Federal Court of Appeal | Cour d'appel fédérale

Date: 20230109

Docket: A-78-22

Citation: 2023 FCA 3

CORAM: **LOCKE J.A.**
MACTAVISH J.A.
MONAGHAN J.A.

BETWEEN:

ATTORNEY GENERAL OF CANADA

Appellant/
Respondent on the Cross-Appeal

and

CATALYST PHARMACEUTICALS, INC.,
KYE PHARMACEUTICAL INC.

Respondents/
Appellants on the Cross-Appeal

and

MÉDUNIK CANADA

Respondent

Heard at Toronto, Ontario, on November 28, 2022.

Judgment delivered at Ottawa, Ontario, on January 9, 2023.

REASONS FOR JUDGMENT BY: LOCKE J.A.

CONCURRED IN BY: MACTAVISH J.A.
MONAGHAN J.A.

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REASONS FOR JUDGMENT

LOCKE J.A.

I. Background

[1] This decision concerns an appeal and a cross-appeal from a decision of the Federal Court (*per* Justice Martine St-Louis, 2022 FC 292, the Decision) that granted an application for judicial review of a decision of the Minister of Health (the Minister), setting aside the Minister's decision and remitting the matter for a new determination. The Attorney General of Canada (the Attorney General) appeals on the basis that the Minister's decision should not have been set aside. Catalyst Pharmaceuticals, Inc. and Kye Pharmaceutical Inc. (collectively, Catalyst) cross-appeal on the basis that the Federal Court should not have remitted the matter for a new determination, and instead should have decided the matter in their favour.

[2] The impugned decision of the Minister concerned a new drug submission (NDS) by Médunik Canada (Médunik) for its drug RUZURGI (for treating Lambert-Eaton myasthenic syndrome, or LEMS), and whether section C.08.004.1 of the *Food and Drug Regulations*, C.R.C., c. 870, and specifically paragraph C.08.004.1(3)(b), applied to prevent the Minister from issuing a notice of compliance (NOC) granting Médunik permission to enter the market with RUZURGI. Section C.08.004.1 of the *Food and Drug Regulations* creates a regime that limits the right of a drug manufacturer to obtain an NOC for a new drug based on a comparison with an innovative drug. This is known as the data protection regime. This regime differs from the patent regime in that it does not provide for exclusive use of the innovative drug. Rather, it limits the

use of data submitted by the manufacturer of the innovative drug. Subsection C.08.004.1(3) of the *Food and Drug Regulations* reads as follows:

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

[3] Catalyst and Médunik filed separate NDSs for drugs with similar ingredients on November 6, 2019 and December 20, 2019, respectively. Catalyst's drug is called FIRDAPSE and it employs a phosphate salt called amifampridine phosphate instead of the free base amifampridine employed by Médunik's RUZURGI. The two NDSs were co-pending until

July 31, 2020 when an NOC was issued for FIRDAPSE. Since there was no approved drug at that time with amifampridine as its medicinal ingredient, FIRDAPSE was designated an innovative drug as contemplated in section C.08.004.1 of the *Food and Drug Regulations*. As a result, before RUZURGI could be approved, it was necessary to consider the application of the data protection regime.

[4] Though the decision to issue an NOC rests with the Minister, it is useful to note that different groups within Health Canada are delegated to the respective tasks of (i) assessing the safety and efficacy of the drug in question, and (ii) determining whether the data protection regime applies thereto. The former task is delegated to the Pharmaceutical Products Directorate, formerly the Therapeutic Products Directorate (TPD), whereas the latter task is delegated to the Office of Submissions and Intellectual Property (OSIP). These names are used interchangeably herein with “Health Canada”.

[5] An NOC was issued for RUZURGI on August 10, 2020, 10 days after issuance of the FIRDAPSE NOC. From this, it is implicit that the Minister (here, OSIP) determined that the data protection regime did not apply in this case. However, as noted by the Attorney General, it was standard practice at the time for OSIP not to provide written reasons for this conclusion.

