Federal Court  Cour fédérale

Date: 20210929

Docket: T-1471-19

Citation: 2021 FC 1015

Ottawa, Ontario, September 29, 2021

PRESENT: Mr. Justice McHaffie

BETWEEN:

MERCK CANADA INC.

Applicant

and

THE MINISTER OF HEALTH

Respondent

JUDGMENT AND REASONS

I. Overview

[1] Merck Canada Inc seeks judicial review of the Minister of Health's refusal to grant it a Certificate of Supplementary Protection (CSP) for Canadian Patent No 2,670,892 ['892 Patent]. The claims of the '892 Patent cover suvorexant, the medicinal ingredient in Merck's drug product BELSOMRA. Merck argues it satisfies the requirements for a CSP, since it first filed a New Drug Submission (NDS) for BELSOMRA in Canada within the prescribed period after approval was sought in the United States, even though that first NDS was not approved. Rather,

a second NDS filed about three and a half years later was ultimately approved and resulted in a Notice of Compliance (NOC) being issued for BELSOMRA.

[2] Merck presented to the Minister a number of statutory interpretation arguments as to why its first NDS satisfied the "timely submission requirement" in paragraph 106(1)(*f*) of the *Patent Act*, RSC 1985, c P-4. This included arguments based on the object and purpose of the CSP provisions of the *Patent Act*, which implement elements of the *Canada-European Union Comprehensive Economic and Trade Agreement* (*CETA*).

[3] The Minister denied Merck's CSP application by letter dated August 9, 2019. The Minister concluded the first NDS could not satisfy the timely submission requirement since it did not result in the NOC for BELSOMRA, while the second NDS was not filed within the prescribed time. In reaching this conclusion, the Minister referred and responded to some of Merck's arguments. However, the Minister did not address the purpose of the CSP provisions, or Merck's arguments about that purpose.

[4] I conclude the Minister's decision was unreasonable because it failed to meaningfully account for a key argument raised by Merck pertaining to a relevant issue of statutory interpretation. Contemporary administrative law requires an administrative decision to be justified through reasons that "meaningfully grapple with key issues or central arguments" in a party's submissions. Given the nature of Merck's submissions, the administrative context, and the principles of statutory interpretation, I conclude the Minister's failure to address Merck's legislative purpose arguments undermined the decision to the extent that it was unreasonable.

[5] Merck asks the Court to order the Minister to issue a CSP for BELSOMRA. In essence, it asks the Court to conclude the only reasonable interpretation of subsection 106(1) of the *Patent Act* is one that recognizes that a drug such as BELSOMRA should obtain a CSP. I am not prepared to do so. While the Minister did not address all of Merck's arguments, the Minister is tasked by Parliament with interpreting and applying subsection 106(1) and is best positioned to make the determination. I do not consider this an appropriate situation for an order of indirect substitution, effectively making the decision for the Minister.

[6] The Minister's decision is therefore set aside and Merck's application for a CSP for BELSOMRA is remitted for redetermination.

II. Issue and Standard of Review

[7] The only issue raised in this application for judicial review is whether the Minister erred in denying Merck's application for a CSP for BELSOMRA. The parties agree, as do I, that the reasonableness standard applies to the Minister's decision: *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at paras 16–17, 23–25; *Canada (Health) v Glaxosmithkline Biologicals SA*, 2021 FCA 71 at para 34.

[8] A reasonable decision is one that is justified, transparent, and intelligible, reflecting "an internally coherent and rational chain of analysis" when read as a whole and taking into account the record before the decision maker: *Vavilov* at paras 81, 85, 91, 96, 99. Reasonableness is to be assessed in relation to the factual and legal constraints that bear on the decision: *Vavilov* at

para 99. These constraints include the governing statutory scheme, the principles of statutory interpretation, and the submissions of the parties: *Vavilov* at paras 108–110, 115–124, 127–128.

III. Analysis

[9] The focus of reasonableness review is the decision made by the decision maker, including both the reasoning process and the outcome: *Vavilov* at para 83. However, assessing the reasonableness of the Minister's decision requires an understanding of the relevant statutory framework and the regulatory context of Merck's application for a CSP. I will therefore discuss the relevant statutory and regulatory provisions and set out the pertinent factual background before turning to the reasons the Minister gave for refusing Merck's application.

