if any, of the data protection provisions on the RUZURGI NDS. These exchanges refer to a meeting having taken place on or around July 21, 2020, where the data protection provisions were discussed.

[170] The written exchanges relevant to the data protection start on July 22, 2020, when Médunik, prompted by the BCANS's request to reinstate the FIRDAPSE Impugned Information, asked the BCANS if Médunik was allowed to use another company's data in its Product Monograph (AR at 5655). Médunik wondered if the data protection was going to be an issue in this case.

[171] The TPD specialists first discussed amongst themselves as how to respond to Médunik and venture into some interpretation of the data protection provisions. However, they soon deferred the matter to specialists at the OSIP and put them in contact with Médunik. We understand from an email from Médunik to the BCANS that the OSIP confirmed there was no issue with Médunik using Catalyst's data. This is "[…] because this information was already submitted in the original NDS and at the time of review, there was no other similar product with data protection in Canada" (AR at 5669). Médunik went on to confirm that the OSIP mentioned that "[…] even if Catalyst receives approval a few weeks before us, as long as re-instate this non-clinical information before their approval, there would be no issue" (AR at 5669).

[172] One can easily infer from the information conveyed to Médunik by the OSIP that, were it not for the timing, there would have been an issue with the data protection. The OSIP concluded that Médunik could use the information *as long as it was in before* FIRDAPSE's approval as an innovative drug. Had it not considered the inclusion of the Impugned Information as a *comparison*, the OSIP would not have been solely concerned with the timing of Médunik's NDS.

[173] On July 30, 2020, a BCANS reviewer addressed a "Pharmaceutical Safety and Efficacy Assessment: (Supplemental) New Drug Submission" to the Manager of BCANS in regards to RUZURGI. The reviewer determined that the NDS is considered acceptable with respect to the safety, efficacy, and pharmacokinetic data reviewed, and that a NOC pursuant to section C.08.004 should be issued. Under the heading related to overall Benefit-Harm-Uncertainty, the assessment confirms that the NDS did not contain carcinogenicity or juvenile toxicity studies. It adds that due to the very rare nature of LEMS, the fact that amifampridine has been administered

to at least 600 patients over the last 27 years, judgment was made to defer these studies for the time being (AR at 5683). It makes no mention of the FIRDAPSE non-clinical studies.

[174] Also on July 31, 2020, an external consultant for the CNSD addressed a "Non-clinical Pharmaceutical Safety and Efficacy Assessment: (Supplemental) New Drug Submission" to the Manager of BCANS in regards to RUZURGI. The consultant noted the gaps in the non-clinical development plan by the absence, *inter alia*, of carcinogenicity studies and reproductive and development studies, being part of the post market requirement and commitments.

[175] On July 31, 2021, the Manager of the CNSD addressed a Clinical Memo to the Director of the BCANS in regards to RUZURGI. The Manager also noted that studies to characterize potential risks associated with carcinogenicity, reproductive and development toxicity including juvenile toxicity were not conducted at the time of this submission and are part of the Post market Requirement and Commitment issued by the FDA upon approving RUZURGI in the US (AR at 229). The Manager specified that the main source of data to support safety of amifampridine in adult LEMS patients is the compassionate use programs. Under the "Benefit-Harm-Uncertainty Assessment", the Manager indicated that the RUZURGI NDS did not contain carcinogenicity or juvenile toxicity studies, but that due to the very rare nature of LEMS, the fact that amifampridine has been administered to at least 600 patients over the last 27 years, the results of these studies are not considered critical for the time being. They added that the sponsor has committed to providing completed study reports to Health Canada when available. The Manager made no mention of the FIRDAPSE studies.

[176] On July 31, 2020, the Director of the BCANS addressed the Executive Summary for the RUZURGI NDS to the Director General of the TPD recommending the issuance of the NOC to RUZURGI (AR at 228). Under the "Benefit-Harm-Uncertainty Assessment", it was indicated that the RUZURGI NDS did not contain carcinogenicity or juvenile toxicity studies, but that due to the very rare nature of LEMS, the fact that amifampridine has been administered to at least 600 patients over the last 27 years, the results of these studies (the yet-undone RUZURGI studies) are not considered critical for the time being. It was added that the sponsor has committed to providing completed study reports to Health Canada when available. There is no mention of the FIRDAPSE studies.

[177] I did not find, in the Executive Summary, an indication that "[…] the Impugned Information was not necessary for its safety and efficacy approval of RUZURGI, and was included in the RUZURGI PM only because it was publicly available safety information" as the AGC states at paragraph 25 of its Memorandum of Fact and Law. As the Applicants suggest, the Rationale was only added in the SBD and the RDS, months after the RUZURGI NOC was issued.

[178] The fact that the RUZURGI documents indicate that there is no approved treatment in Canada has been confirmed as an oversight, and this is not at play in this application.

