Federal Court Cour fédérale

Date: 20230105

Docket: T-1867-21

Citation: 2023 FC 7

Ottawa, Ontario, January 5, 2023

PRESENT: The Honourable Mr. Justice Manson

BETWEEN:

JANSSEN INC.

Applicant

and

ATTORNEY GENERAL OF CANADA AND THE MINISTER OF HEALTH

Respondents

JUDGMENT AND REASONS

I. Introduction

[1] This is an application for judicial review by Janssen Inc. ["Janssen"] of the decision [the "Decision"] of the Minister of Health [the "Minister"] dated November 10, 2021, which found that SPRAVATO (esketamine hydrochloride) nasal spray ["SPRAVATO"] was not an "innovative drug" as defined under subsection C.08.004.1(1) of the *Food and Drug Regulations*, CRC, c 870 [the "*Regulations*"] and therefore not entitled to data protection.

II. Background

[2] The Applicant, Janssen, is a manufacturer and seller of drug products in Canada. One such product is SPRAVATO.

[3] The Applicant and its affiliates developed SPRAVATO as a treatment for Major Depressive Disorder [MDD]. SPRAVATO is designed to meet the needs of patients who suffer from MDD and have not responded adequately to at least two different antidepressants of adequate dose and duration in the current depressive episode or who are experiencing a moderate to severe episode of MDD, which according to clinical judgement requires urgent psychiatric care.

[4] The medicinal ingredient in SPRAVATO is esketamine, present in the form of esketamine hydrochloride. Esketamine hydrochloride is an enantiomer of ketamine hydrochloride. The Minister has previously approved drugs containing ketamine hydrochloride.

[5] The Minister approved SPRAVATO for sale in Canada on May 20, 2020. Prior to doing so, on April 25, 2019, the Minister found that SPRAVATO was not an "innovative drug" as defined by section C.08.004.1(1) of the *Regulations*. Janssen sought judicial review of this determination. The Court of Appeal upheld the Minister's decision (*Janssen Inc v Attorney General of Canada (Minister of Health)*, 2021 FCA 137 [*SPRAVATO 2021*]). The Court of Appeal found the Minister's determination was consistent with governing case law which held enantiomers of previously approved drugs did not fit under the subsection C.08.004.1(1)

definition of "innovative drug" (*Takeda Canada Inc v Canada (Health)*, 2013 FCA 13 at paras 121-122 [*Takeda*]).

[6] After the Minister's initial determination, on July 1, 2020, the Canada-United States-Mexico Agreement [CUSMA] replaced the North American Free Trade Agreement [NAFTA].

[7] In the proceedings before this Court with respect to the Minister's initial determination, Janssen did not urge the Court to interpret the *Regulations* consistently with CUSMA. Janssen did attempt to adduce fresh evidence to advance this argument on appeal; however, the Court of Appeal declined to admit the evidence, as it was inconsistent with the governing principles of appeals of judicial review decisions (*SPRAVATO 2021* at paras 45-58).

[8] In October 2020, Janssen wrote to the Minister, requesting that the Minister consider SPRAVATO an "innovative drug" and grant data protection given that Canada had implemented CUSMA and, though the language of the definition of "innovative drug" in the *Regulations* had not changed, the Minister now had to interpret the *Regulations* consistently with CUSMA.

[9] On November 10, 2021, the Minister refused Janssen's request. The Minister concluded that it was not appropriate for Janssen to seek a reassessment of SPRAVATO's eligibility since section C.08.004.1 contemplates that the SPRAVATO's data protection eligibility is to be determined at the time it is approved. The Minister went on to find that, if it were appropriate to reassess data protection, SPRAVATO still did not meet the definition of an "innovative drug".

[10] Janssen believes the Minister's determinations are fatally flawed. They argue that the Minister was obliged to reconsider the initial determination that SPRAVATO was not an innovative drug and that the Minister's interpretation of the *Regulations* is inconsistent with principles of statutory interpretation and therefore unreasonable.