[6] Catalyst initiated a first application for judicial review of the Minister’s decision to issue an NOC in respect of RUZURGI. Catalyst noted that the Product Monograph (PM) for RUZURGI refers to carcinogenicity and reproductive and development toxicity studies concerning amifampridine that came from Catalyst’s US regulatory submission for FIRDAPSE

(the FIRDAPSE studies). Catalyst argued that this amounted to a comparison between RUZURGI and the innovative drug FIRDAPSE, and hence it was unreasonable in these circumstances for OSIP to have concluded that paragraph C.08.004.1(3)(b) of the *Food and Drug Regulations* did not apply to prohibit the issuance of the NOC.

[7] In the absence of written reasons, the Federal Court was left unsure as to the basis for OSIP's conclusion that paragraph C.08.004.1(3)(b) did not apply. The Court therefore issued a decision on May 31, 2021 granting Catalyst's first application, and remitting the matter to the Minister for redetermination: see *Catalyst Pharmaceuticals, Inc. v. Canada (Attorney General)*, 2021 FC 505.

II. The Decision under Review

[8] Health Canada (here, OSIP) issued its redetermination decision by letter dated June 24, 2021 to Médunik and Catalyst (the Redetermination Letter, Appeal Book volume 1, tab 7, page 000110). In this letter, OSIP concluded once again that the data protection regime did not apply to RUZURGI. OSIP provided two distinct grounds for this conclusion. First, it concluded that paragraph C.08.004.1(3)(b) of the *Food and Drug Regulations* did not apply to prohibit the issuance of the NOC because FIRDAPSE had not yet been designated an innovative drug at the time the NDS for RUZURGI was filed. By OSIP's interpretation of subsection C.08.004.1(3), an NDS that was not prevented from being filed by paragraph (a) was likewise not prevented from being approved (and an NOC issued) by paragraph (b), so long as the NDS at the time of approval was the same as at the time of filing. In other words, OSIP concluded that

the subsection is to be interpreted in a forward-looking manner and as a joint prohibition, such that the Minister is only prohibited from approving an NDS if an innovative drug existed at the time that same NDS was filed. This is referred to herein as the "timing issue".

[9] The second ground cited by OSIP to conclude that the data protection regime did not apply was that, though the PM for RUZURGI referred to the FIRDAPSE studies, those studies were not relied upon by the TPD to establish the safety and efficacy of RUZURGI. OSIP concluded that subsection C.08.004.1(3) was not engaged based on this factual finding, and that Médunik therefore did not seek an NOC for RUZURGI "on the basis of a direct or indirect comparison" with FIRDAPSE. Rather, the FIRDAPSE studies were included in the PM merely as publicly available safety information that may be relevant to the optimal, safe and effective use of RUZURGI. This is referred to herein as the "reliance issue".

[10] Catalyst then commenced a second application for judicial review, this time concerning OSIP's redetermination decision. This application led to the Federal Court decision that is the subject of the present appeal.

III. The Federal Court's Decision

[11] As indicated above, the Federal Court granted Catalyst's second application for judicial review, once again remitting the matter to the Minister for another redetermination. The Federal Court found that OSIP's conclusions on both the timing issue and the reliance issue were unreasonable.

[12] On the timing issue, the Federal Court concluded that OSIP's interpretation of the interrelationship between paragraphs (a) and (b) of subsection C.08.004.1(3) of the *Food and Drug Regulations* was unreasonable. The Federal Court took issue with OSIP's reasoning that an NDS that had been properly filed under paragraph (a) (because the innovative drug in question had not yet been designated as such) could not later be prevented under paragraph (b) from being approved (and an NOC issued), even if the innovative drug had by then been designated as such.

[13] On the reliance issue, the Federal Court accepted OSIP's view that material that is included in an NDS merely for informational purposes, but is not relied upon to establish the safety and efficacy of a drug, cannot prompt the application of subsection C.08.004.1(3) of the *Food and Drug Regulations* because the NOC is not sought "on the basis of" information related to the other drug. However, the Federal Court found OSIP's analysis of the reliance issue unreasonable for two reasons. First, the Federal Court found that OSIP conflated reliance on information by an NDS applicant, on the one hand, and by the Minister, on the other. The Federal Court criticized OSIP for considering whether the TPD relied on the FIRDAPSE studies rather than whether Médunik did so. Second, the Federal Court found that OSIP erred in concluding that the TPD had not relied on the FIRDAPSE studies without considering various documents and exchanges of correspondence on the subject. The Federal Court found that some of the evidence that had not been considered by OSIP showed that the FIRDAPSE studies were relied on. I expand on these findings below in my analysis of the reliance issue.

