Federal Court  Cour fédérale

Date: 20200710

Docket: T-353-19

Citation: 2020 FC 756

Ottawa, Ontario, July 10, 2020

PRESENT: The Honourable Madam Justice Fuhrer

BETWEEN:

VIIV HEALTHCARE ULC

Applicant

and

THE MINISTER OF HEALTH

Respondent

JUDGMENT AND REASONS

I. Overview

[1] To comply with its obligations under the Canada-European Union Comprehensive Economic and Trade Agreement, also known as *CETA*, Canada enacted the *Canada-European Union Comprehensive Economic and Trade Agreement Implementation Act*, SC 2017 c 6, Part 2 [*CIA*]. To implement the *sui generis* regime of additional "patent-like" protection for pharmaceuticals described in *CETA* Article 20.27, Canada introduced the Certificate of

Supplementary Protection or CSP in new sections 104-134 to the *Patent Act*, RSC 1985, c P-4. The *Certificate of Supplementary Protection Regulations*, SOR/2017-165 [*CSPR*] round out this new pharmaceutical protection regime in Canada, administered by the Minister of Health.

[2] To compensate for time spent researching and obtaining market authorization for innovative products, eligible patentees may obtain up to two years of additional protection for the medicinal ingredient or combination of medical ingredients listed in a CSP. This additional protection includes the right to exclude others from "making, constructing, using, and selling any drug that contains the medicinal ingredient or combination of medicinal ingredients set out in the [CSP]": *Patent Act* ss 113, 115(1); *CSPR* s 4. As a precondition to obtaining a CSP, the ingredient or combination must be listed in an approved authorization for sale, also known as a Notice of Compliance or NOC.

[3] The applicable facts are not in dispute. ViiV filed a New Drug Submission with Health Canada seeking a NOC for JULUCA®, a fixed-dosed combination therapy in a single pill. JULUCA is designed to treat human immunodeficiency virus [HIV] in adults who are virologically stable and suppressed, and is an alternative to multi-dose drug regimens. It is comprised of the medicinal ingredients dolutegravir and rilpivirine, and is the first fixed-dose combination drug approved in Canada containing this innovative combination. Health Canada issued the NOC, citing both of these medicinal ingredients: *Food and Drug Regulations*, CRC c 870 [*CFDR*] s C.08.004(1)(a).

[4] JULUCA was listed on the Register of Innovative Drugs, citing Canadian Patent No. 2,606,282 entitled "Polycyclic Carbamoylpyridone Derivatives Having HIV Integrase Inhibitory Activity" ("282 Patent"): *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*PM(NOC)R*] ss 2, 4(2), 4(2.1). Some of the 437 claims of the 282 Patent, owned by ViiV Healthcare Company and Shionogi & Co., Ltd., are directed to dolutegravir; none of the claims, however, is directed to rilpivirine, the other medicinal ingredient contained in JULUCA.

[5] ViiV, a manufacturer authorized by the owner of the 282 Patent, subsequently applied for a CSP for JULUCA. The *Patent Act* s 106 and *CSPR* s 3(2) set out the requisite criteria for obtaining a CSP. The Minister (represented by the Health Products and Food Branch of Health Canada) advised ViiV of the preliminary assessment that ViiV's application was not eligible for a CSP because the 282 Patent does not pertain to the combination of the medicinal ingredients dolutegravir and rilpivirine in the manners prescribed in *CSPR* s 3(2). ViiV filed responding evidence and submissions. The Minister denied ViiV's application based on these same concerns. ViiV now seeks judicial review of the Minister's decision.