[11] Janssen seeks the following relief:

i. An order setting aside the Decision and compelling the Office of Submissions and Intellectual Property [the "OSIP"] of Health Canada to grant SPRAVATO data protections under section C.08.004.1 of the *Regulations* and add it to the Register of Innovative Drugs effective July 1, 2020.

ii. A declaration that SPRAVATO is an "innovative drug" and eligible for data protection for purposes of C.08.004.1 of the *Regulations*, effective July 1, 2020, with the period of data protection commencing May 20, 2020.

iii. An injunction preventing the Minister from accepting any new drug submission, supplement to a new drug submission, abbreviated new drug submission from any manufacturer seeking a Notice of Compliance for a new drug based on a direct or indirect comparison between the new drug and SPRAVATO, until the final determination of this judicial review and any appeal thereof.

iv. Costs.

III. Decision Under Review

[12] As stated above, in a decision dated November 10, 2021, the Minister refused Janssen's request for reconsideration. The reasons for refusal were communicated by the OSIP.

[13] The OSIP outlined two reasons for refusing Janssen's request. First, the Minister found that it was not appropriate to reassess data protection eligibility for SPRAVATO due to CUSMA entering into force, as under the regulatory framework, data protection eligibility is determined at the time the first notice of compliance [NOC] is issued. Second, the Minister found that even if reassessment were appropriate, SPRAVATO did not meet the section C.08.004.1(1) definition of "innovative drug".

[14] The OSIP first reviewed the regulatory framework through which data protection is afforded to innovative drugs in Canada, including:

i. The process through which the Minister issues a NOC. Brand-name drugs enter the Canadian market through a new drug submission [NDS] under section C.08.002 of the *Regulations* and generic drugs enter the market through a comparison to the brand-name drug in an abbreviated new drug submission [ANDS] pursuant to section C.08.002.1 of the *Regulations.*

ii. The nature of the data protection to an "innovative drug" is defined in subsection C.08.004.1(1) of the *Regulations*. Under paragraph C.08.004.1(3)(a) of the *Regulations*, a manufacturer seeking a NOC based on a comparison to an

"innovative drug" may not file its drug submission before the end of a six-year period after the day on which the NOC was issued for the "innovative drug" [no-filing period]. Similarly, under paragraph C.08.004.1(3)(b) of the *Regulations*, the Minister will not issue a NOC for a comparison-based drug for a period of eight years after the day on which the NOC was issued for the "innovative drug" [no-marketing period]. Under subsection C.08.004.1(9) of the *Regulations*, the Minister maintains a Register of Innovative Drugs.

iii. The data protection provisions serve to implement various treaty provisions. Subsection 30(3) of the *Food and Drug Act*, RSC 1985, c F-27 [the *Act*] allows the Governor in Council to make regulations to implement Articles 20.48 and 20.49 of CUSMA or paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights [TRIPS] set out in Annex 1C to the Agreement Establishing the World Trade Organization. Subsection C.008.004.1(2) of the *Regulations* explicitly provides that the purpose of the data protection provisions is to implement these international obligations. Although not explicitly specified in the *Regulations*, they also implement Article 20.29 of the Canada-European Union Comprehensive and Economic Trade Agreement [CETA].

[15] The OSIP held that it was inappropriate to consider whether SPRAVATO was an "innovative drug" under subsection C.08.004.9(1), at a time after the NOC had issued. The OSIP points to the fact that the data protection provisions in the *Regulations* contemplate that the term of protection begins on the day the Minister issues a NOC to an innovator. This provides stability

and predictability in the Canadian pharmaceutical marketplace to innovators and generic manufacturers.

[16] Furthermore, the OSIP observed that Canada's international obligations under CUSMA and CETA state only that Canada is obligated to provide data protection from the date of marketing approval of the new pharmaceutical product.

