Federal Court  Cour fédérale

Date: 20210531

Docket: T-984-20

Citation: 2021 FC 505

Ottawa, Ontario, May 31, 2021

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 August 10, 2020 decision of the Minister of Health [the Minister] to issue Médunik Canada [Médunik] a Notice of Compliance [NOC] with respect to

Médunik's New Drug Submission [NDS] for its amifampridine product, RUZURGI [the Decision].

[2] The Applicants challenge the Minister's Decision as contrary to the data protection provisions of subsection C.08.004.1(3)(b) of the *Food and Drug Regulations*, CRC, c 870 [the *Food and Drug Regulations*].

[3] The Applicants seek a number of reliefs, including (1) quashing the Minister's Decision and the NOC issued to Médunik; (2) prohibiting the Minister from issuing a NOC to Médunik in respect of its RUZURGI product until after August 1, 2028 (eight years after the date of issuance of Catalyst's NOC for its amifampridine phosphate product, FIRDAPSE); and (3) in the alternative, referring the matter back to the Minister for redetermination in accordance with subsection C.08.004.1(3)(b) of the *Food and Drug Regulations*.

[4] In brief, and as a preliminary matter, I conclude that the Applicants have standing to bring their Application for judicial review [the Application], as they are directly affected by the Minister's Decision, per section 18.1 of the *Federal Courts Act* (RSC 1985, c F-7 [the *Federal Courts Act*]). In particular, and as detailed below, I am satisfied that the Applicants' challenge is not directed to the Minister's Decision with respect to RUZURGI's safety and efficacy, but to the application of the aforementioned data protection provisions of the *Food and Drug Regulations*.

[5] As to the merits, and for reasons set out below, I will grant the Application, quash the Minister's Decision, and return it to the Minister for redetermination.

[6] As per the instructions of the Supreme Court of Canada in *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 [*Vavilov*]. The Attorney General of Canada [AGC] and Médunik have each presented to the Court legal and factual constraints that must guide it in reviewing the Decision. They have first asserted that the legal constraints they present are reasonable and have been condoned by the Court in *Hospira Healthcare Corporation v Canada (Health)*, 2015 FC 1205 [*Hospira 2015*] and, second, that these legal constraints were those actually applied by the Minister before issuing Médunik its NOC.

[7] The Court is not convinced that the Respondents' interpretation of the *Food and Drug Regulations* data protection provisions, as presented by the AGC through his affiant, Dr. Kendra Cann, Patent Officer at "Legal, Health Canada," and by both Respondents through their submissions, is proper or that it was condoned by the Court in *Hospira 2015*. However, even assuming that it is, and was, the evidence does not show that the Minister in fact applied the proposed scheme before issuing Médunik its NOC. In the absence of reasons in the Decision itself, of information in the CTR and the evidence, and of an affiant with more direct knowledge of how the decision was made, assuming the affiant's knowledge could compensate the absence of reasons and lack of information; the Court could not decipher if the interpretation put forth by the Respondents is in fact the one adopted by the Minister at the time he made the Decision, or whether the protection granted to FIRDAPSE was fact even considered before the NOC was issued to Médunik.

[8] For these reasons, I will therefore quash the Decision and send the matter back to the Minister for redetermination.

II. Context

[9] Catalyst is a Florida-based biopharmaceutical company that defines itself as focused on investing in leading-edge science to develop and commercialise innovative therapies for those who suffer from rare and ultra-rare diseases. 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.

[10] Médunik is a manufacturer and supplier of pharmaceutical products based in Blainville, Québec.

[11] Amifampridine treats an ultra-rare and debilitating autoimmune disorder called Lambert-Eaton myasthenic syndrome (LEMS). Currently, some 200 Canadians who suffer from LEMS. Until the approval of FIRDAPSE, 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.

[12] On August 15, 2019, Catalyst requested “Priority Review” status for its New Drug Submission [NDS] pertaining to its amifampridine product, FIRDAPSE. On October 18, 2019, Health Canada granted Catalyst’s request, thus shortening the Minister’s review period from the typical 300 days to 180 days.

[13] On November 6, 2019, Catalyst submitted its NDS for FIRDAPSE. In its filing, it sought data protection, asking the Minister to classify FIRDAPSE as an “innovative drug” under section C.08.004.1 of the *Food and Drug Regulations*. On November 19, 2019, the Minister informed Catalyst that FIRDAPSE appeared to be an “innovative drug,” eligible for data protection.

[14] On February 7, 2020, following a response to a screening deficiency notice, the FIRDAPSE NDS was accepted into review (paragraph 33 of Dr. Cann’s affidavit; Applicants’ Record [AR] at page 1951).

[15] Médunik was also granted the “Priority Review” status it sought for its NDS regarding its amifampridine product, RUZURGI, and in December 2019, Médunik filed its NDS.

[16] The copy of the Original Annotated Product Monograph for RUZURGI, submitted by Médunik with its NDS and contained in the Certified Tribunal Record [CTR] (AR at pages 16 to 46), shows that Médunik included parenthetical references to FIRDAPSE USPI 2018. Dr. Cann believes that these references indicate that the source of the information is the United States Prescribing Information approved by the U.S. Food and Drug Administration in respect of the U.S. market authorisation for FIRDAPSE (paragraph 37 of Dr. Cann’s affidavit; AR at page

1951-52). It refers to two FIRDAPSE studies, one on carcinogenicity and the other on reproductive and development toxicity (AR at page 40).

[17] On July 31, 2020, the Minister granted Catalyst a NOC for its amifampridine product (supplied as amifampridine phosphate), FIRDAPSE, in oral, tablet, 10mg form (AR at page 89). The NOC is signed by Dr. J. Patrick Stewart, MD, CCFP(EM), Director General of the Therapeutics Products Directorate of Health Canada, and the Product Monograph and Certified Product Information Document are enclosed.

[18] The NOC issued to Catalyst includes no reasons. It merely confirms that the NDS complies with the requirements of sections C.08.002 and C.08.005.1 of the *Food and Drug Regulations*, and that it is issued pursuant to section C.08.004 of the *Food and Drug Regulations*.

[19] It is not disputed that, as the first approved amifampridine product in Canada, FIRDAPSE was recognised as an "innovative drug." It was thus entitled to data protection under subsection C.08.004.1(3) of the *Food and Drug Regulations*.

[20] On August 10, 2020, a NOC was issued to Médunik for its RUZURGI amifampridine product, in oral, tablet, 10mg form (CTR at page 76). The NOC is also signed by Dr. J. Patrick Stewart, and the Product Monograph and Certified Product Information Document are again enclosed.

[21] Like the NOC issued to Catalyst, the NOC issued to Médunik contains no reasons. It merely confirms that the NDS complies with the relevant provisions that it is issued pursuant to section C.08.004 of the *Food and Drug Regulations*.

[22] We must turn to the CTR, prepared and certified by Dr. Cann, and to her affidavit and cross-examination for a glimpse into what happened to the RUZURGI NDS, particularly from July 31, 2020, when the NOC was issued to Catalyst for its FIRDAPSE product, which was recognised as an innovative drug, until August 10, 2020, when the NOC was issued to Médunik for its RUZURGI product.

[23] In regards to the RUZURGI NDS, the CTR (at pages 77 and following) reveals that on July 31, 2020, the "Manager, CNSD" addressed a "Manager Memo – Clinical" to the "Director BCANS." At pages 2 and 3 of that Memo, the Manager states that "there is currently no cure or approved treatment for LEMS in Canada" and that "[c]urrently, there are no approved products in Canada for the treatment of LEMS," while acknowledging that FIRDAPSE, produced by a different manufacturer than RUZURGI, was approved in Europe in 2009.

[24] On August 4, 2020, Ms. Jacqueline Farah sent Catalyst its July 31 NOC, along with the cover pages for the approved Product Monograph and Certified Product Information Document.

[25] On August 5, 2020, the "Director, BCANS" addressed a "Pharmaceutical Submission Executive Summary" [the Executive Summary] to the "Director General, Therapeutic Products Directorate," [TPD] as part of the NOC package (AR at pages 52 and following). On the second

page of the Executive Summary, the Director again states: “There is currently no cure or approved treatment for LEMS in Canada.” This statement is repeated at page 3, while the Director again acknowledges that FIRDAPSE was approved in Europe in 2009.

[26] As of August 5, 2020, the documentary evidence relating to the RUZURGI NDS, as contained in the CTR, makes no reference to the fact that another manufacturer’s NDS is under review, let alone to the fact that Catalyst was issued a NOC for FIRDAPSE, on July 31, 2020, as an “innovative drug” with the resulting data protection. To the contrary, on July 31 and August 5, 2020, the documents in the RUZURGI NDS repeatedly confirm that no such drug has yet been approved in Canada.

[27] On August 5, 2020, the Product Monograph for RUZURGI is approved. The name FIRDAPSE no longer appears in relation to the carcinogenicity and reproductive studies.

[28] The RUZURGI NOC signatures snapshot found at page 88 of the AR indicates that ANGZHANG (Ms. Angel Zhang, whose involvement is discussed below) “Performed IP Check,” without any details as to what this check entails or how it was conducted. The date of the IP Check is unclear, as two dates appear on the snapshot: August 5 and August 11, 2020.

[29] The “Notes to DG” section of the snapshot of the RUZURGI NOC package (page 50 and 51 of the AR; and Exhibit W of Dr. Cann’s affidavit) contains a box dedicated to the “OPML,” i.e. the Office of Patented Medicines and Liaison, part of the Office of Submissions and Intellectual Property [OSIP]. The information in this box relates to (1) the “IP CHECK,” where it

is indicated that RUZURGI is “Off IP Hold;” (2) “Data Protection,” where the item “No DATA Protection to Add” is highlighted; and (3) the “PM(NOC) Regulations Requirements,” where the item “No Patents to Add” is highlighted. On August 10, 2020, at 3;51, Ms. Zhang added a note, in the other (right) column of the OPML box, indicating “NOTE to OPML: No longer eligible for DP.”

[30] In regards to the Intellectual Property (IP) Hold, at para 63 or her affidavit (page 1957 of the AR), Dr. Cann indicates that “[w]here the OSIP concludes that a NOC cannot be issued because the data protection provisions are triggered, it places the submission on Intellectual Property Hold and gives written notice to that effect to the manufacturer that submitted the NDS.” There is no information as to whether RUZURGI was ever on IP Hold, and then Off IP Hold, or if it was always Off IP Hold.