[6] The following issues arise:

A. What is the appropriate standard of review?

(1) Was the Minister's refusal to issue a CSP for JULUCA reasonable? This involves the more granular question: was Minister's interpretation of *Patent Act* s 106(1)(c) and *CSPR* s 3(2)(a), namely that an eligible patent must claim all the medicinal ingredients in a combination drug to support the issuance of a CSP, consistent with the text, context and purpose of these provisions? There are three subsidiary issues:

(a) *Is the Minister's interpretation reasonably consistent with "grammatical and ordinary sense" of the text of these CSP provisions?*

(b) *Did the Minister reasonably interpret these CSP provisions in a manner consistent with the Patent Act, having regard to Patent Act s 106(1)(d) and PM(NOC)R s 4(2)(a)?*

(c) *Did the Minister reasonably interpret Patent Act s 106(1)(c) and CSPR s 3(2)(a) in a manner consistent with CETA, as required by CIA s 3, by relying only on the CSPR RIAS and associated Guidance Document?*

[7] I find subsidiary issue (c) determinative. These reasons therefore deal only with the appropriate standard of review and whether the Minister reasonably interpreted *Patent Act* s 106(1)(c) and *CSPR* s 3(2)(a) in a manner consistent with CETA, as required by CIA s 3, by relying only on the *CSPR* Regulatory Impact Analysis Statement ("RIAS") and associated Guidance Document. For the reasons that follow, I grant this judicial review application because the Minister unreasonably considered ViiV's submissions based on CETA Article 20.27 regarding the proper interpretation of *Patent Act* s 106(1)(c) and *CSPR* s 3(2)(a), by failing to consider CETA itself in addition to the *CSPR* RIAS and Guidance Document. This matter will be remitted to the Minister for redetermination.

II. Relevant Provisions

[8] See the attached Annex.

III. Analysis

A. *What is the appropriate standard of review?*

[9] At the hearing, the parties agreed that reasonableness is the applicable standard of review, having regard to the seminal decision of the Supreme Court of Canada in *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 [*Vavilov*]. There now is a rebuttable presumption that all administrative decisions are reviewable on the reasonableness standard: *Vavilov*, above at paras 9-10. I find none of the situations which rebut this presumption (summarized in *Vavilov*, above at paras 17 and 69) are present in the instant proceeding.

[10] The reasonableness standard means that courts should intervene only where necessary. It is not a "rubber-stamping" exercise, but rather a robust review: *Vavilov*, above at para 13. When reviewing an administrative decision under the reasonableness standard, "…a court must consider the outcome of the administrative decision in light of its underlying rationale in order to ensure that the decision as a whole is transparent, intelligible and justified": *Vavilov*, above at para 15. The SCC defined a reasonable decision owed deference as "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": *Vavilov*, above at para 85. In sum, the decision must bear the hallmarks of reasonableness – justification, transparency and intelligibility – and it must be justified in relation to the factual and legal constraints applicable in the circumstances: *Vavilov*, at para 99. Constraints on a decision maker can include the governing statutory scheme and the principles of statutory interpretation, among other considerations applicable in a particular case:

Vavilov, above at para 106. The party challenging the decision has the onus of demonstrating that the decision is unreasonable: *Vavilov*, above at para 100.

[11] As the crux of the judicial review before this Court is a matter of statutory interpretation, it is worth noting the SCC was quite specific in holding that, "[m]atters of statutory interpretation are not treated uniquely and, as with other questions of law, may be evaluated on a reasonableness standard": *Vavilov*, above at para 115. The SCC also reminds us that, "[a] court interpreting a statutory provision does so by applying the 'modern principle' of statutory interpretation, that is, 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'" [citations omitted]: *Vavilov*, above at para 117. Further, "the administrative decision maker must demonstrate in their reasons that they were alive to the 'essential elements' of statutory interpretation[, namely] the text, context and purpose of the provision": *Canada Post Corp v Canadian Union of Postal Workers*, 2019 SCC 67 at para 42; *Vavilov*, above at para 120.

[12] Finally, in the context of the judicial review before this Court, "[i]t is well established that domestic legislation is presumed to comply with Canada's international obligations, and that it must be interpreted in a manner that reflects the principles of customary and conventional international law" [citations omitted]: *Vavilov*, above at para 182.

(1) Was the Minister's refusal to issue a CSP for JULUCA reasonable? Was Minister's interpretation of *Patent Act* s 106(1)(c) and *CSPR* s 3(2)(a), namely that an eligible patent must claim all the medicinal ingredients in a combination drug to support the issuance of a CSP, consistent with the text, context and purpose of these provisions?