[17] The OSIP concluded that Janssen was ineligible for data protection consideration. Janssen filed the NDS for SPRAVATO on December 10, 2018 and received the NOC on May 20, 2020. CUSMA came to replace NAFTA on July 1, 2020 and was therefore not in effect at the time SPRAVATO received its NOC. Since it had already considered SPRAVATO's eligibility in its April 25, 2019 decision and determined that SPRAVATO was ineligible, there was no reason to reconsider this decision.

[18] The OSIP further found that, if it were appropriate to reassess SPRAVATO's data eligibility in light of CUSMA, SPRAVATO would still be ineligible for data protection under the *Regulations*.

[19] The OSIP observed that while the context of Canada's international obligations is relevant and important, ultimately, it is the *Regulations* that implement these obligations into Canadian law.

[20] After reviewing the language of Article 20.49 of CUSMA, paragraph 3 of Article 39 of TRIPS and paragraph 1 of Article 20.29 of CETA, the OSIP concluded that the definition of "innovative drug" in subsection C.08.004.1(1) of the *Regulations* was consistent with these treaties.

[21] The OSIP observed that no material changes were made to the *Regulations* in light of CUSMA. The *Canada-United States-Mexico Agreement – Canadian Statement of Implementation* [the "Statement of Implementation"], which sets out Canada's interpretation of CUSMA, expressly provides that no changes will be required to Canada's regime for the protection of undisclosed test or other data. Furthermore, the Regulatory Impact Analysis Statement, SOR/DORS/2020-74, *Canada Gazette Part II*, Vol 154, No 9 [RIAS] that accompanied the amendments to the *Regulations* did not indicate that a change to the data protection provisions was necessary, save for replacing references to NAFTA with references to CUSMA. The RIAS indicates that Canada viewed its data protection obligations under CUSMA as similar to those under NAFTA.

[22] The OSIP reasoned that this meant that the *Regulations* as they were under NAFTA were consistent with CUSMA and the approach to interpreting the definition of "innovative drug" in subsection C.08.004.1(1) of the *Regulations* had not changed.

[23] As such, the OSIP held its April 25, 2019 determination that SPRAVATO's medicinal ingredient, esketamine hydrochloride is an enantiomer of ketamine hydrochloride was still valid and dispositive of Janssen's request.

IV. Issues

A. Has the Applicant improperly included fresh evidence on judicial review?

B. Was the Decision reasonable?

(1) Did the Minister err by holding that SPRAVATO is not an "innovative drug" under subsection C.08.004.1(1) of the *Regulations*?

(2) Did the Minister err by holding that the relevant time to determine data protection eligibility was at the time SPRAVATO was issued a NOC?

V. Standard of Review

[24] The standard of review applicable to the interpretation of the Minister's interpretation of the *Regulations* is reasonableness (*Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 115 [*Vavilov*]).

VI. Analysis

A. *Has the Applicant improperly included fresh evidence on judicial review?*

[25] Janssen has included three foreign jurisdiction affidavits that outline the process by which SPRAVATO was approved and granted data protection in foreign jurisdictions [the "Foreign Jurisdiction Affidavits"]:

i. Affidavit of Jadwiga Martynowicz (United States);

ii. Affidavit of Sarah Forest (European Union); and

iii. Affidavit of Natalie Kingston (Australia).

[26] The Foreign Jurisdiction Affidavits provide evidence about SPRAVATO's innovativeness as well as the foreign procedures and legislation granting data protection to SPRAVATO.

[27] This evidence was not before the OSIP when it made the Decision.

[28] Absent certain limited exceptions, a reviewing court on judicial review is bound to the same record as that which was before the decision maker (*Association of Universities and Colleges of Canada v Canadian Copyright Licensing Agency (Access Copyright)*, 2012 FCA 22 at para 20).

[29] The Foreign Jurisdiction Affidavits do not fit within any of the applicable exceptions and the Court will disregard them. The Foreign Jurisdiction Affidavits do not serve to highlight procedural defects and they go beyond offering general background information and instead delve the decision-making procedures of foreign health regulators.

[30] There is nothing in the Foreign Jurisdiction Affidavits that will aid the Court in assessing the reasonableness of the OSIP's decision in light of the record before it.