A. *Relevant Provisions in the* Patent Act *and the* Certificate of Supplementary Protection Regulations

[10] The CSP provisions of the *Patent Act*, found in sections 104 to 134 and in consequential amendments throughout the statute, were enacted in 2017 through the *Canada–European Union Comprehensive Economic and Trade Agreement Implementation Act*, SC 2017, c 6. It is common ground that the CSP provisions were enacted to implement Canada's obligations under *CETA*: *Glaxosmithkline (2021)* at paras 23–27, 102; Regulatory Impact Analysis Statement (RIAS), *Certificate of Supplementary Protection Regulations*, SOR/2017-165 [*CSP Regulations*], *Canada Gazette Part II*, Vol 151, Extra No 1 at pp 6–7.

[11] A CSP is a certificate that grants a patentee "patent-like rights" extending up to two years beyond the term of patent, in respect of drugs that contain a medicinal ingredient or combination

of medicinal ingredients that are protected by the patent: *Patent Act*, ss 115–116; RIAS at p 7. The intent is to partly compensate for the patent term lost during the research and regulatory approval of new drugs: RIAS at p 7; *Canada (Health) v Glaxosmithkline Biologicals SA*, 2020 FCA 135 at para 4.

[12] A CSP is only available in certain defined circumstances, set out in subsection 106(1) of the *Patent Act*:

Application	**Demande**
106 (1) On the payment of the prescribed fee, a patentee may apply to the Minister for a certificate of supplementary protection for a patented invention if all of the following conditions are met:	**106 (1)** Le titulaire d'un brevet peut, sur paiement des taxes réglementaires, présenter au ministre une demande de certificat de protection supplémentaire pour l'invention à laquelle le brevet se rapporte si, à la fois :
(a) the patent is not void and it meets any prescribed requirements;	**a)** le brevet n'est pas nul et il satisfait aux exigences réglementaires;
(b) the filing date for the application for the patent is on or after October 1, 1989;	**b)** la date de dépôt de la demande de brevet est le 1 er octobre 1989 ou est postérieure à cette date;
(c) the patent pertains in the prescribed manner to a medicinal ingredient, or combination of medicinal ingredients, contained in a drug for which an authorization for sale of the prescribed kind was issued on or after the day on which this section comes into force;	**c)** le brevet est lié, de la manière prévue par règlement, à un ingrédient médicinal ou à une combinaison d'ingrédients médicinaux contenus dans une drogue pour laquelle une autorisation de mise en marché prévue par règlement a été délivrée à la date d'entrée en vigueur du présent article ou après cette date;

(d) the authorization for sale is the first authorization for sale that has been issued with respect to the medicinal ingredient or the combination of medicinal ingredients, as the case may be;	**d)** l'autorisation de mise en marché est la première autorisation de mise en marché à avoir été délivrée à l'égard de l'ingrédient médicinal ou de la combinaison d'ingrédients médicinaux, selon le cas;
(e) no other certificate of supplementary protection has been issued with respect to the medicinal ingredient or the combination of medicinal ingredients, as the case may be;	**e)** aucun autre certificat de protection supplémentaire n'a été délivré à l'égard de l'ingrédient médicinal ou de la combinaison d'ingrédients médicinaux, selon le cas;
(f) if an application for a marketing approval, equivalent to an authorization for sale, was submitted in a prescribed country with respect to the medicinal ingredient or combination of medicinal ingredients, as the case may be, before the application for the authorization for sale was filed with the Minister, the application for the authorization for sale was filed before the end of the prescribed period that begins on the day on which the first such application for a marketing approval was submitted.	**f)** dans le cas où, avant le dépôt auprès du ministre de la demande d'autorisation de mise en marché, une demande a été présentée auprès d'un pays prévu par règlement relativement à l'ingrédient médicinal ou à la combinaison d'ingrédients médicinaux, selon le cas, dans le but d'obtenir une autorisation de vente équivalant à une autorisation de mise en marché, la demande d'autorisation de mise en marché a été déposée avant l'expiration du délai réglementaire qui commence à la date à laquelle une telle demande d'autorisation de vente a été présentée pour la première fois.
[Emphasis added.]	[Je souligne.]

[13] Two requirements in subsection 106(1) are of particular importance in this application:

(i) the requirement in paragraph 106(1)(*c*) that the patent pertain to a medicinal ingredient in a

drug *for which an authorization for sale was issued* after the provisions came into force (termed the "authorization for sale requirement"), and (ii) the requirement in paragraph 106(1)(*f*) that the Canadian application for authorization *be filed within a prescribed period* after authorization is sought in a foreign country (termed the "timely submission requirement").