(c) Did the Minister reasonably interpret Patent Act s 106(1)(c) and CSPR s 3(2)(a) in a manner consistent with CETA as required by CIA s 3, by relying only on the CSPR RIAS and associated Guidance Document?

[13] There is a statutory interpretation principle that "even where the legislative text is clear, the context and purpose of the legislation nevertheless must be examined in order to see whether there are latent ambiguities that must be resolved": *Entertainment Software Assoc v Society Composers*, 2020 FCA 100 [*Entertainment Software*] at para 84. In this context, *CIA* s 3 requires that any federal law that implements a provision of, or fulfils an obligation under, CETA (such as the CSP regime provisions) must be **interpreted** in a manner consistent with CETA. I find the Minister's decision demonstrates a failure to consider the meaning of the applicable CSP provisions in the wider context and purpose of the legislative scheme in relation to CETA itself for any latent ambiguities, having regard to the substance of ViiV's submissions on this point. This failure renders the decision unreasonable. A summary of the relevant portions of the Minister's decision, ViiV's submissions both before the Minister and this Court, and the Minister's further submissions before this Court, followed by my analysis, illustrate this dispositive gap in the Minister's decision.

i) Minister's Decision

[14] In denying ViiV's CSP application for JULUCA, the Minister found that the 282 Patent "does not pertain to the combination of the medicinal ingredients dolutegravir and rilpivirine in one of the manners prescribed by [CSPR s 3(2)]". This finding stems from the Minister's conclusion that "where the approved drug contains a combination of medicinal ingredients, [an

eligible] patent must include a claim for the combination of all the medicinal ingredients, a claim for the combination of all the medicinal ingredients as obtained by a specified process, or a claim for a use of the combination of all the medicinal ingredients" in order to meet the requirements of *CSPR* s 3(2). The Minister also emphasized that unlike the PM(NOC) regime, the CSP regime is solely for drugs containing a **new** medicinal ingredient or **new** combination of medicinal ingredients.

[15] In arriving at this conclusion, the Minister relied on the *CSPR* RIAS and associated Guidance Document. In her final assessment, the Minister found that all paragraphs of *Patent Act* s 106(1) must be interpreted consistently to meet the intent behind the provision as described in the *CSPR* RIAS: the eligible patent need not protect the approved combination of medicinal ingredients, but it must include at least one claim directed at the same combination of the same medicinal ingredients to pertain to the same combination of the same medicinal ingredients. The Minister's preliminary assessment also referred to the *CSPR* Guidance Document as additional support to find that "where the drug contains a combination of medicinal ingredients, the patent must pertain to the combination 'as such'". The Minister asserts both "provide useful contextual information" for interpretation, and may be consulted: *Takeda Canada Inc v Canada (Minister of Health)*, 2013 FCA 13 [*Takeda*] at para 124. I do not disagree, but these cannot be the only resources on which the Minister relies for consideration of the proper interpretation of the relevant CSP provisions.

[16] The Minister referred only in passing to CETA by quoting from the Objectives section of the *CSPR* RIAS at page 8. The Minister reiterated Canada's commitment to provide "for an

additional period of patent-like protection for drugs containing new medicinal ingredients and new combinations of medicinal ingredients". CETA was not mentioned specifically anywhere else, nor did the Minister consider ViiV's submissions regarding support in CETA for its proposed interpretation of *Patent Act* s 106(1)(c) and *CSPR* s 3(2)(a).