B. *Was the Decision reasonable?*

(1) Did the Minister err by holding that SPRAVATO is not an "innovative drug" under subsection C.08.004.1(1) of the *Regulations*?

[31] Subsection 30(3) of the *Act* enables the Governor in Council to issue regulations to implement Canada's international obligations under Articles 20.48 and 20.49 of CUSMA and paragraph 3 of Article 39 of TRIPS.

[32] Subsection C.08.004.1(1) of the *Regulations* defines an "innovative drug" for purposes of data protection:

innovative drug 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. (drogue innovante)	***drogue innovante*** S'entend de toute drogue qui contient un ingrédient médicinal non déjà approuvé dans une drogue par le ministre et qui ne constitue pas une variante d'un ingrédient médicinal déjà approuvé tel un changement de sel, d'ester, d'énantiomère, de solvate ou de polymorphe. (innovative drug)

[33] Subsection C.08.004.1(2) of the *Regulations* confirms that the purpose of section C.08.004.1 is to implement Articles 20.48 and 20.49 of CUSMA and paragraph 3 of Article 39 of TRIPS. Furthermore, although it is not explicitly stated, the *Regulations* also serve to implement Article 20.29 of CETA.

[34] Under Article 20.48 of CUSMA, Canada agrees to provide data protection to a "new pharmaceutical product". Article 20.49 of CUSMA defines "new pharmaceutical product":

Article 20.49: Definition of New Pharmaceutical Product	**Article 20.49 : Définition de nouveau produit pharmaceutique**
For the purposes of Article 20.48.1 (Protection of Undisclosed Test or Other Data), a new pharmaceutical product means a pharmaceutical product that does not contain a chemical entity that has been previously approved in that Party.	Pour l'application du paragraphe 1 de l'article 20.48 (Protection des données d'essai ou autres données non divulguées), un nouveau produit pharmaceutique désigne un produit pharmaceutique qui ne contient pas d'entité chimique faisant l'objet d'une approbation antérieure sur le territoire de la Partie.

[35] Before CUSMA, the *Act* and *Regulations* implemented paragraph 5 of Article 1711 of NAFTA. Paragraph 1 of Article 20.29 of CETA, paragraph 5 of Article 1711 of NAFTA, and paragraph 3 of Article 39 of TRIPS each use language that instead refer to data protection for pharmaceutical products that "utilize new chemical entities".

[36] According to Janssen, the shift in language from conferring data protection to drugs that "utilize new chemical entities" to drugs that do "not contain a chemical entity that has been previously approved", has sufficiently changed the meaning of "innovative drug" under

subsection C.08.004.1(1) so as to render enantiomers of previously approved drugs within its ambit.

[37] Typically, when evaluating whether a pharmaceutical product is an “innovative drug”, the Minister engages in a two-step inquiry. First, the Minister determines whether the medicinal ingredient was previously approved. If not, the Minister determines whether the drug is a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.

[38] Under Janssen’s view, this second step is unnecessary and antithetical to an appropriate construction of the *Regulations* post-CUSMA. Janssen points out that Canada has implemented CUSMA by passing the *Canada-United States-Mexico Agreement Implementation Act*, SC 2020, c 1 [*CUSMA Implementation Act*] and section 3 of the *CUSMA Implementation Act* requires that federal legislation is interpreted consistently with CUSMA. Furthermore, amendments to subsection C.08.004.1(2) of the *Regulations* make clear that the purpose of the data protection provisions is to implement Articles 20.48 and 20.49 of CUSMA. Relying on these provisions, Janssen insists that the *Regulations* must be interpreted in a manner wholly consistent with CUSMA.