[14] For the purposes of paragraph 106(1)(*c*), an "authorization for sale of the prescribed kind" is, exclusively, an NOC: *CSP Regulations*, s 4. Section 106 came into force on September 21, 2017: *Order Fixing September 21, 2017 as the Day on which the Act Comes into Force, other than Certain Provisions*, SI/2017-47. Thus paragraph 106(1)(*c*) requires that the patent pertain to a medicinal ingredient contained in a drug for which an NOC was issued after September 21, 2017.

[15] While an "authorization for sale" for purposes of paragraph 106(1)(*c*) must be an NOC, Merck points out that the general definition of "authorization for sale" in the *CSP Regulations* is broader. It covers any authorization under the *Food and Drugs Act*, RSC 1985, c F-27, save for certain exclusions: *CSP Regulations*, s 1(2). It therefore includes natural health product approvals and authorizations for non-prescription drugs. This broader term applies elsewhere in subsection 106(1), including in particular paragraph 106(1)(*d*), which requires the authorization for sale to be the first authorization for sale. As a result, a CSP cannot be issued for a drug that has received prior approval as, say, a natural health product.

[16] For purposes of paragraph 106(1)(*f*), the United States is a "prescribed country" and the applicable "prescribed period" is 12 months: *CSP Regulations*, s 6(1). There is no dispute that the term "application for the authorization for sale" in paragraph 106(1)(*f*) refers to, at least, an

NDS. The timely submission requirement therefore requires that the Canadian NDS be filed within 12 months of when the first foreign application for marketing approval was filed. The RIAS states that the goal of the timely submission requirement in paragraph 106(1)(*f*) is to "incentivize the early introduction of innovative drugs into the Canadian market": RIAS at p 11.

[17] To obtain a CSP, the patentee must apply for one within 120 days of the date of their NOC or, if later, the date the patent is granted: *Patent Act*, s 106(3); *CSP Regulations*, s 6(2). Subsection 106(5) of the *Patent Act* sets out what must be in an application for a CSP:

Contents of application	**Contenu de la demande**
106 (5) An application for a certificate of supplementary protection shall	**106 (5)** La demande de certificat de protection supplémentaire :
(a) set out the number, as recorded in the Patent Office, of the patent — as well as the medicinal ingredient or combination of medicinal ingredients and the number of the authorization for sale — in relation to which the certificate is sought;	**a)** mentionne le numéro d'enregistrement du brevet au Bureau des brevets, l'ingrédient médicinal ou la combinaison d'ingrédients médicinaux et le numéro de l'autorisation de mise en marché à l'égard desquels le certificat est demandé;
(b) if paragraph (1)(f) applies with respect to the application, specify the day on which the first application for a marketing approval that is equivalent to an authorization for sale was made and the country in which that application was made; and	**b)** précise, dans le cas où l'alinéa (1)f) s'applique à la demande, la date à laquelle la demande pour une autorisation de vente équivalant à une autorisation de mise en marché a été présentée pour la première fois et le pays auprès duquel elle l'a été;
(c) set out any prescribed information.	**c)** contient tout autre renseignement prévu par règlement.

[Emphasis added.] [Je souligne.]

[18] In addition to the requirements in paragraphs 106(5)(*a*) and (*b*), the *CSP Regulations* require the application to include the applicant's name and contact information, information about the patent, an attestation that the applicant is the patentee or an authorized manufacturer, an attestation that the requirements of paragraph 106(1)(*f*) are met, and payment information: *CSP Regulations*, s 6(3).

B. *The Relevant Regulatory History*

(1) Merck's New Drug Submissions for BELSOMRA

[19] BELSOMRA is a drug to treat insomnia. As indicated, it contains the active ingredient suvorexant. BELSOMRA is the first drug approved in Canada containing suvorexant.

[20] On August 30, 2012, Merck's American affiliate filed an application for approval of BELSOMRA in the United States. That application was ultimately approved in the US in August 2014.

[21] Merck filed an NDS for Canadian approval of BELSOMRA on November 15, 2012. That NDS was given number 160233.

[22] In 2013, Health Canada issued a Notice of Deficiency (NOD) raising a concern that NDS 160233 contained insufficient information for an adequate benefit/risk profile of

suvorexant. The NOD required additional clinical trial data to satisfy this concern. Merck concluded it could not provide this data and withdrew NDS 160233 in February 2014.