[17] The Minister acknowledged ViiV's submission (in response to the preliminary assessment) that JULUCA is the first drug containing a combination of dolutegravir and rilpivirine approved and issued a NOC by Health Canada. The Minister responded, however, that to issue a CSP where the underlying patent relates to a single, old medicinal ingredient, but the drug approved in the NOC contains a new combination with that older ingredient, would result in a CSP having a much broader scope than the *sui generis* protection envisaged for drugs containing **new** medicinal ingredients or **new** combinations of medicinal ingredients. For example, ViiV's interpretation would render previously approved drugs such as TIVICAY and TRIUMEQ, both of which contain dolutegravir as medicinal ingredients, eligible for CSP protection. I note that in setting forth the objectives of CETA Chapter 20, however, CETA Article 20.1 does not mention "new" but rather "innovative and creative" products.

ii) ViiV's CETA Submissions

[18] ViiV provided substantial submissions in response to the Minister's preliminary objection and to this Court on how the Minister's preferred interpretation does not conform with Canada's obligations under CETA, and how its preferred interpretation does. In short, ViiV contends that based on CETA Article 20.27, Canada's *sui generis* regime is intended to provide protection for

single medicinal ingredients or combinations of medicinal ingredients contained in new drug "products" (such as JULUCA) protected by a "basic patent" in force (such as the 282 Patent). In ViiV's view, a "basic patent" includes a patent containing a claim to at least one medicinal ingredient contained in a combination drug because that patent, even though it only lists one ingredient in the combination, nonetheless protects the entire product; in other words, it protects the product "as such". This is consistent with *Patent Act* s 115(1), which provides that a CSP covering a single medicinal ingredient will protect a drug containing that medicinal ingredient in addition to any others, as would be the case for a combination drug like JULUCA. ViiV submits the Minister's interpretation ignores altogether this possibility.

[19] ViiV further asserts the Minister's interpretation fails to protect fixed-dose combination drug products adequately by denying access to these additional protections. Emphasizing individual medicinal ingredients contained in combination products are often developed by unrelated manufacturers and therefore subject to distinct patent rights, ViiV submits that without additional CSP protections, manufacturers would be incentivized to continue marketing treatments as two (or more) separate products and discouraged from innovating fixed-dose combination therapies. This would be at odds with the objectives of CETA Chapter 20 (Intellectual Property), namely, to (a) facilitate the production and commercialisation of innovative and creative products, and the provision of services, between the Parties; and (b) achieve an adequate and effective level of protection and enforcement of intellectual property rights: CETA Article 20.1

[20] Finally, ViiV submits the fixed-dose drug therapy JULUCA meets the requirements of *CIA* s 2 because (a) a marketing authorization (that is, a NOC in the Canadian context) has been granted; (b) the product has not been the subject of a period of *sui generis* protection; and (c) the marketing authorization referred to in (a) is the first such authorization for the product.

iii) Minister's Further Submissions in Response to ViiV

[21] The Minister disagrees and contends in this judicial review that her preferred interpretation of *Patent Act* s 106(1)(c) and *CSPR* s 3(2)(a) corresponds with Canada's obligations because CETA signatories are "free to determine the appropriate method of implementing the provisions of CETA within their own legal system and practice": CETA Article 20.2(2); *R v Hape*, 2007 SCC 26 [*Hape*] at para 53. The Minister emphasizes that Canada's choice to extend the CSP regime only to those products compliant with their interpretation of *CSPR* s 3(2) accurately reflects CETA's requirement that a basic patent protects "a product as such". She also points to the *CSPR* RIAS as evidence of the Governor in Council's intention that CSP eligibility involves a direct matching of all medicinal ingredients between the patent and authorized drug. The Minister therefore submits that their interpretation falls within CETA's regulatory mandate and is presumed to be compliant with Canada's international obligations: *Sullivan*, above at paras 18.5 and 18.6.

[22] Responding to ViiV's assertion that one of the purposes of the CSP regime is to recognize innovators' research efforts resulting in fixed-dose combination drugs like JULUCA, the Minister submits the CSP regime will reward innovators where they have an eligible patent

with claims to the combination of all medicinal ingredients, and the other requirements of the CSP regime are met.

iv) Analysis

[23] I acknowledge that the Minister relies on the *CSPR* Guidance Document and the *CSPR* RIAS to support her position, whereas ViiV emphasizes that these documents have no force in law: *Apotex Inc v Canada (Health)*, 2017 FC 857 at para 70; *Gilead Sciences Canada Inc v Canada (Health)*, 2012 FCA 254 at para 44; *Teva Canada Ltd v Sanofi-Aventis Canada Inc*, 2014 FCA 67 at paras 77-78; *Campana v Canada (Citizenship and Immigration)*, 2014 FC 49 at paras 19-20; *Eli Lilly Canada Inc v Canada (Minister of Health)*, 2003 FCA 24 at paras 6, 29-36. In my view, these positions are not inconsistent.