[179] On October 8, 2020, a scientific technical writer from the Health Products and Food Branch of Health Canada and the TPD sent the SBD prepared for RUZURGI to Médunik for comments (AR at 4728). Under the "Non-clinical Basis for Decision" heading, the SBD sets out

the basis for the recommendation for RUZURGI's approval. The SBD repeats the language used in the three memos dated July 30 and July 31, 2020, and in the Executive Summary. The SBD thus essentially outlines that studies to characterize potential risks of carcinogenicity and reproductive and developmental toxicity, including juvenile toxicity, were not conducted at the time of this submission. Due to the very rare nature of LEMS and the fact that amifampridine has been administered to at least 600 patients over the last 27 years, it was determined that the results of these studies were not essential for approval. It confirms that the sponsor has committed to providing completed study repots to Health Canada when available.

[180] However, it adds, for the first time, the Rationale which states, again: "While not essential for market authorization, publicly available safety information for the phosphate salt of amifampridine is included on the Product Monograph to ensure that it contains known information relevant to the optimal, safe, and effective use of Ruzurgi". On October 22, 2020, the SBD was issued for RUZURGI and contained this new information.

[181] This Rationale was repeated in the RDS and in the Addendum.

[182] The information revealed in the emails, despite best efforts from the AGC to assert otherwise, undermines the Rationale. The information indicates that (1) Médunik relied on the FIRDAPSE data to seek its NOC; (2) the FIRDAPSE data was required by the TPD for market authorization; and (3) the data protection was in play, but its application was discarded based on the timing.

[183] There is an evidentiary gap between these exchanges and the creation of the Rationale.

[184] The AGC confirmed that the decision-maker is not solely Ms. Bowes acting in silo. In turn, it is clear the OSIP knew about these exchanges. During her cross-examination, Ms. Bowes confirmed that when she refers to the OSIP in her affidavit and in the redetermination decision, she is including individuals who are part of the OPML such as the manager of the OPML Ms. Michelle Ciesielski who reports to her (AR at 5941-5942).

[185] At paragraph 126 of its *Vavilov* decision, the Supreme Court of Canada stated clearly that "[t]he reasonableness of a decision may be jeopardized where the decision-maker has fundamentally misapprehended or failed to account for the evidence before it" [Emphasis added.] The Court notes that the Federal Court of Appeal has characterized this as a high threshold (*Makivik Corporation v Canada (Attorney General)*, 2021 FCA 184 at para 98) and "[…] that care must be taken to ensure that arguments alleging failure to account for evidence not erode the general prohibition (see *Vavilov* at para 125, referred to above at paragraph 62) on a reviewing court's 'reweighing and reassessing the evidence considered by the decision-maker'" (*Gordillo v Canada (Attorney General)*, 2022 FCA 23 at para 122). The Court also notes that the Federal Court of Appeal has cited the *Cepeda-Gutierrez v Canada (Minister of Citizenship and Immigration)*, [1999] 1 CF 53 decision which states at paragraph 17 that when a decision-maker refers in some detail to evidence supporting its finding, but is silent on evidence pointing to the opposite conclusion, it may be easier to infer that the decision-maker overlooked the contradictory evidence when making its finding of fact (*Canada (Attorney General) v Best Buy Canada Ltd*, 2021 FCA 161 at para 123).

[186] I am mindful that the role of the Court, on judicial review, is not to weigh or reweigh the evidence. My assessment of the evidence leads me to find that there existed contradictory evidence known to the decision-maker, but ignored. I find that the OSIP ignored or failed to account for the evidence before it, rendering the Minister's Decision unreasonable.

C. *Conclusion on the two points of interpretation*

[187] In the end, I am satisfied that the Minister's reasoning does not "add up" (*Vavilov* at para 104). The intervention of the Court is therefore warranted.

VII. Remedies

[188] The Applicants submit that the appropriate remedy is to quash the Minister's Decision, and not send it back for redetermination. The Applicants add that "[…] this Court should direct the Minister not to issue a NOC to RUZURGI before (i) the end of a period of eight years after the day on which FIRDAPSE received its NOC; or (ii) until Médunik files its own carcinogenicity and reproductive and developmental toxicity data" (AR at 7589).

[189] If the Court agrees with the Applicants' position, there is no more discretion to issue a NOC where a comparison is made to an innovative drug like FIRDAPSE. The Applicants argue that no useful purpose would be served if the Minister were to redetermine the matter and cite *Canada (Citizenship and Immigration) v Tennant*, 2019 FCA 206 at paragraph 72 and *Canada (Attorney General) v Bétournay*, 2018 FCA 230 at paragraph 69. Citing paragraph 142 of *Vavilov*. The Applicants add that "[t]his is especially true because the Minister has already had a

genuine opportunity to weigh in on the issues, and in doing so, has made the same unreasonable decision twice" (AR at 7589).