[39] As a starting point, Canada remains a dualist system when it comes to treaty law. What this means is that a treaty is only binding under Canadian law if the legislature gives the treaty provisions effect through domestic legislation (*Kazemi Estate v Islamic Republic of Iran*, 2014 SCC 62 at para 149; *Capital Cities Communications Inc v Canadian Radio-Television*

Commission (1977), [1978] 2 SCR 141 at 173 [*Capital Cities*]). While, as a matter of construction, statutes are presumed to comply with Canada's international obligations, this presumption cannot override the clear and express language of legislation (*R v Hape*, 2007 SCC 26 at para 53; *Capital Cities* at 173; *Natco Pharma (Canada) Inc v Canada (Health)*, 2020 FC 788 at para 52).

[40] In the recent case, *Society of Composers, Authors and Music Publishers of Canada v Entertainment Software Association*, 2022 SCC 30 [*Entertainment Software*], the Supreme Court restated and clarified these principles. The Supreme Court observed that treaties are relevant to a proper contextual inquiry of a statute (*Entertainment Software* at paras 44-46):

> [44] A treaty should be considered when interpreting statutes that purport to implement the treaty, in whole or in part. The treaty is relevant at the context stage of the statutory interpretation exercise.
>
> [45] There is no need to find textual ambiguity in a statute before considering the treaty. The modern approach to statutory interpretation requires interpreting the statute's text in its "entire context". The statute's context includes any relevant international legal obligations.
>
> [46] If a statute implements a treaty without qualification, the interpretation of the statute needs to be wholly consistent with Canada's obligations under the treaty. If the statute is less explicit as to the extent to which it gives effect to a treaty, the weight given to obligations under the treaty will depend on the circumstances of the case, such as the treaty's specificity and the statute's text. Where the text permits, legislation should be interpreted so as to comply with Canada's treaty obligations, in accordance with the presumption of conformity.
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> [Internal citations omitted]

[41] Janssen claims that CUSMA was implemented "without qualification" and therefore interpretation must be *wholly* consistent with it.

[42] When the Supreme Court refers to the need to be wholly consistent when the treaty is implemented "without qualification" the Court cites *Office of the Children's Lawyer v Balev*, 2018 SCC 16 where Ontario legislation implemented a treaty through the following provisions (*Children's Law Reform Act*, RSO 1990, c C12):

> **Definition**
>
> **46 (1)** In this section, "convention" means the Convention on the Civil Aspects of International Child Abduction, set out in the Schedule to this section. R.S.O. 1990, c. C.12, s. 46 (1).
>
> **Convention in force**
>
> **(2)** On, from and after the 1st day of December, 1983, except as provided in subsection (3), the convention is in force in Ontario and the provisions thereof are law in Ontario. R.S.O. 1990, c. C.12, s. 46 (2).

[43] As well, in *Pushpanathan v Canada*, [1998] 1 SCR 982 at para 51, what was in dispute was the interpretation of Convention refugee provisions in the old *Immigration Act*, RSC 1985, c I-2 that expressly incorporated Articles of the *Convention relating to the Status of Refugees*.

[44] However, in this case there is no unqualified adoption of CUSMA. There is a general provision in section 3 of the *CUSMA Implementation Act* that states that federal legislation is to be interpreted consistently with CUSMA, but then there are specific provisions in the

Regulations that implement the data protection provisions of CUSMA and these provisions do not refer to the treaty "as is" or incorporate its language "without qualification".

[45] What ultimately governs in Canada is domestic legislation, not international agreements, and the context provided by a treaty cannot be used to support an interpretation that is not permitted by the text of legislation (*Entertainment Software* at paras 47-48):

> [47] The presumption of conformity is an aid to interpretation. The task remains to give effect to legislative intent. The separation of powers requires that courts give effect to a statute that demonstrates legislative intent not to comply with treaty obligations. Negotiation, signing, and ratification of treaties are acts of the executive. Once ratified, treaties do not automatically become part of domestic law; rather, they are given effect through domestic legislation.
>
> [48] Accordingly, while a treaty can be highly relevant to statutory interpretation, it cannot overwhelm clear legislative intent. The court's task is to interpret what the legislature (federally and provincially) has enacted and not subordinate this to what the federal executive has agreed to internationally. It is always the domestic statute that governs because international law cannot be used to support an interpretation that is not permitted by the words of the statute.
>
> [Internal citations and quotations omitted]

[46] In this case, while CUSMA and the *CUSMA Implementation Act* provide important context, it is ultimately the data protection provisions in section C.08.004.1 of the *Regulations* through which Parliament has chosen to implement Articles 20.48 and 20.49 of CUSMA.