[23] Merck filed a second NDS in 2016, after Health Canada indicated that other post-market data could satisfy the need for additional safety evidence. This second NDS, which was given a new NDS number (196367), contained largely the same data and information that was in the first NDS, together with further safety evidence. After a number of exchanges between Merck and Health Canada and the submission of further information by Merck, the Minister issued an NOC to Merck for BELSOMRA on November 29, 2018. The NOC bears Merck's name and sets out the Submission Number (196367), the product name (BELSOMRA), the medicinal ingredient (suvorexant), and the drug identification numbers, routes of administration, drug forms, and strength of the approved products.

(2) Merck's application for a Certificate of Supplementary Protection

[24] After receiving its NOC for BELSOMRA on November 29, 2018, Merck filed an application for a CSP for the '892 Patent in relation to BELSOMRA on March 26, 2019.

[25] Health Canada's CSP application form includes a number of fields, many of which are indicated as "required" and which correlate to the requirements set out in subsection 106(5) of the *Patent Act* and subsection 6(3) of the *CSP Regulations*. These include:

- under the heading "Applicant Information," the applicant's name and contact information;

- under the heading “Patent Information,” the patent number, filing date, grant date, and expiration date of the patent;
- under the heading “New Drug Submission (NDS) Information,” the “NDS Number”;
- under the heading “Notice of Compliance (NOC) Date,” the “NOC Date”; and
- under the heading “Attestations,” an attestation that the applicant is the patentee or an authorized manufacturer, and an “Attestation as to Timely Submission.”

[26] Merck’s CSP application gave the patent information of the ’892 Patent. It identified the “NDS Number” as 160233, the number of its first NDS. It identified the NOC Date as November 29, 2018, the date it received an NOC for BELSOMRA arising from the second NDS, 196367. And it gave the Attestation as to Timely Submission on the basis that the “above noted NDS” was filed within 12 months of the first foreign application for marketing approval, namely the August 30, 2012 application in the US.

(3) The Minister’s preliminary view and Merck’s submissions

[27] On May 13, 2019, Health Canada, on behalf of the Minister, sent a letter to Merck indicating its preliminary view that Merck was not eligible to receive a CSP. The letter noted that subsection 106(5) of the *Patent Act* requires the CSP application to refer to the number of the “authorization for sale,” *i.e.*, the NOC. As the CSP application was in relation to NDS 160233, which was withdrawn and did not receive an NOC, the letter expressed the view that the authorization for sale requirement had not been met. The Minister’s letter also noted that since

no NOC was granted, it was not possible to file the CSP application within the 120 days of the NOC being issued, as required by subsection 106(3) of the *Patent Act* and subsection 6(2) of the *CSP Regulations*. The Minister invited written representations on the letter.

[28] Merck filed submissions by letter dated June 26, 2019. The submissions were thorough, spanning 16 pages. They were supported by an affidavit from the head of Merck's regulatory department setting out the Canadian and foreign regulatory history for Merck's suvorexant tablets.

[29] Merck's submissions argued the Minister had misinterpreted the *Patent Act* and the *CSP Regulations*. Merck claimed it met the authorization for sale requirement in paragraph 106(1)(*c*) since it obtained an NOC for BELSOMRA on November 29, 2018. It also argued it met the timely submission requirement in paragraph 106(1)(*f*) since it filed an NDS in Canada within 12 months of the first filing for authorization in the US. Merck submitted it had pursued an NOC diligently, but had to withdraw the first NDS because of Health Canada's requirement for further data, a position from which it claimed Health Canada "ultimately resiled." Merck's summary of its submissions concluded with the following two arguments:

> The fact that the resubmitted NDS received a different NDS number is a matter of administrative form only. The suvorexant NDSs relied on the same pivotal clinical safety and efficacy data and should be treated as one and the same. Nothing in the plain language of the CSP Legislation prevents the Minister from treating the suvorexant NDSs as one and the same.
>
> Furthermore, the [Minister]'s preliminary decision is contrary to the object and purpose of the *Patent Act* and *CSP Regulations* to promote innovation and investment in new drugs in Canada by compensating innovators for patent term lost during research and while obtaining marketing authorization. Merck Canada's application for an authorization for sale for suvorexant necessitated

> an extended time obtaining marketing authorization in Canada by reason of Health Canada requirements. The [Minister]'s interpretation of the CSP regime results in a denial of CSP rights on the basis of the exact harm a CSP is intended to address.