IV. Issues in Dispute

[14] The Attorney General challenges the Federal Court's conclusions on both the timing issue and the reliance issue. Catalyst opposes the Attorney General on the appeal and maintains that the Federal Court did not err on either issue. Médunik makes no argument on the appeal.

[15] As indicated above, Catalyst also cross-appeals the Federal Court's decision to remit the matter, once again, to the Minister for redetermination. Catalyst argues that the Federal Court should instead have made the decision the Minister should have made: order that the Minister apply the data protection regime and not issue an NOC for RUZURGI until the prescribed period of data protection expires. Catalyst argues that, in the two decisions that have already been judicially reviewed, as well as in a preliminary second redetermination that the Minister has recently circulated, the Minister has shown himself incapable of deciding this matter with an open mind. Both the Attorney General and Médunik contest the cross-appeal.

V. Standard of Review

[16] On appeal of a decision on a judicial review application, the standard of review is as contemplated in *Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 S.C.R. 559 at para. 45 (*Agraira*), and confirmed in *Northern Regional Health Authority v. Horrocks*, 2021 SCC 42 at para. 12: this Court must determine whether the court below correctly identified the standard of review on the judicial review and, if so, whether it correctly applied that standard of review. Effectively, this Court steps into the shoes of the lower court and

focuses on the administrative decision. Though this approach accords no deference to the Federal Court, the Attorney General, as appellant, bears a tactical burden to show a flaw in the Federal Court's reasoning where it has given a complete answer to an argument advanced on judicial review: *Canada (Attorney General) v. Lloyd*, 2022 FCA 127 at paragraph 27.

[17] The parties agree that the Federal Court correctly identified the applicable standard of review as reasonableness. The dispute on both the timing issue and the reliance issue concerns whether the Federal Court properly applied that standard of review.

[18] The Supreme Court of Canada provided helpful guidance in the assessment of reasonableness of a decision under judicial review in *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, 441 D.L.R. (4th) 1. The following passages are particularly helpful:

> [83] … [T]he focus of reasonableness review must be on the decision actually made by the decision maker … The role of courts in these circumstances is to *review*, and they are, at least as a general rule, to refrain from deciding the issue themselves. Accordingly, a court applying the reasonableness standard does not ask what decision it would have made in place of that of the administrative decision maker, attempt to ascertain the "range" of possible conclusions that would have been open to the decision maker, conduct a *de novo* analysis or seek to determine the "correct" solution to the problem… [Original emphasis]
>
> [84] … A principled approach to reasonableness review is one which puts those reasons first…
>
> [85] … [A] reasonable decision is one that is based on an internally coherent and rational chain of analysis and that is justified in relation to the facts and law that constrain the decision maker…
>
> [86] … Reasonableness … "is concerned mostly with the existence of justification, transparency and intelligibility within the decision-making process",

> as well as "with whether the decision falls within a range of possible, acceptable outcomes which are defensible in respect of the facts and law"…
>
> …
>
> [91] … [T]he written reasons given by an administrative body must not be assessed against a standard of perfection. That the reasons given for a decision do "not include all the arguments, statutory provisions, jurisprudence or other details the reviewing judge would have preferred" is not on its own a basis to set the decision aside…
>
> …
>
> [102] To be reasonable, a decision must be based on reasoning that is both rational and logical…

[19] Catalyst argues that *Agraira* does not apply to all of the issues in dispute. It argues that, where the Federal Court has made its own findings of fact or of mixed fact and law, such findings should not be disturbed in the absence of a palpable and overriding error: *Sturgeon Lake Cree Nation v. Hamelin*, 2018 FCA 131 at paragraph 37 (*Sturgeon Lake*). Catalyst argues that this more deferential standard applies to several of the Federal Court's findings on the reliance issue.