[47] I find that the OSIP reasonably interpreted the text of the "innovative drug" definition under subsection C.08.004.1(1) and applied it to SPRAVATO. The OSIP correctly observed that,

while the context provided by CUSMA is important, in the end, it is the *Regulations* as implemented by the Governor in Council that govern.

[48] The definition of "innovative drug" expressly excludes enantiomers of previously approved medicinal ingredients (see also *Takeda* at paras 121-122). There is no dispute in this case that the medicinal ingredient in SPRAVATO, esketamine hydrochloride, is an enantiomer of ketamine hydrochloride and that the Minister has previously approved drugs containing ketamine hydrochloride. Therefore, it was reasonable to find that SPRAVATO is not an "innovative drug" under the *Regulations*.

[49] Moreover, the OSIP reasonably considered the additional context and purpose of the data protection provisions and concluded that the definition of "innovative drug" under subsection C.08.004.1(1) is compliant with CUSMA. In its reasons, the OSIP thoroughly and intelligibly canvasses the context of the whole of Canada's relevant international obligations, the process through which CUSMA was implemented into Canadian law and the leeway the Governor in Council has under CUSMA to implement its provisions in a manner consistent with Canadian law.

[50] The Court of Appeal has found that subsection 30(3) of the *Act* gives the Governor in Council significant leeway to implement treaty provisions (*Apotex Inc v Canada (Health)*, 2010 FCA 334 at para 85). Additionally, Canada has latitude under Paragraph 2 of Article 20.5 of CUSMA itself "to determine the appropriate method of implementing the provisions of [the Intellectual Property Rights] Chapter within its own legal system and practice".

[51] Insight into Canada and the Governor in Council's exercise of this discretion is found in the Statement of Implementation and the RIAS (Regulatory Impact Analysis Statements can provide reasoned explanations for decisions of the Governor in Council: *Portnov v Canada (Attorney General)*, 2021 FCA 171 at paras 33-34). The Statement of Implementation "sets out Canada's interpretation of the Parties' rights and obligations under CUSMA". Under Canada's interpretation, Article 20.48 did "not require changes to Canada's regime for the protection of test or other data". The RIAS states that the "amendments are necessary to fully implement CUSMA" and indicates that data protection under CUSMA is "similar to Article 1711 of NAFTA".

[52] The OSIP reviewed much of this context and reasonably found that it was open to Canada to implement the data protection provisions of CUSMA as it has done through the *Regulations*. The OSIP points out that the definition of "new pharmaceutical product" under Article 20.49 of CUSMA refers to a "pharmaceutical product that does not contain a chemical entity that has been previously approved"; however, the term "chemical entity" is not defined in the treaties. Consequently, it was open for Canada to interpret "chemical entity" to exclude structural variations, such as enantiomers, of previously approved drugs.

[53] The OSIP's decision was transparent, intelligible and reasonable and contained an appropriate regard to the principles of statutory interpretation including the text, context and purpose of the data protection provisions under the *Regulations*.

[54] I also agree with the Respondent that since the data protection provisions in the *Regulations* have not materially changed since *Takeda*, Janssen's argument, ultimately, is not that the OSIP's interpretation of subsection C.08.004.1(1) is unreasonable; rather it is that the Governor in Council's legislation is inadequate. I agree with Justice Zinn's comments from Janssen's challenge to SPRAVATO's data protection eligibility under NAFTA (*Janssen v Attorney General of Canada*, 2020 FC 904 [*SPRAVATO 2020 TD*]). Even if it were the case that Canada's domestic legislation is inconsistent with CUSMA, the appropriate remedy lies through amendments to the Regulations by the Governor in Council and not through Order of this Court (*SPRAVATO 2020 TD* at paras 27-28; see also *Takeda* at para 131).