[30] Merck further developed each of these arguments in the remainder of the submission letter. This included a lengthy submission on "statutory interpretation," arguing the Minister did not take into account the "grammatical and ordinary meaning" of the provisions. In particular, Merck argued there was no requirement in the *Patent Act* that the "authorization for sale requirement" be linked to any specific "application for an authorization for sale," and that the review of NDS 196367 was simply a continuation of NDS 160233.

[31] Merck's submission letter concluded with a section arguing that the preliminary decision was contrary to the "object and purpose" of the CSP provisions. Referring to the obligations arising from *CETA*, Merck noted that the object and purpose of the legislation was to promote innovation and investment of drug products in Canada by providing an additional period of protection to partly compensate for the time spent in research and obtaining marketing authorization. Merck argued the Minister's preliminary decision did not interpret the legislative provisions in accordance with this object and purpose.

C. *The Minister's Decision*

[32] The Minister issued a final decision by letter dated August 9, 2019. The Minister noted that in its submission letter, Merck took the position that the preliminary decision was based on an erroneous interpretation of the relevant provisions regarding the authorization for sale requirement and the timing requirements for a CSP application.

[33] As in the preliminary decision, the Minister noted that Merck's CSP application set out the NDS number as 160233 and the NOC date as November 29, 2018. With respect to NDS 160233, it concluded that no NOC was issued, such that NDS 160233 did not support the grant of a CSP. It went on to consider NDS 196367, since an NOC was granted for that NDS, and concluded it did not meet the timely submission requirement, since it was filed more than 12 months after the first US application was filed.

[34] The Minister expressly responded to Merck's argument that there was no requirement that the NOC contemplated by paragraphs 106(1)(*c*) and (*d*) be issued in respect of the same NDS that is referred to in paragraph 106(1)(*f*). It disagreed, for the following reasons:

> A notice of compliance is inextricably linked to its associated NDS, and as such, the notice of compliance date required to be specified on the CSP application must be the date of marketing authorization issued to the very NDS required to be specified on the CSP application. Paragraph 106(5)(a) of the *Patent Act* indeed confirms that the application for a CSP shall include the NDS number for which the authorization for sale has been granted […].

[35] The Minister also observed that Merck's apparent criticism of Health Canada's requests for additional information could not now be raised, given that they were not challenged by Merck at the time. The Minister therefore maintained the position that a CSP should not be granted for the '892 Patent in respect of BELSOMRA.

D. *The Minister's Decision is Unreasonable since it Fails to Address a Central Argument*

[36] On this application, Merck makes three main arguments. First, it argues the Minister improperly added a requirement that the "authorization for sale" (NOC) referred to in

paragraph 106(1)(*c*) be issued in respect of the same NDS referred to as the "application for an authorization for sale" in paragraph 106(1)(*f*), based on the stated "inextricable link" that derives from the Minister's own non-binding administrative approach to NDS numbering. Second, it argues the Minister's interpretation did not consider the context and purpose of the CSP regime set out in the *Patent Act* and *CSP Regulations*. Third, it argues the Minister's interpretation is inconsistent with the text of *CETA*.

[37] In my view, the second of these arguments is determinative. As a result, and for the reasons I discuss further below, I believe I should not comment on the first and third arguments.

(1) Context and purpose as a relevant factor in statutory interpretation

[38] The Supreme Court of Canada in *Vavilov* confirmed that the long-accepted "modern principle" of statutory interpretation applies to interpretation by an administrative tribunal: *Vavilov* at paras 115–124. That principle provides that the words of a statute must be read "in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament": *Bell ExpressVu Limited Partnership v Rex*, 2002 SCC 42 at para 26. The Supreme Court has summarized the principle as requiring consideration of the "text, context and purpose" of the legislation: *Vavilov* at paras 118, 120–122.

[39] An administrative decision maker is not always required to engage in a "formalistic statutory interpretation" and may express their views in a way that looks different from judicial reasons. However, a reasonable statutory interpretation must be consistent with the text, context,

and purpose of the provision, applying the administrative decision maker's particular insight into the statutory scheme at issue: *Vavilov* at paras 119–121; *Glaxosmithkline (2021)* at para 75.