[24] I find, however, that the Minister's sole reliance on the *CSPR* RIAS and associated Guidance Document, without considering ViiV's CETA submissions, unreasonable. I agree that while neither the *CSPR* RIAS nor the Guidance Document has legislative force, and therefore cannot supplant the words used in the legislation, they can be a useful tool for determining the intent behind an impugned provision: *Takeda*, above at para 124. The Minister did not act unreasonably in referring to the *CSPR* RIAS to find the specific provisions within *Patent Act* s 106(1) must be interpreted consistently. That said, I note the *CSPR* RIAS, under the heading "(b) Authorizations for sale" states: "[t]he Act also defines that in order for a medicinal ingredient or a combination of medicinal ingredients to be eligible for a CSP it must be the medicinal ingredient or combination of all medicinal ingredients in a drug which is authorized for sale in

Canada". This is not accurate because the *Patent Act* s 106(1) mentions only "a medicinal ingredient or combination of medicinal ingredients"; the *CSPR* s 3(2) is the source of the wording "the medicinal ingredient or combination of all medicinal ingredients".

[25] I further note that the *CSPR* Guidance Document appears to "read in" the following "clarifications" which seem to belie the Minister's assertion that the grammatical and ordinary sense of the words of *CSPR* s 3(2) can be understood without such clarifications:

> A claim for the medicinal ingredient **(in the case of a drug containing only one medicinal ingredient)** or combination of all the medicinal ingredients **(in the case of a drug containing more than one medicinal ingredient)** contained in a drug for which the authorization for sale set out in the CSP application was issued; [Bold emphasis added]

[26] More importantly, I find it is unreasonable for the Minister to rely only on these documents to the exclusion of CETA. The text of CETA, rather than, or in addition to, the *CSPR* RIAS, also must be consulted for shedding light on and determining Canada's intentions for the scope of protection applicable to Canada's CSP regime: *CIA* s 3; *Appulonappa v Canada (Citizenship and Immigration)*, 2015 SCC 59 at para 40; *Thibodeau v Air Canada*, 2014 SCC 67 at paras 112-113; *Office of the Children's Lawyer v Balev*, 2018 SCC 16 at paras 32-33. I agree with ViiV's submission that CETA does seem to provide a broader scope of protection than the Minister's interpretation allows. As I noted above, in setting forth the objectives of CETA Chapter 20, CETA Article 20.1 does not mention "new" but rather "innovative and creative" products; *Takeda* confirms that a drug will not be registered under the Register of Innovative Drugs if it is a minor variant of a pre-existing product: *Takeda*, above at para 121. JULUCA cannot be said to be a minor variant of a pre-existing product and in fact is considered innovative by reason of the issuance of the NOC. Further, I am persuaded that ViiV's interpretation—

namely, that the 282 Patent protects the product (i.e. JULUCA) as such—is not inconsistent on its face with CETA. Accordingly, I find the Minister should have considered these arguments more robustly, with direct reference to CETA for the purpose of detecting any latent ambiguities, before rendering her final decision.

[27] The Minister, emphasizing that Canada is permitted to implement *CETA* in accordance with its own preferences, submits that the CSPR *RIAS* and Guidance Document demonstrate clearly that Canada intended to apply a narrow approach when implementing the CSP regime: *CETA* Article 20.2; *Hape*, above at para 53. I disagree. In my view, a provision permitting signatories to implement given schemes in accordance with their own rules does not in itself absolve decision makers from adequately explaining that a more limited domestic interpretation was intended. There is nothing on the record in this matter to suggest Canada intended a more limited approach than what was contemplated in CETA, or always had interpreted CETA in a more limited way than the alternative suggested by ViiV. Indeed, neither of these documents consider the text of CETA itself, nor the CIA, when describing the intended scope of CSP protection. In such situations, the focus must be on what the legislator actually did in the legislation, not on what was said in such accompanying documents. Because domestic legislation is presumed to conform with a relevant treaty, the focus must be on what the legislator actually did in the legislation; this presumption requires the administrative decision-maker to take into account any relevant international law as part of the context surrounding the enactment of the legislation when interpreting it: *Entertainment Software*, above at paras 90-91. *CIA* s 3 reinforces this principle in the matter before me: *Glaxosmithkline Biologicals SA v Canada (Health)*, 2020