[31] There is no indication that the Executive Summary addressed on August 5, 2020 to the Director General of the TPD, who seems to be the person who signed the RUZURGI NOC, was amended to indicate that another (“innovative”) drug had been approved.

[32] It is not disputed, in these proceedings, that Médunik did not amend or supplement its NDS after July 31, 2020. However, I have found no indication, in the record, that any verification was done by the relevant authorities to verify if an amendment had been made between July 31 and August 10, 2020.

[33] On August 10, 2020, hence ten days after the NOC had been issued to Catalyst for FIRDAPSE, and the same day the RUZURGI NOC was issued, the Patent Officer – Science Office of the OPML addressed their final data protection eligibility assessment [DPEA] to the Director of the OSIP, and determined that FIRDAPSE was eligible for data protection.

[34] On August 13, 2020, a printout of the Register of Innovative Drugs (CTR at pages 117 and following) confirms FIRDAPSE's status as an "innovative drug," with a NOC date of July 31, 2020, a 6 year "no file" date of July 31, 2026, and data protection ending on July 31, 2028. The data protection is thus apparently granted from the date the NOC was issued, while there is no mention of FIRDAPSE's marketing status (see discussion below).

[35] On August 14, 2020, Catalyst and KYE signed a License Agreement. KYE filed for an administrative NDS, and on September 24, 2020, the Minister issued a NOC to KYE.

[36] On August 26, 2020, the Applicants filed their Notice of Application, initially naming the Minister as one of the Respondents. The Minister was subsequently removed by Order on consent on September 15, 2020. In their Notice of Application, the Applicants included a request under Rule 317 of the *Federal Courts Rules* (SOR/98-106) [the Rules], for the Minister to send the Applicants and the Registry, while taking appropriate steps to maintain confidentiality, a certified copy of all material considered and created by the Minister, including all internal documentation and communications pertaining, or relevant, to the Minister's Decision.

[37] On September 15, 2020, Dr. Cann certified that the documents attached, as listed, are true copies of the material requested by the Applicants, produced in accordance with Rules 317 and 318 of the Rules. Dr. Cann attached 13 documents to her Certificate under Rule 318, including an extract of the Register of Innovative Drugs as of August 13, 2010, hence after the Minister's Decision was issued. On cross-examination, Dr. Cann explained that she selected the documents in consultation with three other persons at OPML and OSIP, i.e. Ms. Michelle Ciesielski, manager of OPML, Ms. Anne Bowes, director of OSIP, and Ms. Angel Zhang (AR at page 2454).

[38] On September 16, 2020, Madam Prothonotary Aylen issued a Protective Order, which was amended on October 20, 2020.

[39] On October 26, 2020, KYE informed Health Canada that it had begun selling FIRDAPSE in Canada (Reply Affidavit of Mr. Douglas Reynolds at para 3; AR at page 950).

[40] On October 16, 2020, Médunik addressed a letter to Health Canada to provide sponsor responses to the Summary Basis of Decision [SBD] Health Canada had provided (pages 2644 and following of the AR). The SBD sets out the basis for the recommendation for RUZURGI's approval. Dr. Cann described this SBD as a key document. Again, months after FIRDAPSE's approval, Health Canada's SBD contains the statement that "[c]urrently, there is no cure or approved treatment for LEMS in Canada," which Médunik crossed out, adding a comment to the effect that FIRDAPSE was approved in July 2020 (AR at page 2648).

[41] On November 5, 2020, Médunik filed its Motion to Strike the Notice of Application (for lack of standing) / Motion to Exclude the Applicants' Evidence [the Motion]. The exclusion issues specifically concerned four fact affidavits and one expert affidavit, which were not before the Minister when the Minister's Decision was rendered. The Applicants also filed a proposed reply affidavit by Mr. Reynold, which Médunik submits is equally inadmissible.

[42] I have ruled on this Motion separately. However, the parties agreed that the admissibility of the reply affidavit would be decided herein. I will admit the reply affidavit, which essentially provides information regarding the marketing of FIRDAPSE (this information is of no impact on my decision). I will nonetheless strike from the record paragraph 4 of the affidavit, where Mr. Reynolds appears to provide unsubstantiated opinion evidence or inadmissible expert evidence on the NOC process and the marketing of approved drugs.

III. The Applicants' Standing to Bring the Application for Judicial Review

[43] I have not exercised my discretion to decide on the standing issue upon rendering my Order on Médunik's Motion, having solely concluded that Médunik had not satisfied the stringent test required to strike the Application. I must therefore first decide whether or not the Applicants have standing to bring this Application, as per the parties' submissions regarding the Motion.

[44] I am satisfied that the Applicants do have standing to bring their application for judicial review, as I am satisfied that they are not challenging the Minister's Decision to grant a NOC on safety and efficacy grounds. They are rather challenging the Decision on the issue of whether the

issuance of the NOC contravened the data protection provisions of the *Food and Drug Regulations*.

[45] Section 18.1 of the *Federal Courts Act* enables the AGC or anyone *directly affected* by the matter in respect of which relief is sought to file an application for judicial review. As per the words of Madam Prothonotary Tabib in *Hospira Healthcare Corporation v Canada (Health)*, 2014 FC 179 at para 9 [*Hospira 2014*]:

> […] the appropriate test for determining whether a party has a direct interest is the same whether the party is a proposed applicant or a proposed respondent, and that it was most recently articulated by the Federal Court of Appeal in *Forest Ethics Advocacy Assn. v Canada (National Energy Board)*, 2013 FCA 236 as follows:
>
> > "20. A party has a "direct interest" under subsection 18.1 (1) of the Federal Courts Act when its legal rights are affected, legal obligations are imposed on it, or it is prejudicially affected in some direct way : *League for Human Rights of B'Nai Brith Canada v. Odynsky*, 2010 FCA 307 at paragraphs 57-58; *Rothmans of Pall Mall Canada Ltd. v. Canada (M.N.R.)*, [1976] 2 F.C. 500 (C.A.); *Irving Shipbuilding Inc. v. Canada (A.G.)*, 2009 FCA 116."

[46] In regards to the NOC challenge, the parties agree that a constant line of cases from this Court and the Federal Court of Appeal, outlined by Médunik in its Motion Record, confirms that a drug manufacturer does not have standing to challenge the Minister's decision to grant a NOC on safety and efficacy grounds.

[47] However, as even the AGC outlines, that line of cases does not necessarily preclude a drug company from challenging another drug manufacturer's NOC on the distinct and narrow

issue of whether the issuance of the NOC contravened the data protection provisions of the *Food and Drug Regulations*.

[48] Two of the decisions cited by the parties involve the data protection provisions, and are thus most relevant to these proceedings: they are (1) *Lundbeck Canada Inc v Canada (Health)*, 2008 FC 1379 [*Lundbeck*], in which the innovator company's drug was not, and could not be, listed on the Register of Innovative Drugs, and which does not discuss the principles of standing as they might apply to the data protection provision; and (2) *Hospira 2014*, where it was decided that the innovator whose product is listed on the Register of Innovative Drugs is a person directly affected by the order sought and that it is to be added by as a respondent to the Application (the Federal Court of Appeal confirmed that this conclusion is not clearly wrong and that *Lundbeck* is properly distinguishable in *Hospira Healthcare Corporation v Canada (Health)*, 2014 FCA 194). I am satisfied that the Applicants are in a position akin to that of Sanofi in *Hospira 2014*, although the Minister's decision placed Sanofi, the innovator, as a respondent, as the NOC had been denied to Hospira; while Catalyst and KYE, also innovators, are Applicants, as the NOC has been granted to Médunik.

[49] I note that paragraph 4 of *Hospira 2014* and paragraphs 1-15 and 17 of *Hospira 2015* confirm that Hospira had indeed filed a NDS.

[50] As the Applicants submit, I agree that this line of decisions support the proposition that an innovator whose drug is listed on the Register of Innovative Drugs has standing to challenge a

NOC issued to another company if it alleges that the NOC was issued in violation of the data protection afforded to its own product.

[51] Now, the difficulty here may reside in determining whether the Applicants in fact do allege solely that the Médunik NOC was issued in violation of Catalyst's data protection, or, as the AGC argues, whether the Application tenably raises any genuine issue regarding the interpretation or application of the data protection provisions rather than challenging the Decision on safety and efficacy.

[52] I am satisfied that the nature of the Applicants' challenge is directed at the interpretation and application of the data protection provisions of the *Food and Drug Regulations*, that their legal rights are affected, and that they have a direct interest under section 18.1 of the *Federal Courts Act*.

[53] Hence, given the aforementioned decisions, confirming that the Applicants have standing to challenge the Minister's Decision to issue a NOC to Médunik if relying upon the data protection provisions, and given that I am satisfied the Applicants' challenge is directed at the application of the data protection provisions, I conclude the Applicants have standing to bring their Application.

IV. The Regulatory Framework

[54] Per section C.08.002(1) of the *Food and Drug Regulations*, all drug manufacturers who wish to advertise and sell a new drug in Canada must first obtain a NOC by filing a new drug submission with the Minister.

[55] These proceedings concern new drug submissions [NDS], not abbreviated new drug submissions [ANDS]. In the case of a NDS, if the NDS complies with subsection C.08.002(2) and the Minister is satisfied that the drug is safe and effective, subsection C.08.004(1) provides that the Minister "shall" issue a NOC pursuant to the data protection regime.

[56] As per the AGC's representations, section C.08.004.1.of the *Food and Drug Regulations* creates a data protection regime. It 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 an NOC) for a drug that uses a new chemical entity.

[57] 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*).

[58] Drugs determined to be “innovative drugs” are listed on the Register of Innovative Drugs, which the Minister is required to maintain pursuant to subsection C.08.004.1(9) of the *Food and Drug Regulations*.

[59] Where a NOC has been issued to an “innovative drug,” subsection C.08.004.1(3) protects for prescribed periods the undisclosed data that was filed to obtain the NOC by preventing the filing and approval of a submission that seeks approval “on the basis of a direct or indirect comparison” to the innovative drug.

[60] Section C.08.004.1 indeed states:

> (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,
>
> > (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
> >
> > (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.

[61] Subsection C.08.004.1(5) provides that subsection C.08.004.1(3) does not apply if the innovative drug is not being marketed in Canada.

[62] The determination as to whether a manufacturer of a new drug is seeking a NOC on the basis of a direct or indirect comparison between the new drug and an innovative drug so as to contravene the data protection provisions is distinct from the Minister's determination that a submission meets regulatory requirements for safety and efficacy.