[20] The Attorney General responds to this argument by noting that there is a distinction between findings by a reviewing court on issues that the decision maker has not been able to address (like bias), and findings properly made by a decision maker. The Attorney General argues that the more deferential standard of review contemplated in *Sturgeon Lake* should apply only to the former, and that the Court owes deference to the decision maker on the latter. I will expand on this point in my analysis below.

VI. Analysis

[21] As I explain below, it is my view that the Federal Court erred in finding that OSIP's analysis of the reliance issue was unreasonable. It follows from this that OSIP did not err in concluding that the data protection regime does not apply in this case. Accordingly, the Federal Court should not have interfered with the Minister's decision, on redetermination, to issue an NOC to Médunik for RUZURGI.

[22] Because of my view on the reliance issue, it is not necessary for me to consider the timing issue. The issues of timing and reliance are independent, and a finding in Médunik's favour on either was sufficient for OSIP to conclude that paragraph C.08.004.1(3)(b) does not prohibit the issuance of an NOC for the RUZURGI NDS. I have no comment on the Federal Court's reasoning on the timing issue and its related statutory interpretation – this question will wait for another day. It is also not necessary for me to consider Catalyst's cross-appeal.

[23] In order to explain my view concerning the reliance issue, it is necessary to present OSIP's and the Federal Court's respective analyses of this issue in greater detail than discussed in paragraphs 9 and 13 above.

A. *OSIP's Analysis*

[24] OSIP dealt with the reliance issue in paragraphs 58 to 66, 87 and 105 to 130 of the Redetermination Letter. It found that the data protection regime applies only where the manufacturer seeking an NOC relies on the data in question. This much is not in dispute.

Catalyst appears to accept that an NDS could refer to data relating to an innovative drug without relying on it, and that an NOC could be issued in such a case without regard to the periods of data protection contemplated in subsection C.08.004.1(3) of the *Food and Drug Regulations*. As stated by OSIP at paragraph 108 of the Redetermination Letter, "[t]here would have to be some material reliance on information in support of establishing the safety and efficacy of RUZURGI."

[25] The dispute arises because OSIP saw no distinction between reliance on the FIRDAPSE studies by Médunik or by the TPD. OSIP concluded that Médunik had not relied on the FIRDAPSE studies based on a finding that the TPD had not done so. OSIP found as a fact that the TPD had not required Médunik to provide carcinogenicity and reproductive and development toxicity studies in order to establish the safety of RUZURGI (see paragraphs 117 and following of the Redetermination Letter). OSIP reasoned that it was the TPD that determined what information was required to establish the safety and efficacy of RUZURGI, and if the TPD did not require certain information for that purpose, then there was no basis for concluding that such information was relied on by Médunik in seeking its NOC (see paragraph 121 of the Redetermination Letter).

[26] The factual finding that the TPD did not require the FIRDAPSE studies to establish the safety of RUZURGI is the subject of another disputed aspect of the reliance issue. In support of this finding, OSIP cited the Pharmaceutical Submission Executive Summary dated July 31, 2020 that addressed the RUZURGI NDS (Executive Summary). At paragraph 118 of the

Redetermination Letter, OSIP quoted the following passage from the Benefit-Harm-Uncertainty Assessment and Management section of the Executive Summary:

> This NDS did not contain carcinogenicity (anticipated study completion date: 2023-2024) or juvenile toxicity studies (anticipated study completion date: 2021-2022). Due to the very nature of LEMS, the fact that amifampridine has been administered to at least 600 patients over the past 27 years, the results of these studies are not considered critical for the time being. The sponsor has committed to providing completed study reports to [H]ealth Canada when available.

[27] OSIP confirmed its factual conclusion by reference to the Summary Basis of Decision dated October 22, 2020 (SBD), and the Regulatory Decision Summary dated May 31, 2021 (RDS), related to RUZURGI. Each of these documents reproduced the substance of the above-quoted passage from the Executive Summary, and added the following sentence:

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

[28] In the Decision, the Federal Court defined this added sentence as the Rationale. I will adopt that nomenclature.