FC 397 at paras 27-28. The Minister's failure to even consider whether *CSPR* s 3(2)(a) could be read in harmony with CETA, rather than expressly limiting it, was fatal to her assessment.

[28] Where the submissions relate to key issues or central arguments raised by the parties, the decision maker must grapple with them: *CIA* s 3; *Vavilov*, above at para 128. I find the Minister's failure to analyze the scope of protection intended by CETA Article 20.27 when considering the appropriate interpretation of *Patent Act* s 106(1)(c) and *CSPR* s 3(2)(a) renders the decision-making process unjustified and thus unreasonable: *Vavilov*, above at para 86.

[29] Finally, the Minister's written and oral submissions on CETA in this judicial review merely serve to underscore this dispositive gap in the Minister's decision, and cannot be relied on at this stage to bolster an otherwise unreasonable decision. For example, Minister's counsel advanced arguments that the language used in *Patent Act* s 115 and wording in ss 106(1)(d)-(e) support a more limited reading. The Minister, however, did not provide this analysis in her actual decision. While the Court may look to supplement the decision with reasons which "would have been offered had the issue been raised", this is not the case here: *Vavilov*, above at para 98. The proper interpretation of the provision was at issue before the Minister, and the Minister had the opportunity to look at the wider scheme for further interpretive justification and chose not to do so. Should the Minister wish to rely on such justifications in the future, the Minister should conduct such an analysis in the decision, which the Court then may review: *Vavilov*, above at para 98, citing *Alberta (Information and Privacy Commissioner) v Alberta Teachers' Association*, 2011 SCC 61 at para 54.

IV. Conclusion

[30] The Minister failed to consider ViiV's CETA submissions adequately regarding the proper interpretation of *Patent Act* s 106(1)(c) and *CSPR* s 3(2)(a). Because these submissions speak to the core of this matter, failing to consider them rendered the Minister's decision denying a CSP for JULUCA unreasonable. I therefore grant ViiV's judicial review application; the matter is to be remitted to the Minister for redetermination.

[31] Having regard to the *Patent Act* s 131, I award no costs in this matter.

JUDGMENT in T-353-19

THIS COURT'S JUDGMENT is that: (i) this judicial review application is granted; (ii) the matter is to be remitted to the Minister for redetermination; (iii) no costs are awarded.

"Janet M. Fuhrer"

Judge

Annex – Relevant Provisions

A. *CETA Article 20.27*

1. For the purposes of this Article:	1. Pour l'application du présent article :
basic patent means a patent which protects a product as such, a process to obtain a product or an application of a product, and which has been designated by the holder of a patent that may serve as a basic patent, as the basic patent for the purpose of the granting of *sui generis* protection; and	**brevet de base** désigne un brevet qui protège un produit en tant que tel, un procédé d'obtention d'un produit ou une application d'un produit, et qui est désigné par le détenteur d'un brevet pouvant servir de brevet de base comme brevet de base aux fins de l'octroi d'une protection sui generis;
product means the active ingredient or combination of active ingredients of a pharmaceutical product.	**produit** désigne le principe actif ou la composition de principes actifs d'un produit pharmaceutique.
2. Each Party shall provide a period of *sui generis* protection in respect of a product that is protected by a basic patent in force at the request of the holder of the patent or his successor in title, provided the following conditions have been met:	**2.** Chaque Partie prévoit une période de protection sui generis à l'égard d'un produit qui est protégé par un brevet de base en cours de validité, sur demande du détenteur du brevet ou de son ayant droit, si les conditions suivantes sont réunies :
(a) an authorisation has been granted to place the product on the market of that Party as a pharmaceutical product (referred to as "marketing authorisation" in this Article);	**a.** le produit a obtenu, en tant que produit pharmaceutique, l'autorisation de mise sur le marché de cette Partie (dénommée "autorisation de mise sur le marché" au présent article);
(b) the product has not already been the subject of a period of *sui generis* protection; and	**b.** le produit n'a pas déjà fait l'objet d'une période de protection sui generis;
(c) the marketing authorisation referred to in subparagraph (a) is the first authorisation to place the product on the market of that Party as a pharmaceutical product.	**c.** l'autorisation de mise sur le marché visée à l'alinéa a) est la première autorisation de mise sur le marché de cette Partie du produit en tant que produit pharmaceutique.