[63] The regulatory framework does not directly address situations, such as the one at play in these proceedings, where: two NDSs are submitted almost concurrently, one potentially comparing its drug to the other; the NDSs for the two drugs are then processed almost concurrently; and the first one is approved and recognised as an innovative drug, thus benefiting from data protection before the second one is approved.

[64] The AGC has outlined its interpretation of the regulatory framework and the IP verification process which he submits is applied by Health Canada. The Respondents submit the process accords with the regulation and that it was in fact applied in approving RUZURGI's NOC. It thus appears useful to outline this IP verification process and examine what information in the record in fact indicate if it was indeed applied.

V. IP Verifications in Health Canada's NDS Approval Process

[65] The AGC, in its submissions, and Dr. Cann, in her affidavit, outline the IP verifications that are conducted by the OSIP, first when a NDS is filed, and second at the time it is examined for approval.

[66] This process is important to the Minister and Médunik's case, as they essentially allege that (1) it represents in fact the Minister's interpretation and application of the data protection provisions; (2) it accords with the data protection provisions and has been sanctioned by the Court in *Hospira 2015*; and (3) it was in fact applied in the process leading to the issuance of the NOC to Médunik for RUZURGI.

[67] The process described by the AGC and Dr. Cann consist of two main verifications, each containing two steps. As per the description, the first verification occurs at the time the NDS is presented (i.e. at the time of filing) to the Minister, and the second verification occurs before the NOC is issued. However, this first presentation of the process already warrants a caveat given that, as outlined below, Dr. Cann confirmed that the second verification does not, in fact, entirely occur "before" the NOC is issued.

A. *First verification, at the time of filing: OSIP's preliminary review of NDSs*

(1) OSIP's preliminary review of NDSs as described by Dr. Cann

[68] As per Dr. Cann's affidavit, and I will purposively stick to the language used by Dr. Cann, the preliminary review of NDSs at the time of filing includes two steps: (1) the preliminary DPEA; and (2) the preliminary Intellectual Property Check [IP Check].

[69] In regards to the preliminary DPEA, Dr. Cann outlines that the OSIP makes two determinations. First, it determines whether or not the medicinal ingredient under consideration is a new chemical entity; and second, it determines whether or not the generation of the data that

supports the approval of the medicinal ingredient under consideration required considerable effort.

[70] If a drug 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, and if approval is sought on the basis of data, the origination of which involved considerable effort, the drug will be considered eligible for data protection. Only the first drug issued a NOC could qualify for data protection.

[71] In regards to the preliminary IP Check, it includes a determination of whether the submission seeks approval based on a comparison with an innovative drug listed on the Register of Innovative Drugs that is currently marketed in Canada.

[72] The OSIP's practice in this regard, again per Dr. Cann's testimony, is to review each submission to determine, in a variable order, whether (1) the Register of Innovative Drugs lists a relevant innovative drug; (2) the submission seeks approval based on a comparison with the innovative drug; and (3) the innovative drug is marketed in Canada. The OSIP forwards the submission for screening and review only if no innovative drug meets these three criteria.

[73] However, conversely, if there is no drug approved in Canada that could serve as a reference product, i.e. is listed on the Register of Innovative Drugs, the manufacturer cannot be seeking a NOC on the basis of a "direct or indirect comparison between the new drug and an innovative drug" (that is currently marketed in Canada) (AR at pages 2491-92). In those

circumstances, the OSIP considers that the data protection provisions are not engaged, and the NDS can therefore be accepted into screening.

(2) OSIP's preliminary review of the FIRDAPSE and RUZURGI NDSs

[74] It is not disputed that both the Catalyst and Médunik's NDSs were pending before the Minister at the same time. The Minister granted "priority review" status to both NDSs, such that each review was conducted on a shortened timeline.

[75] In regards to the preliminary DPEA, as per Dr. Cann's affidavit, the OSIP conducted it on each of FIRDAPSE and RUZURGI.

[76] In regards to FIRDAPSE, on November 15, 2019, a Patent Officer from the OPML sent FIRDAPSE's preliminary DPEA. At page 10 of this preliminary DPEA, the Patent Officer indicates that (1) amifampridine phosphate has not been previously approved in a drug by the Minister, and it is not a variation of a previously approved medicinal ingredient; and (2) the FIRDAPSE drug submission seeks a notice of compliance on the basis of new and significant clinical trial data and is not a literature-based submission. The Patent Officer found FIRDAPSE to be eligible for data protection.

[77] On November 19, 2019, Dr. Cann, for Ms. Michelle Ciesielski, Manager OPML, wrote to Catalyst and indicated: "At this time, FIRDAPSE appears to be an 'innovative drug' and is therefore eligible for data protection" (AR at page 2100).

[78] Similarly, on January 10, 2020, a Patent Officer from the OPML sent RUZURGI's preliminary DPEA. At page 12 of this preliminary DPEA, the Patent Officer indicates that (1) amifampridine has not been previously approved in a drug by the Minister and it is not an enumerated variation of a previously approved medicinal ingredient; and (2) the RUZURGI drug submission appear to seek a NOC on the basis of new and significant trial data and is not a literature-based submission (as seen from Section 4 of this document). The Patent Officer found RUZURGI to be eligible for data protection.

[79] Notably, under the section 2 "Previous Approvals" header of the assessment, the Patent Officer noted that amifampridine is "found in the DSTS" with respect to FIRDAPSE's NDS, "with a CR date of 2019.11.06 and a classification of Priority-NAS" and is currently "INACTIVE 45" (AR at page 2120). The Officer also notes that the target date of 2020.01.11 "has passed and no response was received" (AR at page 2120).

[80] Under the aforementioned section 4, titled "Clinical Trial Information," the Patent Officer notes that "reference is made to FIRDAPSE (Amifampridine phosphate) studies for Carcinogenicity and Reproductive and Development Toxicity in the Annotated Product Monograph" (AR at page 2121 [emphasis in original]). Finally, on page 12 of the assessment, immediately after confirming that RUZURGI is eligible for data protection, the Patent Officer again notes that the FIRDAPSE NDS has a status of "INACTIVE 45" (AR at page 2129).

[81] As we will see below, Dr. Cann confirmed that the OSIP relied on the preliminary DPEA for RUZURGI's final IP verification. It is not known how, or if, the indications that FIRDAPSE is "inactive" were considered.

[82] On January 13, 2020, Ms. Michelle Ciesielski wrote to Médunik and indicated: "At this time, RUZURGI appears to be an 'innovative drug' and is therefore eligible for data protection" (AR at pages 2114-15).

[83] Exhibit J to Dr. Cann's affidavit, which she confirmed was part of the RUZURGI preliminary DPEA, contains a note that reads "check approved PM at final DPEA stage" (AR at page 2165). Dr. Cann refrained from speculating as to the meaning of this note, and the Court is equally in the dark as to its meaning.

[84] However, again, Dr. Cann confirmed that the Minister relied on the preliminary DPEA at the final IP verification.

[85] In regards to the preliminary IP Check, Dr. Cann confirms that the OSIP's preliminary IP Check resulted in the FIRDAPSE NDS being accepted into screening. She adds that, at the time of filing, there was no drug approved in Canada that could serve as a reference product for FIRDAPSE, and no relevant drug was listed on the Register of Innovative Drugs.

[86] Dr. Cann also confirms that the OSIP's preliminary IP Check similarly resulted in the RUZURGI NDS being accepted into screening (AR at page 1951). As there was no relevant

innovative drug listed on the Register of Innovative Drugs when Médunik filed the RUZURGI NDS, there was therefore no reason for the OSIP to reject the NDS.

[87] Dr. Cann confirms, in her affidavit, that OSIP's preliminary IP Check includes a determination of whether the submission seeks approval based on a comparison with an innovative drug listed on the Register that is currently marketed in Canada. However, in regards to RUZURGI, she confirmed on cross-examination that, at the time of filing, OSIP would not have reviewed RUZURGI's NDS to see whether it includes a comparison to an innovative drug as no such drug was listed on the Register of Innovative Drugs. Dr. Cann confirmed that in the absence of an innovative drug on the Register of Innovative Drugs, no one reviewed the submission to check whether there was a comparison.

[88] It is unknown why the RUZURGI January 10 preliminary DPEA, mentioned previously, contains a note that the RUZURGI NDS makes a "reference" to FIRDAPSE, or what that means.

[89] Dr. Cann confirmed that, despite what she indicated was included in OSIP's preliminary IP Check, in RUZURGI's case (1) no verifications were made as to whether or not RUZURGI's NDS sought a NOC for a new drug on the basis of a direct or indirect comparison with an innovative drug, as there was no relevant innovative drug on the Register of Innovative Drugs; and (2) no verification was made as to whether or not the drug was marketed in Canada;

B. *Second verification, before the NOC is issued: OSIP's final checks for recommended NOCs*

(1) OSIP's final check for recommended NOCs as described by Dr. Cann

[90] As per the AGC's submissions and Dr. Cann's affidavit, once an NDS is accepted into screening, the relevant Health Canada Directorate assesses its compliance with the *Food and Drug Regulations*, including the requirements related to safety and efficacy. In the case of FIRDAPSE and RUZURGI, the BCANS, a bureau within the Therapeutic Products Directorate, carried out the clinical and non-clinical reviews. I need not address this in these proceedings.

[91] Dr. Cann outlines that, when Health Canada reviewers recommend that a drug receive a NOC, they prepare a "NOC package" of documents to support their recommendation. The NOC package undergoes various approvals until, ultimately, the Director General, here of TPD, determines whether to issue a NOC.

[92] The NOC package includes an executive summary setting out the basis for the recommendation for approval, including summaries and key findings and issues for the various types of reviews.

[93] The final check includes two steps, i.e. the final IP Check and the final DPEA.

[94] In regards to the final IP check, Dr. Cann explains that, *en route* to the final decision-maker, the NOC package, which includes the aforementioned executive summary, is routed to the OSIP for final IP Check.

[95] In her affidavit and on cross-examination, Dr. Cann indicated that the final IP Check includes (1) a determination of whether the submission seeks approval based on a comparison

with an innovative drug listed on the Register of Innovative Drugs that is currently marketed in Canada; and (2) identifying submissions that require a final DPEA.

[96] In regards to the first of the two steps, as per Dr. Cann's affidavit (at paragraph 45; AR at pages 1953-54), OSIP's final IP Check process first evaluates whether an innovative drug has been listed on the Register of Innovative Drugs in the period between the filing and the approval.

[97] If no innovative drug is found in the search, the OSIP does not conduct the rest of the final IP Check.