[29] OSIP also made reference to the Addendum to Pharmaceutical Submission Executive Summary dated June 23, 2021 for the RUZURGI NDS (Addendum), which reproduced the substance of the above-quoted passage from the Executive Summary, and added the following:

> Given this statement, it is clear that the approval of FIRDAPSE has no bearing on the recommendation for approval of RUZURGI. However, some information related to carcinogenicity and reproductive and developmental toxicity was considered important safety information worth adding to the Product Monograph of RUZURGI. This safety information was publically available from the US marketed FIRDAPSE product. It is often the case that known safety information, whether it be for individual active pharmaceutical ingredients or for classes of products, is included for awareness for the prescribers.

[30] The Executive Summary, the SBD, the RDS and the Addendum are referred to herein collectively as the Official Documents.

B. *The Federal Court's Analysis*

[31] The Federal Court analyzed the reliance issue at paragraphs 151 to 186 of the Decision. As indicated above, it accepted as reasonable OSIP's view that the data protection regime does not apply unless the drug manufacturer relies on innovative drug data to support its NDS. However, it found that OSIP incoherently focused its analysis on reliance by the Minister (here, the TPD) rather than by Médunik, and failed to explain this approach. The Federal Court found OSIP's analysis in this regard unreasonable.

[32] Most of the Federal Court's analysis of the reliance issue concerns the second, factually suffused aspect: OSIP's conclusion that the TPD had not relied on the FIRDAPSE studies when it approved Médunik's NDS for RUZURGI. The Federal Court criticized OSIP for "unreasonably rel[ying] solely on the TPD's post-review documents (i.e. the SBD, the RDS, and the Addendum)" in reaching its conclusion, while ignoring exchanges between OSIP, Médunik and the TPD from April to July 2020 (see paragraph 153 of the Decision). It found that these

exchanges paint a picture different from the Rationale found in the SBD and the RDS, and adopted by OSIP.

[33] The exchanges that were the focus of the Federal Court's concern are found in a group of documents that were not produced in the first judicial review but were included in the certified tribunal record prepared for the judicial review of the Redetermination Letter at the request of Catalyst. The Attorney General did not admit that these documents were relevant to the issues in the second judicial review. They are found in Exhibit O of the Affidavit of Diane Zimmerman sworn August 18, 2021 and are referred to hereinafter as the Additional Reliance Documents (Appeal Book volume 17, tab 13O). They were not reviewed by Anne Bowes, Director of OSIP and author the Redetermination Letter, for the purposes of that letter, although were available to OSIP's employees. The Additional Reliance Documents address the question of the inclusion of the FIRDAPSE studies in the RUZURGI PM, and the implications thereof on the application of the data protection regime.

[34] At paragraph 158 of the Decision, the Federal Court discussed one of the Additional Reliance Documents, a Clarification Request dated April 22, 2020 from Health Canada to Médunik (Appeal Book volume 17, tab 13O, Exhibit 1, page AB005219). This Request noted that the proposed PM for RUZURGI contained text that raised concerns relating to carcinogenicity and reproductive toxicity, and noted that studies thereof were missing from the NDS. The Request sought a rationale for not conducting such studies and reporting their results in the PM.

[35] As noted at paragraph 160 of the Decision, Médunik responded to the April 22, 2020 Clarification Request by letter dated May 6, 2020 (Appeal Book volume 17, tab 13O, Exhibit 2, page AB005224). On the issue of the missing studies, Médunik cited the ultra-rare nature of LEMS, the severity of the disease and the unmet medical need, as well as an agreement with the US regulator to conduct carcinogenicity studies post-approval. Médunik also stated that it believed that "the available nonclinical data, and the extensive clinical experience in an ultra-rare disease population, are adequate to support the safe and effective use of this drug." The Federal Court found that the only "available nonclinical data" to which Médunik's response could be referring was the FIRDAPSE studies. Based on this, the Federal Court concluded that it appeared that Médunik had indeed relied on the FIRDAPSE studies in seeking its NOC.