(2) Did the Minister err by holding that the relevant time to determine data protection eligibility was at the time SPRAVATO was issued a NOC?

[55] Janssen argues that the Minister's determination that it was not necessary to reconsider Janssen's reassessment request was unreasonable. Janssen believes that the OSIP based its reasons on a faulty and absurd interpretation that Janssen was requesting data protection from the date CUSMA came into force, July 1 2020, and not the date that SPRAVATO's NOC issued, May 20, 2020, as specified in the *Regulations*. Janssen claims it never made such a request.

[56] Further, Janssen argues that the OSIP unreasonably conflates two distinct aspects of the data protection regime:

i. The timing of assessing data protection eligibility; and

ii. The date on which data protection commences.

[57] Under the *Regulations* data protection commences on the date a NOC is issued. However, it is not clear when data protection eligibility is determined; Janssen argues that, while as a matter of administrative practice, the Minister has usually assessed data protection eligibility before issuing a NOC, there is no such timing requirement in the *Regulations*. Janssen points to the text of subsection C.08.004.1(3) which provides the no-filing period and the no-marketing period:

> **(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
>
> **(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)** 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)** 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.

[58] In Janssen's view, the Minister is required to assess data protection each time a generic drug seeks a NOC based on a comparison with an existing approved drug.

[59] I find that the OSIP reasonably interpreted Janssen's request and did not read into the *Regulations* a pre-NOC timing requirement for assessing data protection eligibility. Read as a whole, the OSIP's reasons do not stand for the proposition that in each case the Minister must only assess data protection eligibility before issuing a NOC; rather, the OSIP's reasons support the position that the relevant state of the law when assessing data protection eligibility is as it was when the NOC issued. The OSIP points to the starting date of the six-year no-filing period and eight-year no-marketing period, each of which begin on the day a NOC is issued. This language is consistent with CUSMA, which provides for data protection "from the date of marketing approval of the new pharmaceutical product".

[60] There is no dispute that SPRAVATO was not an "innovative drug" when its NOC was issued (see *SPRAVATO 2021*). If the OSIP were to reassess SPRAVATO and reach a contrary conclusion, there would be a regulatory anomaly in that SPRAVATO would be afforded data protection from a date and for a portion of a period where it was clearly not an "innovative drug" under Canadian law. Such an interpretation is inconsistent with a purposive and contextual regulatory interpretation.

[61] The OSIP reasonably concluded that it was unnecessary to consider Janssen's reassessment request, as it had already assessed data protection as of the date the NOC issued in its April 25, 2019 decision (upheld in *SPRAVATO 2021*).

[62] The confusion over the dates in Janssen's request for relief – whether Janssen requested relief from July 1, 2020 or May 20, 2020 – stems from Janssen's own submissions to the OSIP.

In these submissions, Janssen requests relief “effective July 1, 2020”. In its Notice of Application to this Court, Janssen uses clearer language, requesting relief “effective July 1, 2020, with the period of data protection commencing on May 20, 2020”. The Court must evaluate the OSIP’s reasons in light of the record before it and in light of that record the OSIP reasonably interpreted Janssen’s request for relief (*Vavilov* at para 94).

[63] The OSIP was responsive to Janssen’s request and reasonably interpreted the *Regulations.*

VII. Conclusion

[64] The application is dismissed.

JUDGMENT in T-1867-21

THIS COURT'S JUDGMENT is that:

1. The application is dismissed.

2. Costs to the Respondents, the amount of which has been agreed to by the parties.

"Michael D. Manson"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1867-21
STYLE OF CAUSE:	JANSSEN INC v THE ATTORNEY GENERAL OF CANADA AND THE MINISTER OF HEALTH
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	DECEMBER 14, 2022
JUDGMENT AND REASONS:	MANSON J.
DATED:	JANUARY 5, 2023

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