[98] If the search detects an innovative drug, the OSIP then checks whether, after the innovative drug's approval and marketing (Dr. Cann's affidavit; AR page 1954), the NDS was amended such that the approval of the drug was being sought and recommended on the basis of a newly-introduced comparison with the now-approved and marketed innovative drug. This is the "amendment check."

[99] Hence, if a relevant innovative drug has been approved and listed since the NDS was filed, the OSIP determines whether (1) the NDS has been *amended* since the approval of the relevant innovative drug; and (2) as a result of the amendment, an NDS has been evaluated, and has been recommended for approval, as an "NDS that seeks approval on the basis of a direct or indirect comparison with the *now-approved and marketed innovative drug*" (AR at page 1954 [my emphasis]).

[100] Where such an amendment (an amendment that post-dates the innovative drug's NOC) results in such a comparison (a comparison that is the basis of the new drug's approval), the data protection provision is triggered, and the OSIP places the NDS on intellectual property hold until the expiry of the innovative drug's data protection term.

[101] As confirmed in her cross-examination, Dr. Cann did not attach to her affidavit any guidance documents, standard operating procedures, or other internal OSIP documents that would describe and substantiate the process outlined at paragraph 45 of her affidavit (pages 1953-54).

[102] Dr. Cann stressed that the drug's marketing in Canada is a factor in the application of the data protection provisions.

[103] In regards to the final DPEA, it is worth noting again that it is conducted *after* the NOC is issued, because per Dr. Cann's testimony, "there's just not time to do it before the NOC issues" (AR at page 2465). Dr. Cann confirmed that the decision to issue the NOC is thus based on the preliminary DPEA, i.e. the one conducted at the time the NDS is submitted.

[104] One of the reasons the OSIP proceeds with a final DPEA is that another drug could have been approved since the preliminary DPEA was conducted. Hence, OSIP checks whether the Minister has approved a relevant innovative drug and listed it on the Register of Innovative Drugs while Health Canada was reviewing the new drug. Dr. Cann confirmed that OSIP thus recognises, in conducting its DPEA, that there may have been changes to the regulatory

landscape after the submission is filed. In other words, a drug that was assessed as eligible for data protection at the time of filing may no longer be eligible at the time the NOC is approved.

(2) OSIP's final checks for FIRDAPSE and RUZURGI

[105] In regards to FIRDAPSE's final IP Check, the NOC package included an Executive Summary to the Director General of the TPD, and, before the NOC package was forwarded to the Director General for final approval, it was routed through the OSIP for the final IP Check according to the normal procedure.

[106] Per Dr. Cann's affidavit, the fact that Catalyst was issued a NOC for FIRDAPSE, confirms that the OSIP concluded from its final IP Check that there were no IP impediments, under the data protection provisions, to the issuance of the NOC.

[107] In regards to FIRDAPSE's final DPEA, on August 10, 2020, hence 10 days after the NOC had been issued for FIRDAPSE, the "Patent Officer – Science Office" of the OPML addressed their final DPEA to the Director of the OSIP, and determined that FIRDAPSE was eligible for data protection.

[108] The extract of the Register of Innovative Drug dated August 13, 2020 confirms FIRDAPSE as an innovative drug with data protection starting July 31, 2020. However, there is no indication as to when, from August 10 to August 13, 2020, FIRDAPSE was actually registered in the Register of Innovative Drug, and would thus appear to somebody conducting a search of the Register.

[109] I have found no mention of any verification of FIRDAPSE's marketing date, nor of any reservation to data protection contingent on the drug being marketed, or even indication of what marketing entails. In fact, Dr. Cann confirms that FIRDAPSE was placed on the Register of Innovative Drugs "shortly thereafter" (after its approval) (AR at page 1955). On cross-examination, Dr. Cann also confirmed that no verifications were made as to the marketing of FIRDAPSE at any time during the examination of the FIRDAPSE and RUZURGI NDSs.

[110] In regards to RUZURGI's final IP Check, the NOC package included the August 5, 2020 Executive Summary that confirmed, and in fact repeated, that no drug had been approved in Canada, as well as the manager's memo that contained the same mention. Before the NOC package for RUZURGI was forwarded to the Director General of the TPD for final approval, it was routed through the OSIP for a final IP Check. There is no indication that these statements were corrected or amended by OSIP.

[111] Dr. Cann did not know on what date the RUZURGI NOC package was received or examined by OSIP, or if the date was on or before August 10, 2020, i.e. if it was done before or after FIRDAPSE's final DPEA was actually issued, or before or after the time when FIRDAPSE was in fact registered in the Register of Innovative Drugs.

[112] As per Dr. Cann's affidavit, generally, the fact that Médunik was issued a NOC for RUZURGI confirms that the OSIP concluded from its final IP Check that there were no IP impediments under the data protection provisions to the NOC issuance. Furthermore, Dr. Cann

stresses that the same people were responsible for the two NDSs and that they know “what’s in the pipeline” (AR at page 2538).

[113] However, as late as October 2020, OSIP continued to confirm, in the RUZURGI documentation (SBD) that no drug had been approved in Canada.

[114] In her affidavit and on cross-examination, Dr. Cann indicated that the final IP Check includes (1) a determination of whether the submission seeks approval based on a comparison with an innovative drug listed on the Register of Innovative Drugs that is currently marketed in Canada; and (2) identifying submissions that require a final DPEA.

[115] As part of the first item, Dr. Cann indicated that OSIP would first verify whether or not an innovative drug was approved and listed on the Register of Innovative Drugs since the RUZURGI NDS was submitted. Dr. Cann confirmed that if no innovative drug is found in the search, the OSIP does not conduct the rest of the final IP Check.

[116] There is no indication that such a verification was in fact executed in the RUZURGI final IP Check. Even more importantly, there is no indication that a search of the Register of Innovative Drugs, conducted on or before RUZURGI’s approval date of August 10, 2020, would have identified FIRDAPSE as an innovative drug given the timeline of its final DPEA, and given that the date it was actually put on the Register of Innovative Drug remains unknown.

[117] Assuming that a search of the Register of Innovative Drugs was conducted in the RUZURGI final IP Check, and that it would have produced a hit so as to identify FIRDAPSE, then, Dr. Cann indicates, another process is followed whereby the OSIP checks whether, after the innovative drug's approval *and marketing*, the NDS was amended such that the approval of the drug was being sought and recommended on the basis of a newly-introduced comparison with the now-approved and marketed innovative drug.

[118] However, Dr. Cann confirmed that OSIP did not know FIRDAPSE's marketing status at the time the RUZURGI NOC was issued. In addition, there is no indication that OSIP verified if there were any amendment to the RUZURGI NDS since FIRDAPSE was approved, or if the RUZURGI NDS was made on the basis of a direct or indirect comparison.

[119] As mentioned above, per the snapshot of the RUZURGI NOC package (page 50 and 51 of the AR), on August 10, 2020 at 3;51, Ms. Zhang added a note, in the right column of the OPML box, indicating "NOTE to OPML: No longer eligible for DP." There is no information on what that means and on why the note was added before the final RUZURGI DPEA was conducted.

VI. Submissions of the Parties

A. *The Applicants*

[120] The Applicants essentially submit that (1) the standard of review is reasonableness; (2) the decision is unreasonable in that the record precludes reasonableness review; and (3) the decision is inconsistent with the factual and legal constraints that bear on the decision-maker.

[121] First, the Applicants submit that the standard of review is reasonableness, as a result of the presumption set out in *Vavilov*.

[122] Second, they add that the decision is unreasonable in that the record precludes reasonableness review, as there are no reasons for the decision and no rationale emerges from reviewing the record, while, on the contrary, the CTR indicates that the Minister never turned his mind to the key question whether the *Food and Drug Regulations* prohibited the Minister from granting a NOC to Médunik (*Vavilov* at paras 85-85, 99-100, 103; *Leahy v Canada (Citizenship and Immigration*) 2012 FCA 227 at para 100 [*Leahy*]). There is no intelligibility or transparency, and the CTR reflects no consideration of FIRDAPSE's data protection. In the absence of such information, the Court cannot perform its role on judicial review (*Canada v Kabul Farms Inc*, 2016 FCA 143 [*Kabul Farms*]). Dr. Cann's evidence on the decision, which supplements the CTR, should be given no weight, as she had no personal knowledge of the decision and her evidence is hearsay. Individuals with first-hand knowledge of the relevant information could have, but did not, testify.

[123] Finally, they submit the decision is inconsistent with the factual and legal constraints that bear on the decision-maker, specifically given that (1) FIRDAPSE was an innovative drug; (2) Médunik sought its NOC based on a comparison to FIRDAPSE; and (3) the Minister was therefore prohibited from granting the NOC. The decision is contrary to the text, context and purpose of the *Food and Drug Regulations*.

B. *Respondent the Attorney General of Canada*

[124] I have already found the Applicants' challenge to be properly directed at the application of the data protection provision, and I will not address this matter further.

[125] The AGC agrees that reasonableness is the applicable standard of review and responds that (1) the record is sufficient for the Court to conduct a reasonableness review; (2) the Applicants incorrectly allege that the decision was a complete oversight; (3) the OSIP reasonably interpreted and applied subsection C.08.004.1 of the *Food and Drug Regulations*; and (4) prohibiting a RUZURGI NOC is not an appropriate remedy.

[126] The AGC responds that the record is sufficient to permit a reasonableness review. The AGC distinguishes *Leahy* as (1) here, the CTR includes the relevant documents that were before the OSIP, including clear and explicit evidence on a fundamental aspect of the question as to whether the data protection regulations were engaged, namely the relevance (or rather irrelevance) of the impugned information in determining the safety and efficacy of RUZURGI; and (2) *Leahy* pre-dates *Vavilov*, in which the Supreme Court of Canada expressly directed a

reviewing court to undertake a robust reasonableness review in all circumstances regardless of the state of the record (*Vavilov* at paras 137-138).

[127] The AGC refers to consistent guidance from the Court that a decision-maker ought not to supplement or provide *ex post facto* reasons for a decision (*Sellathurai v Canada (Minister of Public Safety and Emergency Preparedness*, 2008 FCA 255 [*Sellathurai*]) and stresses that the evidence he adduced from Dr. Cann, who is not the decision-maker, (1) provided background information on the regulatory framework in which the OSIP operates and on the OSIP's review processes and practices; and (2) pointed out reasonable inferences to be drawn from the CTR regarding the basis for the OSIP's decision that there was no obstacle to the issuance of the RUZURGI NOC, notably in response to Ms. Costaris' affidavit on the same issue. The AGC explains that adducing information from the decision-maker would have been impermissible.