[36] At paragraphs 163 and following, the Federal Court also discussed a June 16, 2020 Clarification Request (Appeal Book volume 17, tab 13O, Exhibit 6, page AB005361) in which Health Canada requested that references to the FIRDAPSE studies be removed from the RUZURGI PM. This request was subsequently reversed by a Clarification Request dated July 16, 2020 (Appeal Book volume 17, tab 13O, Exhibit 8, page AB005467). In a subsequent email dated July 21, 2020 (Appeal Book volume 17, tab 13O, Exhibit 8, page AB005469), Health Canada explained its reversal as being based on "the fact that there may be a significant delay before the results of carcinogenicity and juvenile and reproductive toxicity studies for RUZURGI become available."

[37] The Federal Court concluded that this explanation appeared to confirm that reference to the FIRDAPSE studies was intended to compensate for the lack of RUZURGI studies (see paragraph 164 of the Decision).

[38] The Federal Court cited two related internal Health Canada emails dated July 22, 2020 (Appeal Book volume 17, tab 13O, Exhibits 14 and 15, pages AB005595 and AB005600) as reinforcing this conclusion. These emails were prompted by a query from Médunik as to whether restoring the FIRDAPSE studies to the RUZURGI PM as Health Canada proposed would give rise to any data protection issues. The Federal Court quoted Anne Decrouy of the TPD justifying the request to reinstate reference to the FIRDAPSE studies by saying that Health Canada could not ignore the safety signal that was seen in the FIRDAPSE carcinogenicity study. The Federal Court also quoted Ramin Siushansian of the TPD querying whether "describing studies of another similar product" was "going a step further" than disclosing risks associated with drugs of the same class.

[39] As a result of these internal exchanges at Health Canada, it was decided that the specialists on data protection (OSIP) should respond to Médunik's query. The record we have of this response is second-hand: an email dated July 24, 2020 from Ms. Nguyen of Médunik to Mr. Siushansian describing the response (Appeal Book volume 17, tab 13O, Exhibit 18, page AB005617). At paragraph 171 of the Decision, the Federal Court noted that the email indicated that OSIP confirmed that the data protection regime would not apply because the FIRDAPSE studies were "already submitted in the original NDS and at the time of review, there was no other similar product with data protection in Canada." The explanation continued as follows: "…even

if Catalyst receives approval a few weeks before us, as long as we re-instate this non-clinical information before their approval, there would be no issue." The Federal Court concluded from Ms. Nguyen's email that, "were it not for the timing, there would have been an issue with the data protection."

[40] The Federal Court noted the explanation provided in the Executive Summary for not insisting on carcinogenicity and juvenile toxicity studies (as quoted in paragraph 26 above), and concluded that it did not support the Rationale found in the SBD and the RDS (as quoted in paragraph 27 above): see paragraphs 176 and 177 of the Decision. The Federal Court noted that the Rationale was added only months after the RUZURGI NOC had issued.

[41] At paragraph 182 of the Decision, the Federal Court concluded that the Additional Reliance Documents reveal that (i) Médunik relied on the FIRDAPSE studies to seek its NOC, (ii) the FIRDAPSE studies were required by the TPD for market authorization, and (iii) data protection was ruled out based on timing.

C. *First Aspect of the Reliance Issue: Distinction between Reliance by Médunik and Reliance by TPD*

[42] Catalyst maintains that the Federal Court was correct to criticize the decision in the Redetermination Letter for focusing on the Minister's reliance on the FIRDAPSE studies, rather than Médunik's reliance.

[43] The Attorney General counters that the Redetermination Letter:

A. Cited the relevant wording at the beginning of subsection C.08.004.1(3) of the *Food and Drug Regulations* ("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") (see paragraph 59 of the Redetermination Letter);

B. Found that, for this wording to apply (and for the data protection regime to be engaged), there must be effective use and reliance on data concerning an innovative drug to establish the safety and efficacy necessary for approval of the new drug, and that mere reference to such data is insufficient (see paragraph 108 of the Redetermination Letter); and

C. Applied this finding such that (i) the data must be required to establish safety and efficacy, and (ii) it is TPD that assesses safety and efficacy (see paragraph 121 of the Redetermination Letter).