B. *Canada-European Union Comprehensive Economic and Trade Agreement Implementation Act, SC 2017, c 6, Part 2*

3 For greater certainty, this Act and any federal law that implements a provision of the Agreement or fulfils an obligation of the Government of Canada under the Agreement is to be interpreted in a manner consistent with the Agreement.	**3** Il est entendu que la présente loi et tout texte législatif fédéral qui met en oeuvre une disposition de l'Accord ou vise à permettre au gouvernement du Canada d'exécuter une obligation contractée par lui aux termes de l'Accord s'interprètent d'une manière compatible avec celui-ci.

C. *Patent Act, RSC 1985, c P-4:*

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 1er 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.
(2) Another certificate of supplementary protection is considered to have been issued for the purposes of paragraph (1)(e) even if that other certificate is subsequently held to be invalid or void or it never takes effect or ceases to have effect.	**(2)** Pour l'application de l'alinéa (1)e), un autre certificat de protection supplémentaire est réputé avoir été délivré indépendamment du fait qu'il soit subséquemment tenu pour invalide ou nul ou qu'il ne prenne jamais ou cesse d'avoir effet.
(3) An application for a certificate of supplementary protection shall be filed with the Minister before the end of the prescribed period that begins on	**(3)** La demande de certificat de protection supplémentaire est déposée auprès du ministre avant l'expiration du délai réglementaire qui commence à la date de délivrance de l'autorisation de mise en marché ou, si elle lui est postérieure, à la date d'octroi du brevet.
(a) the day on which the authorization for sale is issued, if the patent is granted on or before that day; or	
(b) the day on which the patent is granted, if the patent is granted after the day on which the authorization for sale is issued.	

(4) Despite subsection (3), no application shall be filed within the prescribed period preceding the expiry of the term of the patent under section 44 without taking into account section 46.	**(4)** Malgré le paragraphe (3), aucune demande ne peut être déposée à l'intérieur du délai réglementaire qui précède la date à laquelle le brevet est périmé en application de l'article 44, compte non tenu de l'article 46.
(5) An application for a certificate of supplementary protection shall	**(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.
(6) Each application is permitted to set out only one patent.	**(6)** La demande ne mentionne qu'un seul brevet.
…	**…**
107 (2) Whenever the Minister is satisfied that any of the requirements set out in section 106 are not met with respect to an application for a certificate of supplementary protection, the Minister may refuse the application. The Minister shall notify the applicant of a refusal and of the grounds for it.	**107 (2)** S'il est convaincu que toute exigence prévue à l'article 106 n'est pas remplie relativement à une demande de certificat de protection supplémentaire, le ministre peut rejeter la demande, auquel cas, il en avise le demandeur, motifs à l'appui.