[128] The AGC further submits that the evidence contradicts the Applicants' assertion that the OSIP overlooked the FIRDAPSE NOC entirely. The AGC points to Dr. Cann's statement that the same individuals worked on both NDS reviews and to the "Notes to DG" section of the snapshot of the RUZURGI NOC package, which indicates that RUZURGI is no longer eligible for data protection.

[129] The AGC also argues that the OSIP reasonably interpreted and applied subsection C.08.004.1(3) of the *Food and Drug Regulations*. The AGC submits that the prohibition on comparative submissions applies at the time of filing (absent amendments to the submission) and that a contrary interpretation is inconsistent with the purpose, context, and wording of the

Regulations (citing *Hospira 2015*). The AGC adds that the RUZURGI NOC was not issued on the basis of a comparison to FIRDAPSE, as a comparison must equate to reliance in establishing a drug's safety and efficacy. The AGC cites the Executive Summary and the SBD to show that the Minister did not rely on the FIRDAPSE data. The AGC adds that comments by Health Canada employees at the FIRDAPSE pre-NDS meeting regarding studies Health Canada requires to approve a NDS is impermissible and contradicted by Health Canada's guidance documents. Finally, the AGC notes that there is nothing in the CTR regarding the marketing of FIRDAPSE as of August 10, 2020, a date at which Catalyst had not yet signed its agreement with KYE.

[130] On remedies, the AGC briefly notes that the typical remedy should apply if the Court finds the Decision unreasonable. The Decision should be set aside and remitted to the decision-maker with the benefit of the Court's reasons.

C. *Respondent Médunik*

[131] Respondent Médunik agrees that the reasonableness standard applies and responds that the Minister's Decision is reasonable. Médunik submits that the Minister acted reasonably in issuing the RUZURGI NOC after Firdapse was added to the Register of Innovative Drugs.

[132] Médunik disagrees with the way in which the Applicants have characterised the standard of review and applied it to the facts. Médunik does not directly address the impact of absence of reasons, but does stress that *Vavilov* confirms that reasons for decisions are not required in all cases, that the duty of procedural fairness is flexible and context-specific, and that "what is

reasonable in a given situation will always depend on the constraints imposed by the legal and factual context of the particular decision under review" (*Vavilov* at para 90).

[133] Médunik further submits that (1) the Minister's past practices, i.e. his interpretation of the data protection provisions was found to be both reasonable and correct in the *Hospira 2015*, where the amendment check process was at play; (2) the reference or even comparison made prior to the designation of an innovative drug are not captured by the data protection provisions; (3) there is no protection for "disclosed" data; (4) not all references can be considered comparisons; (5) there was in fact no comparison; (6) the marketing requirement applies and was not met; (7) the missteps or incorrect beliefs found in the CTR do not render the Minister's Decision unreasonable; (8) there is no merit to Catalyst's arguments in regards to procedural fairness.

[134] Médunik also asked the Court for the opportunity to file additional submissions should it decide to set aside the Minister's Decision. I find this unnecessary.

VII. Analysis

A. *The Standard of Review in the Absence of Formal Reasons*

[135] As mentioned above, we are essentially confronted with two barriers to conducting a typical reasonableness review in this case. First, the Minister's Decision does not include reasons which I could use, at least as a starting point, in reviewing the Decision. Second, the record does

not shed light on the Minister's interpretation of the data protection provision, or on all of the steps that led to the Minister's Decision.

[136] In *Vavilov*, the Supreme Court established a presumption that reasonableness review applies when this Court reviews an administrative decision.

[137] The Court confirmed its earlier guidance from *Newfoundland and Labrador Nurses' Union v Newfoundland and Labrador (Treasury Board)*, 2011 SCC 62 [*Newfoundland Nurses*] that reviewing courts cannot speculate when the reasons are inadequate: they must be able to "connect the dots":

> Indeed, *Newfoundland Nurses* is far from holding that a decision maker's grounds or rationale for a decision is irrelevant. It instead tells us that close attention must be paid to a decision maker's written reasons and that they must be read holistically and contextually, for the very purpose of understanding the basis on which a decision was made. We agree with the observations of Rennie J. in *Komolafe v. Canada (Minister of Citizenship and Immigration)*, 2013 FC 431, 16 Imm. L.R. (4th) 267, at para. 11:
>
> > *Newfoundland Nurses* is not an open invitation to the Court to provide reasons that were not given, nor is it licence to guess what findings might have been made or to speculate as to what the tribunal might have been thinking. This is particularly so where the reasons are silent on a critical issue. It is ironic that *Newfoundland Nurses*, a case which at its core is about deference and standard of review, is urged as authority for the supervisory court to do the task that the decision maker did not do, to supply the reasons that might have been given and make findings of fact that were not made. This is to turn the jurisprudence on its head. *Newfoundland Nurses* allows reviewing courts to connect the dots on the page where the lines, and the direction they are headed, may be readily drawn . . . . (*Vavilov* at para 97).

[138] This guidance concerns cases where reasons are indeed given by the administrative decision-maker.

[139] The Supreme Court also provided some helpful, albeit summary, guidance on how reasonableness review should be conducted in the *absence* of formal reasons. The Court first notes that formal reasons are not always required or necessary:

> Administrative decision makers are not required to engage in a formalistic statutory interpretation exercise in every case. As discussed above, formal reasons for a decision will not always be necessary and may, where required, take different forms. And even where the interpretive exercise conducted by the administrative decision maker is set out in written reasons, it may look quite different from that of a court. The specialized expertise and experience of administrative decision makers may sometimes lead them to rely, in interpreting a provision, on considerations that a court would not have thought to employ but that actually enrich and elevate the interpretive exercise (*Vavilov* at para 119).

[140] Under the header "Review in the Absence of Reasons," the Supreme Court provides the following additional guidance:

> [136] Where the duty of procedural fairness or the legislative scheme mandates that reasons be given to the affected party but none have been given, this failure will generally require the decision to be set aside and the matter remitted to the decision maker: see, e.g., *Congrégation des témoins de Jéhovah de St-Jérôme-Lafontaine*, at para. 35. Also, where reasons are provided but they fail to provide a transparent and intelligible justification as explained above, the decision will be unreasonable. In many cases, however, neither the duty of procedural fairness nor the statutory scheme will require that formal reasons be given at all: *Baker*, at para. 43.
>
> [137] Admittedly, applying an approach to judicial review that prioritizes the decision maker's justification for its decisions can be challenging in cases in which formal reasons have not been provided. This will often occur where the decision-making process does not easily lend itself to producing a single set of reasons, for example,

> where a municipality passes a bylaw or a law society renders a decision by holding a vote: see, e.g., *Catalyst*; *Green*; *Trinity Western University*. However, even in such circumstances, the reasoning process that underlies the decision will not usually be opaque. It is important to recall that a reviewing court must look to the record as a whole to understand the decision, and that in doing so, the court will often uncover a clear rationale for the decision: *Baker*, at para. 44. For example, as McLachlin C.J. noted in *Catalyst*, "[t]he reasons for a municipal bylaw are traditionally deduced from the debate, deliberations, and the statements of policy that give rise to the bylaw": para. 29. In that case, not only were "the reasons [in the sense of rationale] for the bylaw . . . clear to everyone", they had also been laid out in a five-year plan: para. 33. Conversely, even without reasons, it is possible for the record and the context to reveal that a decision was made on the basis of an improper motive or for another impermissible reason, as, for example, in *Roncarelli*.
>
> [138] There will nonetheless be situations in which no reasons have been provided and neither the record nor the larger context sheds light on the basis for the decision. In such a case, the reviewing court must still examine the decision in light of the relevant constraints on the decision maker in order to determine whether the decision is reasonable. But it is perhaps inevitable that without reasons, the analysis will then focus on the outcome rather than on the decision maker's reasoning process. This does not mean that reasonableness review is less robust in such circumstances, only that it takes a different shape.

[141] However, these comments should be understood in the broader context of how the *Vavilov* decision affected reasonableness review. The guidance cited above is an exception to the rule that decision-makers must justify their decisions, and one which does not necessarily require the Court to move away from the broader principles set out in *Vavilov. Vavilov* generally *limited* the extent to which courts, on judicial review, can look to the outcome of a decision to justify its reasonableness, in the absence of adequate reasons or information that demonstrate how the decision was reached (*Vavilov* at paras 15, 82-87, 96-98; see also Donald JM Brown & John M Evans, *Judicial Review of Administrative Action in Canada* (Toronto: Thomson Reuters, 2009)

(loose-leaf updated 2020), “View from the Top: Administrative Law in the Supreme Court of Canada”).

[142] At paragraph 87, the Supreme Court specifically notes that its “jurisprudence since *Dunsmuir* should not be understood as having shifted the focus of reasonableness review away from a concern with the reasoning process and toward a nearly exclusive focus on the *outcome* of the administrative decision under review.”

[143] At paragraph 98, the Court adds: “Where a decision maker’s rationale for an essential element of the decision is not addressed in the reasons and cannot be inferred from the record, the decision will generally fail to meet the requisite standard of justification, transparency and intelligibility.”

[144] As a result, looking to the record to understand an administrative decision is not tantamount to speculating as to the decision-maker’s reasoning process.

[145] While *Vavilov* limited the extent to which courts can look to the record to supplement deficient reasons and provided some guidance on conducting reasonableness review in the absence of reasons, the decision did not change the rest of the existing framework for conducting reasonableness review in the absence of formal reasons or with limited reasons.

[146] As the Supreme Court’s comments on these issues have yet to be fully fleshed out by lower courts, and given my conclusions in the previous paragraph, I find it necessary to consider

how the Federal Court of Appeal has interpreted and set out the framework for reasonableness review in the absence of (adequate) reasons before *Vavilov*.

[147] The Federal Court of Appeal first had an opportunity to clarify and set out the applicable framework following the Supreme Court's decision in *Dunsmuir v New Brunswick*, 2008 SCC 9. In a unanimous decision in *Vancouver International Airport Authority v Public Service Alliance of Canada* (2010 FCA 158) [*Vancouver International Airport Authority*], Justice Stratas of the Federal Court of Appeal writes:

> [17] The reasons of administrative decision-makers in situations such as this must fulfil these purposes at a minimum. As courts assess whether these purposes have been fulfilled, there are a number of important principles, established by the authorities, to be kept firmly in mind:
>
> > (a) *The relevancy of extraneous material.* The respondent emphasized that information about why an administrative decision-maker ruled in the way that it did can sometimes be found in the record of the case and the surrounding context. I agree. Reasons form part of a broader context. Information that fulfils the above purposes can come from various sources. For example, there may be oral or written reasons of the decision-maker and those reasons may be amplified or clarified by extraneous material, such as notes in the decision-maker's file and other matters in the record. Even where no reasons have been given, extraneous material may suffice when it can be taken to express the basis for the decision. *Baker*, *supra*, provides us with a good example of this, where the Supreme Court found that notes in the administrative file adequately expressed the basis for the decision. See also *Hill v. Hamilton-Wentworth Police Services Board*, [2007] 3 S.C.R. 129 at paragraph 101 for the role of extraneous materials in the assessment of adequacy of reasons.