[40] The purpose of a legislative provision is thus a relevant aspect of its interpretation. Where the legislation seeks to implement obligations arising from an international agreement or treaty, that agreement also forms part of the relevant interpretive context: *Vavilov* at paras 114, 177–182; *Glaxosmithkline (2021)* at paras 105–109, 113–115; *R v Hape*, 2007 SCC 26 at para 53; *Teva Canada Limited v Canada (Health)*, 2012 FCA 106 at paras 34–42.

(2) The Minister did not consider Merck's arguments on this relevant factor

[41] The Minister's conclusions regarding the interpretation of paragraphs 106(1)(*c*) and (*f*) were based on the text of those provisions, the context of the other provisions in the *Patent Act* and the *CSP Regulations*, and the broader administrative context of its assessment of the link between an NOC and its associated NDS. However, the Minister's decision letter contains no discussion of the purpose of the CSP provisions in implementing Canada's obligations under *CETA*, despite Merck dedicating material argument to that issue. Nor does the Minister's earlier letter setting out its preliminary view discuss the issue.

[42] The Supreme Court describes this circumstance and the approach that reasonableness review requires at paragraph 122 of *Vavilov*:

> It can happen that an administrative decision maker, in interpreting a statutory provision, fails entirely to consider a pertinent aspect of its text, context or purpose. Where such an omission is a minor aspect of the interpretive context, it is not likely to undermine the decision as a whole. It is well established that decision makers are

> not required "to explicitly address all possible shades of meaning" of a given provision […]. Just like judges, administrative decision makers may find it unnecessary to dwell on each and every signal of statutory intent in their reasons. In many cases, it may be necessary to touch upon only the most salient aspects of the text, context or purpose. If, however, it is clear that the administrative decision maker may well, had it considered a key element of a statutory provision's text, context or purpose, have arrived at a different result, its failure to consider that element would be indefensible, and unreasonable in the circumstances. Like other aspects of reasonableness review, omissions are not stand-alone grounds for judicial intervention: the key question is whether the omitted aspect of the analysis causes the reviewing court to lose confidence in the outcome reached by the decision maker.
>
> [Emphasis added; citation omitted.]

[43] Where, as here, the pertinent aspect of statutory interpretation was the subject of submissions to the administrative decision maker, the foregoing is reinforced by *Vavilov*'s statement that "[t]he principles of justification and transparency require that an administrative decision maker's reasons meaningfully account for the central issues and concerns raised by the parties": *Vavilov* at para 127.

[44] I conclude that the Minister failed to consider a "pertinent aspect" of the text, context, or purpose of the CSP provisions of the *Patent Act*. As discussed above, the purpose of the provisions, and in particular their purpose in implementing Canada's *CETA* obligations, is a pertinent aspect of their interpretation. It remains to assess whether this is a "minor aspect of the interpretive context" or a "key element" that may well have changed the Minister's conclusion: *Vavilov* at para 122. Ultimately, the question is whether the absence of consideration of this aspect causes the Court to lose confidence in the outcome: *Vavilov* at para 122; *Glaxosmithkline (2021)* at paras 75–76.

[45] I conclude in this case that given the central role of *CETA* in the context of enactment of the CSP provisions, the Minister's failure to consider the purpose of the provisions in the context of *CETA* causes me to lose confidence in the Minister's decision. In particular, Merck's arguments regarding the object and purpose of the legislation being to promote innovation and investment of drug products in Canada and to partly compensate for the time spent in research and obtaining marketing authorization were sufficiently material that I conclude that a reasonable interpretation of subsection 106(1) of the *Patent Act* had to take them into account.

[46] In reaching this conclusion, I do not dispute the Minister's contention that the object and purpose of a provision must be considered in the context of the statutory language used to implement that purpose: *Takeda Canada Inc v Canada (Health)*, 2013 FCA 13 at paras 43, 117–119, 129–131*; Canwell Enviro-Industries Ltd v Baker Petrolite Corp*, 2002 FCA 158 at para 25; *Natco Pharma (Canada) Inc v Canada (Health)*, 2020 FC 788 at paras 20–21, 43, 52. However, the statutory language must similarly be considered in the context of the legislative purpose: *Teva* at paras 34–41; *Takeda* at paras 35, 40–44, 71, 86–87, 123.