[44] I agree. I see nothing unreasonable in the Minister's refusal to consider reliance by Médunik separate from reliance by the TPD. I am satisfied that the Redetermination Letter adequately explained the Minister's reasoning, and that there was nothing incoherent or illogical in looking to the TPD's analysis of safety and efficacy to know what Médunik needed to rely on for that purpose. Catalyst does not take issue with the legal conclusion that, to establish reliance on the data in question, that data must have been required to establish safety and efficacy. Since the TPD did not find the FIRDAPSE studies necessary to assess the safety and efficacy of

RUZURGI, then it is reasonable to conclude that Médunik was not relying on them to obtain its NOC.

D. *Second Aspect of the Reliance Issue: Additional Reliance Documents*

[45] The Attorney General argues that the Additional Reliance Documents do not undermine the Minister's conclusion that the data protection regime does not apply in this case. He cites two grounds to support this argument. First, he argues that Ms. Bowes, the author of the Redetermination Letter, did not have said documents before her, and that she was entitled to focus on the Official Documents to understand the basis for TPD's safety and efficacy analysis. Second, the Attorney General argues in the alternative that, even if the Additional Reliance Documents are treated as relevant, they do not undermine the Minister's conclusion in that they do not contradict the Official Documents.

[46] In my view, it is sufficient for me to address the Attorney General's alternative argument that the Additional Reliance Documents do not undermine the Minister's conclusion even if they are treated as relevant. It is therefore not necessary for me to address the Attorney General's first argument.

(1) Standard of Review

[47] On this alternative argument, Catalyst argues that the Federal Court's conclusions at paragraph 182 of the Decision concerning what the Additional Reliance Documents reveal (see paragraph 41 above) are original findings of fact that are entitled to deference and should be

disturbed only in the case of a palpable and overriding error. Catalyst submits that the Attorney General has not identified any such error.

[48] As mentioned at paragraph 20 above, the Attorney General argues that a distinction should be drawn between findings on issues that the decision maker was not able to address (like bias), and those properly made by the decision maker. I agree with this distinction, and that it applies in this case. By electing not to account for the Additional Reliance Documents, OSIP drew a conclusion concerning their relative importance, which is to be assessed on the reasonableness standard of review.

[49] Catalyst's argument that the Federal Court's assessment of the Additional Reliance Documents should be treated as findings of fact, and not disturbed absent a palpable and overriding error by the Federal Court, turns the issue of deference on its head. I do not accept that a reviewing court may reach its own conclusion on the importance of documents that were available for consideration by a decision maker without deference to the decision maker's assessment of such importance, and then be entitled to deference on that conclusion. Certainly, a party on judicial review may take issue with a decision maker's assessment of the documents available to it, but that assessment is entitled to deference by the reviewing court.

(2) Review of Documents

[50] I turn now to the Official Documents as discussed in the Redetermination Letter, and the Rationale described in those documents, and I consider whether the Additional Reliance Documents paint a different picture, as the Federal Court found and as Catalyst argues.

[51] It is useful to start by noting that the Executive Summary predates the commencement of litigation in this matter. Accordingly, concerns that Catalyst raises about the lack of neutrality of documents prepared by Health Canada in the context of litigation (the SBD, the RDS and the Addendum) do not apply to the Executive Summary.

[52] The relevant passage in the Executive Summary, which is quoted in paragraph 26 above, recognizes that the RUZURGI NDS was missing studies on carcinogenicity and juvenile toxicity, but concludes that these were not necessary for the time being because of (i) the nature of the disease, (ii) the 27-year history of administration of amifampridine, and (iii) Médunik's undertaking to conduct studies and report results in the near future. OSIP relied on this passage at paragraph 117 of the Redetermination Letter. Neither this passage nor any other passage in the Executive Summary indicates expressly whether the FIRDAPSE studies mentioned in the RUZURGI PM were necessary to satisfy the TPD of the safety and efficacy of RUZURGI. However, in my view, it is likely that the FIRDAPSE studies were mentioned in the RUZURGI PM in order to provide publicly available safety information concerning a similar drug that may be relevant to the optimal, safe and effective use of RUZURGI. This conclusion is consistent with the Rationale described in the SBD and RDS (see paragraph 27 above) and with paragraph 119 of the Redetermination Letter.