[190] The Applicants add that "[i]n light of the 'aggressive interventions' displayed by the Minister, fairness requires the matter not be remitted back to her" and cite *Vavilov* at paragraph 142, *Girouard v Canadian Judicial Council*, 2015 FC 307 at paragraph 8 and *Fong v Winnipeg Regional Health Authority*, 2004 MBQB 182 at paragraph 27 (AR at 7589).

[191] Finally, the Applicants submit that an urgent resolution of the matter is needed.

[192] The AGC submits that there is no reason to depart from the Court's usual practice to remit the matter to the OSIP, should this Court find the Minister's Decision unreasonable.

[193] I am not satisfied that there are exceptional circumstances that warrant the remedy sough by the Applicants.

[194] In his decision *Nosistel v Canada (Procureur général)*, 2018 FC 618 at paragraph 55, Justice Gascon notes that "[…] the Court should exercise considerable restraint in issuing directions that amount to a directed decision, because it gives rise to concerns about the Court accomplishing indirectly what it is not authorized to do directly—namely, substituting its own decision for that made by the administrative decision-maker by compelling the decision-maker to reach a specific conclusion (*Scotiabank* at para 56; *Turanskaya v Canada (Minister of Citizenship and Immigration)*, (1995), 111 FTR 314 (FCTD) at para 6, affd by (1997) 145 DLR

(4th) 259 (FCA))". The Federal Court of Appeal states that "[…] the option of directing an administrative tribunal on how to decide an issue within its jurisdiction can only be exercised in exceptional circumstances" (*Canada (Attorney General) v Allard*, 2018 FCA 85 at para 44 [*Allard*]). The Federal Court of Appeal further notes that "[] this type of discretion should only be exercised when there is only one possible reasonable outcome open to the decision-maker" (*Allard* at para 45).

[195] In *Canada (Citizenship and Immigration) v Tennant*, 2019 FCA 206 at paragraph 68 [*Tennant 2019*], the Federal Court of Appeal restates that the "[…] law of judicial review recognizes a power on the part of a reviewing court to substitute its view for that of the administrative decision-maker, provided that certain conditions are met". The Federal Court of Appeal specifies that "[t]he most obvious is to quash the tribunal's decision and give directions requiring the decision-maker to reach a particular result. It is now well-established that this form of relief, a combination of certiorari and mandamus, is available where on the facts and the law there is only one lawful response, or one reasonable conclusion, open to the administrative decision-maker, so that no useful purpose would be served if the decision-maker were to redetermine the matter" (*Tennant 2019* at 72).

[196] The Supreme Court of Canada cites the Federal Court of Appeal's decision in *D'Errico v Canada (Attorney General)*, 2014 FCA 95 to state that "[…] while courts should, as a general rule, respect the legislature's intention to entrust the matter to the administrative decision-maker, there are limited scenarios in which remitting the matter would stymie the timely and effective resolution of matters in a manner that no legislature could have intended" (*Vavilov* at para 142).

The Supreme Court of Canada notes that "[d]eclining to remit a matter to the decision-maker may be appropriate where it becomes evident to the court, in the course of its review, that a particular outcome is inevitable and that remitting the case would therefore serve no useful purpose" (*Vavilov* at para 142). The Supreme Court of Canada specifies that "[e]lements like concern for delay, fairness to the parties, urgency of providing a resolution to the dispute, the nature of the particular regulatory regime, whether the administrative decision-maker had a genuine opportunity to weigh in on the issue in question, costs to the parties, and the efficient use of public resources may also influence the exercise of a court's discretion to remit a matter, just as they may influence the exercise of its discretion to quash a decision that is flawed" (*Vavilov* at para 142).

[197] Given this guidance from the Supreme Court of Canada and the Federal Court of Appeal, and considering as well that it is not the role of this Court to weigh the evidence, I have not been convinced that the situation warrants departing from the general remedy and will thus remit the matter to the Minister for a new determination.

VIII. Costs

[198] At the hearing, the Applicants asked the Court to reserve its decision on costs and provide the parties the opportunity to put in costs submissions.

[199] The AGC and Médunik left it to the discretion of the Court to decide on the Applicants' proposition on costs.

[200] The issue of costs is reserved and the parties are granted the opportunity to provide submissions in this regard. I ask the parties to confer and, within 15 days of this judgment, submit a joint agenda for said submissions to the Court.

JUDGMENT in T-1047-21

1. The Application for judicial review is granted.
2. The Minister's decision is set aside and the matter is sent back for a new determination.
3. The issue of costs is reserved.

"Martine St-Louis"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1047-21
STYLE OF CAUSE:	CATALYST PHARMACEUTICALS, INC AND KYE PHARMACEUTICALS INC v ATTORNEY GENERAL OF CANADA AND MÉDUNIK CANADA
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DATED:	MARCH 10, 2022

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