(b) *The adequacy of reasons is not measured by the pound.* The task is not to count the number of words or weigh the amount of ink spilled on the page. Instead, the task is to ask whether reasons, with an eye to their context and the evidentiary record, satisfy, in a minimal way, the fundamental purposes, above. Often, a handful of well-chosen words can suffice. In this regard, the respondent emphasized that very brief reasons with short-form expressions can be adequate. That is true, as long as the fundamental purposes, above, are met at a minimum. In this regard, the respondent cited the example of the Board sometimes issuing orders without reasons. Whether such orders are adequate depends on the facts of a specific case, but the methodology for assessing adequacy is clear: the preambles, recitals and provisions of the orders, when viewed with an eye to their context and the evidentiary record, must satisfy, in a minimal way, the fundamental purposes, above.

(c) *The relevance of Parliamentary intention and the administrative context.* Judge-made rulings on adequacy of reasons must not be allowed to frustrate Parliament's intention to remit subject-matters to specialized administrative decision-makers. In many cases, Parliament has set out procedures or has given them the power to develop procedures suitable to their specialization, aimed at achieving cost-effective, timely justice. In assessing the adequacy of reasons, courts should make allowances for the "day to day realities" of administrative tribunals, a number of which are staffed by non-lawyers: *Baker*, *supra* at paragraph 44; *Clifford v. Ontario Municipal Employees Retirement System* (2009), 98 O.R. (3d) 210 at paragraph 27 (C.A.). Allowance should also be given for short-form modes of expression that are rooted in the expertise of the administrative decision-maker. However, these allowances must not be allowed to whittle down the standards too far. Reasons must address fundamental purposes – purposes that, as we have seen, are founded on such fundamental principles as accountability, the rule of law, procedural fairness, and transparency.

> (d) *Judicial restraint.* The court's assessment of reasons is aimed only at ensuring that legal minimums are met; it is not an exercise in editorial control or literary criticism. See *Sheppard*, *supra* at paragraph 26.
>
> [18] In the above statement of purposes and principles, nothing should be taken to encourage administrative decision-makers to aim only for the legal minimums, and no higher. Administrative decision-makers should strive to follow best practices so that the public gets the service it deserves, including providing exemplary reasons of high standard: for an example of one authority's helpful view of best practices, see Ombudsman Saskatchewan, *Practice Essentials for Administrative Tribunals* (2009), online: Ombudsman Saskatchewan <http://www.ombudsman.sk.ca/uploads/document/files/omb-tribunal-guide_web-en-1.pdf>.

[148] While the record before the decision-maker can be of assistance, the reasons, when they exist, must nonetheless express why the decision-maker made their conclusions. The sufficiency of the reasons is context-specific and should be assessed with a view to the fact that administrative law often seeks to create simpler and more cost-effective ways of accessing justice.

[149] Nonetheless, as Justice Stratas briefly notes, there is a limit to how brief a decision-maker's reasons can be. The Court must always be able to exercise its supervisory function and assess the reasonableness of the decision.

[150] When applying these principles to the facts in *Vancouver International Airport Authority*, Justice Stratas reiterates the underlying purpose of ensuring that the Court can supervise administrative decision-makers, in contrast to a "trust us, we got it right" approach. Indeed,

without these principles, decision-makers could actively seek to limit the length and detail of their reasons precisely to avoid scrutiny:

> [20] In 13 of the 23 positions found to be in the bargaining unit, the Board simply wrote that "there is no basis to exclude given the job duties," "there is no basis in the information supplied to exclude the position from the unit," or "job duties do not require exclusion." Did the Board apply any principles in these rulings? If so, what are the principles? It is a mystery. The applicants have no idea why they lost, they cannot meaningfully assess whether a judicial review is warranted or formulate any grounds for it in the case of these 13 positions, this Court is unable to conduct any meaningful supervisory role, and there is no transparency, justification or intelligibility in the senses set out above. All we have are conclusions, laudably definitive, but frustratingly opaque.
>
> [21] In effect, for these 13 positions, the Board is telling the parties, this Court, and all others, "Trust us, we got it right." In this regard, this case is strikingly similar to *Canadian Association of Broadcasters, supra*, where the administrative decision-maker asserted a bottom-line conclusion with no supporting information, in effect immunizing itself from review and accountability.

[151] Again in *Vancouver International Airport Authority*, Justice Stratas finds that the reasons at issue, even while they provide some detail (a "hint"), are insufficient. Justice Stratas further sets out another important principle in the case: arguments regarding the burden imposed in requiring more detailed reasons will often fail, as this burden generally only involves adding several words or sentences. He states:

> [22] In 6 of the 23 positions found to be in the bargaining unit, the Board offered slightly more than a bare conclusion in support of its ruling. On these occasions, the Board included a position in the bargaining unit because it was "at the same level on the organizational chart" or because it was similar, for some undisclosed reason, to a position in the bargaining unit. What was it about the level on the organizational chart or the particular position that led to this conclusion? It is a mystery. In effect, the Board is saying, "Trust us, but here is a hint." But the hint does not shed light on the bases for its decision.

[23] The respondent gamely attempted to support the reasons of the Board, sparse as they are. It emphasized that the principles that the Board normally employs in cases such as this one are fairly well-developed and understood by many employers, unions and observers of this area of law. Further, a fairly large number of positions, 66, were in issue, each involving highly specific facts. The respondent stressed that care must be taken not to impose too high an obligation to provide reasons on the Board, affecting its ability to operate efficiently.

[24] I accept that these factors can influence the Court's assessment of the adequacy of the Board's reasons. These factors speak to the issue of whether some allowance should be given to reflect the practical, daily realities that this administrative decision-maker must face. But the fundamental purposes underlying the adequacy of reasons, such as the transparency concern and the supervisory concern, must still be addressed at a minimum. The Board's obligation to write adequate reasons and address fundamental purposes cannot be reduced to naught.

[25] In this case, the purposes underlying the requirement of adequate reasons could have been met without any difficulty, consistent with the practical realities facing the Board. With just a handful of words – "Throughout this decision, we apply the principles in [case name]" – the Board could have shown that it was following some principle. From there, the Board might have written a sentence or two to identify how the principle applies to each position, or to groups of positions that raise similar considerations. A sentence or two, sitting alongside the record in this case, might have disclosed exactly why the Board ruled in the way it did, and might have addressed all of the fundamental concerns underlying the provision of adequate reasons.

[26] So far, I have dealt with 19 of the 23 positions that the Board included into the bargaining unit. In the case of the remaining four positions, "payroll assistant," human resource advisor," "contracts manager," and "project manager," the Board did write a sentence or two. But the bases identified in those sentences seem to conflict with the bases provided for exclusion of other positions: sometimes one factor is determinative, other times an entirely different factor seems determinative. The salient concern here is intelligibility. A single paragraph, perhaps at the start of the reasons could have set out the operative principles to be followed along with governing authority. Then the Board's "sentence or two" approach might have been perfectly adequate. It might have met any intelligibility concerns by eliminating any apparent inconsistency in principle.

> [27] As for extraneous material, it is of no assistance in understanding the Board's reasons. In the circumstances of this case and given the sparseness of the Board's reasons, it is impossible to see anything in the evidentiary record, including the investigation report, as helping to supply a rationale for the Board's decision. It was open to the Board to adopt, through express language or by implication, portions of the record as a basis for its conclusions (see *Sketchley*, *supra* at paragraph 37), but the Board did not do this.

[152] These principles have been repeatedly confirmed in subsequent case law, often with reference to *Vancouver International Airport Authority*.

[153] In *Canada (Attorney General) v Franchi* (2011 FCA 136), a unanimous Federal Court of Appeal confirmed the underlying objective of ensuring that courts can properly supervise administrative decision-makers (at para 36 ["[t]he duty of fairness requires that the reasons of an administrative tribunal must be sufficient to inform the parties and the public of the basis of its decision, to enable the parties to decide whether to pursue an appeal or an application for judicial review, and to equip the reviewing court to perform its function"]). The Court also confirmed that the record can be used in assessing the decision (at para 37) and that reasons can sometimes be brief (at para 41).

[154] In *Stemijon Investments Ltd v Canada (Attorney General)* (2011 FCA 299), a unanimous Court again confirmed that the record can assist in understanding the reasons of an administrative decision-maker (at paras 36-39). However, the Court essentially noted that the record has to point in a particular direction. Otherwise, it cannot help courts understand the reasons. The Court states: "[S]ometimes the record is of no assistance. That is the case here. While the Minister had a broad record before him, his decision letter shows no awareness that he

could go beyond the Information Circular. To the contrary, his decision letter shows an understanding – faulty – that he was governed exclusively by the Information Circular. Further, as explained in paragraph 32, above, the Minister did not seem to have full and accurate regard to key portions of the record before him, namely the explanations and justifications in letters sent by the appellants. In such circumstances, resort to the record to explain why the Minister decided in the way that he did is not possible" (at para 38).

[155] In *Leahy*, the Federal Court of Appeal (again unanimously) availed itself of the opportunity to reiterate and further develop the principles set out *Vancouver International Airport Authority*. *Leahy* arguably became the leading case on these issues.

[156] In *Leahy*, the Court reiterates the role of Court in supervising administrative decision-makers: "The role of the reviewing court on judicial review is well-known. It is to enforce the rule of law: *Dunsmuir* at paragraphs 27 to 33. Broadly speaking, this means that the reviewing court must ensure that the administrative decision-maker has embarked upon the task entrusted to it and has carried it out in a legally acceptable way" (at para 117; see also para 122). This is so regardless of whether the correctness or the reasonableness standard of review applies (at para 118). The Court again rejects what Justice Stratas referred to as a "trust us, we got it right" approach: "In the circumstances of this case explained above, with such little information in the reasons and the record, that is equivalent to an assertion that this Court should just accept the decisions, not test them. In effect, the Crown's submission is 'trust us, we got it right.' Acceptance of that submission is inconsistent with our role on judicial review" (at para 137).