[47] In *Glaxosmithkline (2021)*, the Federal Court of Appeal concluded that the lack of an express reference to *CETA* in interpreting the term "medicinal ingredient" did not make the Court lose confidence in the Minister's reasoning: *Glaxosmithkline (2021)* at para 76. However, in that case, Justice Gauthier for the Court noted that the Minister had referred to the RIAS and therefore demonstrated a clear awareness of the objective and rationale spelled out in it: *Glaxosmithkline (2021)* at paras 76, 86, 102. In the current case, the Minister did not refer to *CETA* or the RIAS and did not acknowledge or respond to Merck's arguments regarding the

object and purpose of the legislation. Given the specific purpose of the CSP provisions, failure to consider that purpose leaves me in doubt that the Minister's interpretation was undertaken in a manner consistent with the "text, context and purpose" of the provision.

[48] This leaves the question of whether the matter must return to the Minister or whether this is a case in which the Court can pronounce on how or whether the missing aspect of the statutory analysis would affect the outcome. In *Vavilov*, the majority reiterated that a court conducting reasonableness review is not to perform a *de novo* analysis to assess the correct interpretation of a statutory provision, but recognized that "it may sometimes become clear in the course of reviewing a decision that the interplay of text, context and purpose leaves room for a single reasonable interpretation of the statutory provision": *Vavilov* at para 124. In such a case, no useful purpose would be served by remitting the matter back.

[49] Merck and the Minister each suggest that there is only one reasonable interpretation, namely their own. Merck asks that the Minister's decision be quashed and that the Minister be ordered to issue a CSP to Merck. The Minister asks that the decision be affirmed and the application dismissed even if the Court concludes that the Minister failed to address a material interpretive argument.

[50] Based on the legislative context and the arguments and submissions of the parties, I am not satisfied the question is so clear that I should reach the conclusion that there is room for only a single reasonable interpretation. In this regard, I am particularly mindful that the Court "should generally pause before definitively pronouncing upon the interpretation of a provision entrusted

to an administrative decision maker" and that the Court's role is not to "choose the [interpretation] they prefer or that they find the most logical from their point of view": *Vavilov* at para 124; *Glaxosmithkline (2021)* at para 64. Interpretation has been entrusted to the Minister at first instance, and the Minister is best positioned to undertake that interpretation considering not only the interpretive issues identified in the decision but also Merck's arguments on the object and purpose of the provisions.

[51] Since I conclude the matter should be remitted to the Minister, I consider the less said about the interpretive issues, the better. This includes in particular commenting on or deciding Merck's other arguments regarding the Minister's interpretation and the extent to which that interpretation is consistent with *CETA*. Providing such comments without undertaking a full interpretive analysis would be akin to undertaking a part of the statutory interpretation exercise in isolation. This would be contrary to the modern interpretive principle.

[52] For clarity, therefore, I underscore that nothing in these reasons should be considered as approving or disapproving of either the Minister's interpretation and arguments or those of Merck. Rather, the Minister's decision is unreasonable because it has failed to consider a relevant aspect of the interpretive context that was expressly raised in argument by Merck.

IV. Conclusion

[53] The application for judicial review is therefore allowed, and Merck's application for a CSP in respect of the '892 Patent and BELSOMRA is remitted to the Minister for redetermination.

[54] Pursuant to sections 104 and 131 of the *Patent Act*, the Minister shall not be ordered to pay the costs of any other party. There is therefore no order as to costs.

JUDGMENT IN T-1471-19

THIS COURT'S JUDGMENT is that

1. The application for judicial review is granted. The August 9, 2019 decision of the Minister of Health, by the Director General's Office, Resource Management and Operations Directorate, Health Products and Food Branch, Health Canada, refusing Merck Canada Inc's application number 900038 for a Certificate of Supplementary Protection for Canadian Patent No 2,670,892 and in respect of the drug BELSOMRA, is set aside and the application is remitted to the Minister of Health for redetermination.
2. There is no order as to costs.

"Nicholas McHaffie"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1471-19
STYLE OF CAUSE:	MERCK CANADA INC v THE MINISTER OF HEALTH
PLACE OF HEARING:	HELD BY VIDEOCONFERENCE
DATE OF HEARING:	JUNE 2, 2021
JUDGMENT AND REASONS:	MCHAFFIE J.
DATED:	SEPTEMBER 29, 2021

APPEARANCES:

Kristin Wall Corey McClary Colin Hyslop	FOR THE APPLICANT
Katrina Longo John Lucki Andrea Bourke	FOR THE RESPONDENT

SOLICITORS OF RECORD:

Norton Rose Fulbright Canada LLP Toronto, Ontario	FOR THE APPLICANT
Attorney General of Canada Toronto, Ontario	FOR THE RESPONDENT