[53] It follows that I disagree with the Federal Court's conclusion that the Rationale is unsupported by the Executive Summary. I conclude that OSIP's view to the contrary in the Redetermination Letter was reasonable, and the Federal Court erred in its conclusion in this regard.

[54] The Federal Court's other concerns about the Rationale relate to (i) Health Canada's April 22, 2020 inquiry about missing RUZURGI studies and Médunik's response thereto, and (ii) internal Health Canada discussions surrounding the removal and later restoration of reference to the FIRDAPSE studies in the RUZURGI PM.

[55] As regards the question of the missing RUZURGI studies, the Federal Court focused on Médunik's response that referred to "available nonclinical data", which the Federal Court found could only be a reference to the FIRDAPSE studies (see paragraph 35 above). It is not clear to me on what basis the Federal Court made this finding. It appears that the RUZURGI NDS included references to many nonclinical studies other than the FIRDAPSE studies: see List of Non-Clinical Studies, section 4.2, Pharmaceutical Safety and Efficacy Assessment: (Supplemental) New Drug Submission dated July 31, 2020 (Appeal Book volume 2, tab 10.10, page AB000340).

[56] In my view, Médunik's reference to "available nonclinical data" did not necessarily refer to the FIRDAPSE studies, and the Federal Court should not have read it as an acknowledgement that Médunik relied on those studies to support its NDS.

[57] As regards the internal Health Canada discussions surrounding the removal and later restoration of reference to the FIRDAPSE studies in the RUZURGI PM, these involved questions and answers about the possible application of the data protection regime. Various views were expressed internally and I note two things. First, I have seen nothing therein that is necessarily inconsistent with the Minister's decision set out in the Redetermination Letter.

Second, even if I saw such an inconsistency, the issue would not be simply whether I see one. Instead, this Court must ask whether there is some flaw in the Minister's ultimate decision that is of sufficient importance to render it unreasonable.

[58] Though it may be true, as found at paragraph 164 of the Decision, that Health Canada's request to restore the FIRDAPSE studies in the RUZURGI PM was because of the lack of RUZURGI studies (see paragraph 37 above), it does not follow from this that the FIRDAPSE studies were relied upon to establish RUZURGI's safety and efficacy. I see nothing in the statement attributed to Ms. Decrouy and discussed in paragraph 38 above that indicates otherwise. The same paragraph above cites Mr. Siushansian raising questions about the applicability of the data protection regime in these circumstances. However, he was not the decision maker, and his questions were insufficient in my view to establish that anything in the Redetermination Letter was unreasonable.

[59] The Federal Court also cited the explanation apparently provided to Médunik by OSIP as to why the data protection regime would not apply despite the restoration of reference to the FIRDAPSE studies (see paragraph 39 above). Though this explanation referred only to the timing issue, I disagree with the Federal Court that this necessarily implies that the reliance issue did not apply. Moreover, it should be noted that, given that this explanation was attributed to OSIP by Médunik, it was a second-hand account that may be less reliable.

VII. Conclusion

[60] For the reasons discussed above, I would allow the appeal and set aside the judgment of the Federal Court. I would also dismiss the cross-appeal. Rendering the judgment that the Federal Court should have rendered, I would dismiss Catalyst's application for judicial review and restore the Minister's decision.

[61] The parties have agreed that the costs of this appeal should be awarded in the fixed amount of $7000 to be paid by Catalyst to the Attorney General. I agree that this amount is appropriate.

"George R. Locke"
J.A.

"I agree.
Anne L. Mactavish J.A."

"I agree.
K. A. Siobhan Monaghan J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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CONCURRED IN BY:	MACTAVISH J.A. MONAGHAN J.A.
DATED:	JANUARY 9, 2023

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