[157] The Court also reiterates that the reasons (and the record, where applicable) should shed light on the decision-maker's reasoning process: "If the reasons for decision are non-existent, opaque or otherwise indiscernible, and if the record before the administrative decision-maker does not shed light on the reasons why the administrative decision-maker decided or could have decided in the way it did, the requirement that administrative decisions be transparent and intelligible is not met" (at para 121; see also para 124). The Court referred to the then recent case of *Newfoundland Nurses* (decided after *Vancouver International Airport Authority*).

[158] Finally, the Court makes comments similar to those of Justice Stratas in *Vancouver International Airport Authority* regarding the burden imposed on decision-makers. The Court finds that providing adequate reasons generally only involves adding limited additional information:

> [141] To reiterate, all that is needed is sufficient information for a reviewing court to discharge its role. In cases like this, this can be achieved by ensuring that there is information in the decision letter or the record that sets out the following: (1) who decided the matter; (2) their authority to decide the matter; (3) whether that person decided both the issue of the applicability of exemptions and the issue whether the information should, as a matter of discretion, nevertheless be released; (4) the criteria that were taken into account; and (5) whether those criteria were or were not met and why.
>
> [142] In many cases, in perhaps no more than a few lines, the decision letter can address items (1), (2) and (3).
>
> [143] Similarly, it is an easy matter for the decision letter to address item (4). This could be accomplished by referring to a single case that sets out the criteria, or to an internal policy statement or instructional document used by the decision-maker and those making recommendations to the decision-maker. Normally, reviewing courts do not take judicial notice of internal policy statements or instructional documents, so if these are relevant, they should be identified and appended to the supporting affidavit.

> [144] As for item (5), this may be evident from the documents themselves which have not been disclosed to the requester but which have been included in a confidential record, or from any annotations made on the documents when information is expunged which appear in the public record. On occasion, a supporting affidavit can be sworn. It can supply additional information that is not evident in the record and known to the decision-maker. For example, with respect to the documents said to be covered by solicitor-client privilege in this case, the affidavit should have identified which persons are lawyers and dealt with whether the confidentiality of the documents was maintained.

[159] The same principles were again confirmed in *Kabul Farms*. The Court found that the decision and the evidentiary record "sheds no light on the matter" (at para 34). As a result, the Court could not fulfill its supervisory role: "To conduct reasonableness review here, we would have to simply assume or trust that the Director had good reasons for the numbers he chose. As this Court said in *Leahy* (at para. 137), that 'is inconsistent with our role on judicial review.' We are to review, not trust or assume" (at para 34). The Court noted that the record generally cannot be supplemented on judicial review to interpret the decision-maker's reasoning or rationale (at paras 36 and following). The Court also again rejected the argument that requiring the administrative decision-maker to write more detailed reasons would hinder their work or be inconsistent with the efficiency of administrative justice: "But nothing said above comes even close to hindering the Director in his work. In this case, jotting down a few words of explanation in the Director's summary of calculation about why he chose the figures for the base amounts and reductions—something that would perhaps have taken a few seconds—probably would have sufficed as far as enabling this Court to review the Director's assessment of penalties is concerned" (at para 49).

[160] The same principles were also confirmed and applied by the Federal Court of Appeal in *Tsleil-Waututh Nation v Canada (Attorney General)*, 2017 FCA 128 (at paras 67-85), *Cold Lake*

First Nations v Noel, 2018 FCA 72 (at paras 26-45), and *Sharif v Canada (Attorney General*, 2018 FCA 205 (at paras 31-37).

[161] I mentioned above that, while *Vavilov* limited the extent to which courts can look to the record to supplement deficient reasons and provided guidance on conducting reasonableness review in the absence of reasons, the decision did not appear to change the rest of the existing framework for conducting reasonableness review in the absence of formal reasons or with limited reasons. It should also be noted the Federal Court of Appeal, ostensibly coming to the same conclusion, applied the major principles I set out above (originating pre-*Vavilov*) in recent, post-*Vavilov* decisions, such as *Canada (Citizenship and Immigration) v Canadian Council for Refugees*, 2021 FCA 72 (at paras 105-107) and *Canada (Attorney General) v Kattenburg*, 2021 FCA 86 (at paras 9-10, 16-17).

B. *The Hospira 2015 Decision*

[162] The AGC and Médunik submit that their proposed interpretation and past practices were found to be reasonable and correct by the Court in *Hospira 2015*. They point in particular to the proposition that the prohibition on comparative submissions applies at the time of filing, and to the amendment check outlined at paragraph 45 of Dr. Cann's affidavit.

[163] As mentioned earlier, per Dr. Cann's testimony, when conducting final IP Check, OSIP examines if an innovative drug has been listed on the Register of Innovative Drugs since the NDS was submitted. If the search yields an innovative drug, the OSIP then checks whether, after the innovative drug's approval and marketing, the NDS was amended such that the approval of

the drug was being sought and recommended on the basis of a newly-introduced comparison to the now-approved and marketed innovative drug.

[164] Where such an amendment (an amendment that post-dates the innovative drug's NOC issuance) results in such a comparison (a comparison that is the basis of the new drug's approval), the data protection provisions are triggered, and the OSIP places the NDS on intellectual property hold until the expiry of the innovative drug's data protection term.

[165] In *Hospira 2015*, the Applicant, Hospira Healthcare Corporation [Hospira] challenged the Minister's decision refusing to issue it a NOC for its product. The Minister had found that Hospira had sought its NOC on the basis of a direct or indirect comparison to Sanofi-Aventis Canada's innovative drug and the Minister had therefore applied the data protection provisions of the *Food and Drug Regulations* and refused the NOC.

[166] Similar to the situation of Catalyst and Médunik in these proceedings, in *Hospira 2015*, both Hospira and Sanofi-Aventis filed their NDSs one month apart in 2006, Hospira having filed its NDS first, although only Sanofi-Aventis' NDS was granted priority status.

[167] There is no mention that Hospira made any reference to Sanofi-Aventis' product at the time of the filing. In fact, Hospira's NDS was rejected at the screening stage, without a substantive review because no pre-clinical or clinical data had been submitted, only literature and reports of post-marketing experience.

[168] A NOC was issued to Sanofi-Aventis' product on June 15, 2007.

[169] Hospira challenged the Minister's decision to reject its NDS at the screening stage. Ultimately, the Federal Court of Appeal sent the file back to the Minister for a redetermination, finding that, based on the ambiguity in the Minister's reasons, it was unclear whether his decision (to determine the nature and form of the information that will be accepted as meeting the requirements of safety and effectiveness) was mindful and made pursuant to the discretion in question or rather the result of a wrong interpretation of those provisions (*Hospira* 2015 at para 20).

[170] In 2011, Hospira's NDS, per the Federal Court of Appeal's decision, was thus reconsidered and ultimately found acceptable for examination, although keeping the initial filing date in 2006. After completion of Hospira's NDS, the Minister issued a Notice of Noncompliance. As confirmed at paragraph 8 of the decision, in such cases, the manufacturer may amend its NDS.

[171] In 2012, in response to the Notice of Noncompliance, Hospira amended its submission and, relevant to these proceedings, indicated that the basis for the request for approval included a *reference* to the Summary Basis of Decision for Sanofi-Aventis' product and to Sanofi-Aventis' Canadian Product Monograph.

[172] There was no question that Hospira's amendment occurred after the NOC had been issued to Sanofi-Aventis for its innovative drug. Interestingly, the Minister's decision to deny

Hospira its NOC appeared to be based on Hospira's *references* to Sanofi-Aventis' material (para 64) and it was not contested that these references constituted a direct or indirect comparison.

[173] The Court first had to decide whether the Minister had breached procedural fairness by failing to inform Hospira earlier that his interpretation of the data protection provisions would prevent the issuance of the NOC. As part of the examination of this question, the Minister outlined the verification process between the assessment of the drug's safety and efficacy and the assessment of the data protection provisions to stress that no decision is made on the latter before the former is completed. Ms. Bowes testified in this regard.

[174] The Court indicated that the second issue was not whether or not Hospira's NDS or supplement to NDS makes a direct or indirect comparison between its drug and Sanofi-Aventis' , as that fact was not contested and as the evidence supported the finding that it was a direct comparison. The Court framed the issue as whether the data protection provisions applied to "post-filing amendments made pursuant to subsection C.08.004(2) [of the *Food and Drug Regulations*]."

[175] The Court decided it was clear that post-filing amendments are subject to the data protection prohibition imposed on the Minister by paragraph (b) of subsection C.08.004.1(3).

[176] However, I have found no indication that either the amendment check process or the proposition that the prohibition of comparison applies at the time of filing was examined in the *Hospira 2015* decision.

[177] I can only conclude, from *Hospira 2015*, that a post-filing amendment is subject to the data protection provisions. This is not at play in these proceedings.

C. *Discussion*

[178] In brief, I agree with the Applicants that the record precludes reasonableness review. The Minister is not required to provide reasons, but the Court is here left with no reasons while no rationale emerges from reviewing the record. In the absence of such information, the Court cannot perform its role on judicial review (*Kabul Farms*).

[179] Furthermore, I am not convinced that the OSIP IP verification process detailed by Dr. Cann accords with the text and context of the data protection provision of the *Food and Drug Regulations*, and I have already outlined that the decision of the Court in *Hospira 2015* does not address the process at play in these processings nor, needless to say, does it condone it.

[180] However, even if I were so convinced, I must conclude there is no indication in the record that this process was in fact applied by the Minister before approving the RUZURGI NOC. On the contrary, the evidence shows that:

a) Dr. Cann could not confirm if the CTR comprises all the documents the decision-maker considered, or that the decision-maker actually considered all of the documents found in the CTR;

b) Dr. Cann was not involved in the decision and could not testify to the reasons leading to the RUZURGI approval despite FIRDAPSE's new status as an innovative drug;

c) At the time of the RUZURGI NDS filing, its preliminary DPEA does mention a "reference" to FIRDAPSE's data (the same term was used in *Hospira 2015*);

d) The RUZURGI preliminary DPEA also indicates that FIRDAPSE is inactive;

e) Dr. Cann confirmed that the OSIP relied on this preliminary DPEA for RUZURGI's final IP check, as the final DPEA is conducted after the NOC issued;

f) Dr. Cann confirmed that, at the time of filing, and since there was no innovative drug on the Register of Innovative Drugs, OSIP did not examine whether the RUZURGI NDS was *made on the basis of a direct or indirect comparison with an innovative drug*;

g) Dr. Cann confirmed that OSIP did not verify FIRDAPSE's marketing status at any time during the RUZURGI NDS assessment, and also confirmed that she did not know what "marketing" referred to exactly, despite the AGC and Médunik's assertion that subsection C.08.004.1(5) of the *Food and Drug Regulations* must be interpreted as subjecting the application of the data protection provisions to a marketing requirement;

h) The CTR contains no mention of FIRDAPSE's data protection prior to the August 13, 2020 printout, although Dr. Cann confirmed that the CTR includes the documents consulted before the RUZURGI NOC was issued;

i) The FIRDAPSE final DPEA, dated August 10, 2020, is not in the CTR;

k) Various key documents originating from Health Canada as part of the RUZURGI NDS process (Manager Memo – Clinical of July 31, 2020; Pharmaceutical Submission Executive Summary of August 5, 2020) confirm there were, as of then, no drugs approved in Canada, despite a NOC having been issued to Catalyst for FIRDAPSE on July 31, 2020; these can hardly be qualified as missteps (as Médunik submits);

l) The RUZURGI SBD of October 2020 repeated this statement, more than two months after FIRDAPSE was approved and granted innovative drug status;

m) The FIRDAPSE final DPEA, confirming that it will be placed on the Register of Innovative Drugs is dated August 10, 2020, and the snapshot of the Register provided by the Minister is dated August 13, 2020-; it is thus not impossible that a search of the Register, assuming it was conducted as part of the RUZURGI amendment check (on or before August 10, 2020) would not have detected FIRDAPSE as listed as an innovative drug;

n) In other words, there is no indication that a search of the Register of Innovative Drugs, conducted on or before August 10, 2020, would have yielded FIRDAPSE as an innovative drug, and Dr. Cann's affirmation that it was essentially unnecessary for OSIP to search and rely on the Register because the same people were working on the review of both NDSs and knew "what's in the pipeline" (AR at page 2538) remains unsubstantiated and, in any event, is unsupported by the *Food and Drug Regulations*. It is troublesome that key RUZURGI documents do, on the contrary, confirm no drug had been approved;

o) Dr. Cann confirmed that OSIP does not follow its own final IP verification process (as outlined by her), as the final DPEA is actually conducted *after* the NOC is approved;

p) Assuming that OSIP employees did not, as the process dictates, rely on the search of the Register of Innovative Drugs and that they did know an innovative drug had been approved, there is no indication in the record that they conducted the amendment check, i.e. verified if Médunik amended its RUZURGI NDS after July 31, 2020;

q) We now know that no such amendments were made, but the CTR makes no reference to this amendment check having been conducted;

r) Assuming the check was conducted, there is no information in the record as to whether someone verified if the NDS was approved on the basis of a direct or indirect comparison, nor as to how this standard was interpreted by the Minister;

s) There is no indication, as the parties submit, that there is no protection for "disclosed" data or that not all references can be considered comparisons. More importantly, there is also no indication the Minister made the assumptions or interpretations;

t) There is no indication that the Minister interpreted the *Food and Drug Regulations* in the manner suggested by the Respondents, i.e. that a reference or even comparison made prior to the designation of an innovative drug is not captured by the data protection provisions;

u) Dr. Cann confirmed that no verification were made to determine FIRDAPSE's marketing status.

[181] The AGC recognises the weaknesses in the record, but essentially asks the Court to draw an inference from the fact that (1) the IP Check process is recognised, and, since the NOC was issued to RUZURGI, the process was followed; and (2) the same persons were conducting both NDS reviews, and they knew FIRDAPSE had been approved;

[182] First, as stated earlier, I cannot find the IP process described in these proceedings to have been recognised by the Court in *Hospira 2015*.

[183] Second, the inference that, since the NOC was issued to RUZURGI, the process was followed is unconvincing. It essentially amounts to what Justice Stratas refers to as a "trust us, we got it right" approach. The consistent and unequivocal case law from the Federal Court of

Appeal cited above makes clear that this approach is impermissible and prevents the Court from exercising its supervisory role on judicial review.

[184] Furthermore, Dr. Cann did not attach to her affidavit procedures or internal documents that would substantiate the IP verification process she outlines (*Vancouver International Airport Authority*). Instead, there are multiple indications the process was not followed.

[185] Third, the same employees may have been conducting both NDS reviews, but given the record, we simply cannot know if they considered, at the time RUZURGI was approved, that another drug had been approved and recognised as an innovative drug. Faced with a record that unequivocally states, on and after July 31, 2020, that no drug had yet been approved in Canada, it is impossible to draw the inferences suggested by the AGC. The few abbreviated pieces of information contained in the snapshots do not displace this finding.

[186] The Court cannot conduct a reasonableness review and find the decision reasonable in the absence of reasons, and when the record contains no indication of the actual process or interpretation applied by the decision-maker. There is simply no clear trace of any of FIRDAPSE's data protection documentation in the RUZURGI process. The evidence in the record indicates that the decision-maker had incorrect information (as of July 31 and August 5, 2020), i.e., that no drug had been approved at the time Health Canada was approving the RUZURGI NDS, that FIRDAPSE's status as an innovating drug was not actually listed on the Register of Innovative Drugs before August 10, 2020, and that it was listed on August 13, 2020.

[187] I have no indication that the Minister's interpretation of the data protection provisions as presented to the Court, whether it is the proper one or not, is in fact the one that was applied, assessed, and considered prior to approving the RUZURGI NDS. (To avoid confusion, I use the word "improper" instead of "incorrect.")

[188] The Respondents ask the Court to adhere to the interpretation provided by Dr. Cann and to infer, assuming it is even proper, that the Minister followed it – all in the absence of any indication of the Minister's actual interpretation of the Regulations at the time the Decision was made.

[189] The role of the Court on judicial review is not to provide the decision-maker the proper interpretation of the *Food and Drug Regulations*. It is to control if the decision-maker's interpretation is reasonable or correct, as the case dictates. As mentioned above, this role has not significantly changed since *Vavilov.* There is here no indication, in the decision or in the record, that the verification process and the regulatory interpretation advanced by the Respondents is in fact the one that was adopted and applied by the Minister when it issued Médunik its NOC.

VIII. Conclusion

[190] Given the facts of the case, I am unable to control the Minister's Decision.

[191] Following the guidance of the Supreme Court in *Vavilov* and of the Federal Court of Appeal, in the absence of reasons in the Decision, I must look to the record to determine whether the Minister's interpretation and application of the law was reasonable. Here, the record does not

assist me in determining how the Minister interpreted the *Food and Drug Regulations*, or whether the Minister even considered the relevant provisions.

[192] As the record does not permit me to review the Minister's Decision, I cannot assume that his interpretation is reasonable or speculate as to what that interpretation may be. I have no other choice than to quash the Decision.

IX. Remedies

[193] Given my conclusions, I cannot control the Minister's Decision. I will therefore quash the Minister's Decision (the RUZURGI NOC) and send the matter back to the Minister for redetermination.

[194] The parties have much debated the proper interpretation of the *Food and Drug Regulations*, and Catalyst seek directions from the Court to the Minister, to the effect that (1) the amendment check process conducted by Health Canada is flawed; (2) Health Canada should not require *reliance* on a comparison with an innovative drug for the data protection provisions to be triggered; and (3) the application of the data protection provisions is not limited to undisclosed information.

[195] However, as mentioned above, I have no indication that these interpretations, which Catalyst labels as improper, were in fact the Minister's interpretations at the time the decision was made. I have no indication of how the Minister did interpret the *Food and Drug Regulations*.

In this context, it is particularly inappropriate for the Court to provide interpretive guidance to the Minister.

[196] Catalyst's request is inconsistent with the Supreme Court's guidance in *Vavilov*. Indeed, when the reasonableness standard of review is applied, the Court's focus must be "on the decision actually made by the decision-maker, including both the decision maker's reasoning process and the outcome" (at para 83) to 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" (at para 85).

[197] Under *Vavilov*, it is not for the Court to substitute its preferred outcome (at para 99). I will thus decline Catalyst's invitation.

X. Costs

[198] As for costs, Catalyst requested a lump sum award of $100,000, plus disbursements, which Catalyst submits is a "small fraction" of the Applicants' actual costs.

[199] The AGC requested costs in accordance with Column V of Tariff B of the Rules. The AGC does not seek disbursements.

[200] Médunik requested costs in accordance with the mid range of Column V of Tariff B of the Rules, plus disbursements. Médunik submits that the criteria for a lump sum award are not met, given that (1) it was not request in the Notice of Application or the Applicants'

Memorandum; (2) in the cases cited by the Applicants, costs were likely not awarded as a lump sum; (3) the case law on lump-sum awards in patent actions does not apply to a judicial review; (4) this case considers a novel issue of public importance (the interpretation of the phrase “on the basis of a direct or indirect comparison”); and (5) the parties’ litigation conduct was not vexatious or improper.

[201] I note that Catalyst has submitted no evidence to support its claim for a lump sum representing but a “small fraction” of actual costs. I am cognizant of the case law allowing for costs to be granted on a lump sum-basis but find it cannot be applied in the present circumstances.

[202] I will therefore award costs in favor of the Applicants, in accordance with the mid-range of Column V of Tariff B of the Rules.

JUDGMENT in T-984-20

THIS COURT'S JUDGMENT is that:

- The reply affidavit of Mr. Douglas Reynolds is admitted into evidence, save for paragraph 4 of the affidavit;
- The Application for judicial review is granted;
- The Minister's Decision of August 10, 2020 is set aside;
- The file is sent back to the Minister for a new determination;
- Costs in accordance with the mid-range of Column V of Tariff B of the Rules, are granted in favour of the Applicants.

"Martine St-Louis"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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APPEARANCES:

Me Yael Bienenstock Ms. Alexandra Peterson	FOR THE APPLICANTS
Me Jason Markwell	FOR THE RESPONDENT: MÉDUNIK
Me Amy Tang	FOR THE RESPONDENT: MÉDUNIK
Me John Lucki	FOR THE RESPONDENT: AGC
Ms. Karen Lovell	FOR THE RESPONDENT: AGC
Ms. Leah Bowes	FOR THE RESPONDENT: AGC

SOLICITORS OF RECORD:

Torys LLP Barrister and Solicitor Toronto, Ontario	FOR THE APPLICANTS
Fasken, Martineau, DuMoulin LLP	FOR THE RESPONDENT: MÉDUNIK
Toronto, Ontario	FOR THE RESPONDENT: MÉDUNIK
Attorney General of Canada Toronto, Ontario	FOR THE RESPONDENT: AGC