D. *Certificate of Supplementary Protection Regulations, SOR/2017-165 s 3(2)*

3 (2) For the purpose of paragraph 106(1)(c) of the Act, the prescribed manners in which a	**3 (2)** Pour l'application de l'alinéa 106(1)c) de la Loi, le brevet est lié à un ingrédient

patent may pertain to a medicinal ingredient or combination of medicinal ingredients are the following:	médicinal ou à une combinaison d'ingrédients médicinaux de l'une ou l'autre des manières suivantes :
(a) the patent contains a claim for the medicinal ingredient or combination of all the medicinal ingredients contained in a drug for which the authorization for sale set out in the application for a certificate of supplementary protection was issued;	**a)** le brevet contient une revendication de l'ingrédient médicinal ou de la combinaison de tous les ingrédients médicinaux contenus dans une drogue pour laquelle l'autorisation de mise en marché mentionnée dans la demande de certificat de protection supplémentaire a été délivrée;
(b) the patent contains a claim for the medicinal ingredient or combination of all the medicinal ingredients as obtained by a specified process and contained in a drug for which the authorization for sale set out in the application for a certificate of supplementary protection was issued; and	**b)** le brevet contient une revendication de l'ingrédient médicinal ou de la combinaison de tous les ingrédients médicinaux tels qu'ils sont obtenus au moyen d'un procédé déterminé et tels qu'ils sont contenus dans une drogue pour laquelle l'autorisation de mise en marché mentionnée dans la demande de certificat de protection supplémentaire a été délivrée;
(c) the patent contains a claim for a use of the medicinal ingredient or combination of all the medicinal ingredients contained in a drug for which the authorization for sale set out in the application for a certificate of supplementary protection was issued.	**c)** le brevet contient une revendication d'une utilisation de l'ingrédient médicinal ou de la combinaison de tous les ingrédients médicinaux contenus dans une drogue pour laquelle l'autorisation de mise en marché mentionnée dans la demande de certificat de protection supplémentaire a été délivrée.

E. *Food and Drug Regulations, CRC c 870*

C.08.004.01 (1) Subject to section C.08.004.1, the Minister shall, after completing an examination of an extraordinary use new drug submission or an abbreviated extraordinary use new drug submission or a supplement to either submission,	**C.08.004.01 (1)** Sous réserve de l'article C.08.004.1, après avoir terminé l'examen d'une présentation de drogue nouvelle pour usage exceptionnel, d'une présentation abrégée de drogue nouvelle pour usage exceptionnel ou d'un supplément à l'une de ces présentations, le ministre :
(a) if that submission or supplement complies with section C.08.002.01, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance; or	**a)** si la présentation ou le supplément est conforme aux articles C.08.002.01, C.08.002.1 ou C.08.003, selon le cas, et à l'article C.08.005.1, délivre un avis de conformité;
…	**…**
C.08.004.1 (9) The Minister shall maintain a register of innovative drugs that includes information relating to the matters specified in subsections (3) and (4).	**C.08.004.1 (9)** Le ministre tient un registre des drogues innovantes, lequel contient les renseignements relatifs à l'application des paragraphes (3) et (4).

F. *Patented Medicines (Notice of Compliance) Regulations, SOR/93-133:*

2 (1) In these Regulations,	**2 (1)** Les définitions qui suivent s'appliquent au présent règlement.
notice of compliance means a notice issued under section C.08.004 or C.08.004.01 of the Food and Drug Regulations; (avis de conformité)	**avis de conformité** Avis délivré au titre de l'article C.08.004 ou C.08.004.01 du Règlement sur les aliments et drogues. (notice of compliance)
…	**…**
4 (2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains	**4 (2)** Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache à la présentation de drogue nouvelle, s'il contient, selon le cas :

(a) a claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission;	**a)** une revendication de l'ingrédient médicinal, l'ingrédient médicinal ayant été approuvé par la délivrance d'un avis de conformité à l'égard de la présentation;
(b) a claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of a notice of compliance in respect of the submission;	**b)** une revendication de la formulation contenant l'ingrédient médicinal, la formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;
(c) a claim for the dosage form and the dosage form has been approved through the issuance of a notice of compliance in respect of the submission; or	**c)** une revendication de la forme posologique, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;
(d) a claim for the use of the medicinal ingredient, and the use has been approved through the issuance of a notice of compliance in respect of the submission.	**d)** une revendication de l'utilisation de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation.
4 (2.1) The following rules apply when determining the eligibility of a patent to be added to the register under subsection (2):	**4 (2.1)** Les règles ci-après s'appliquent au moment de la détermination de l'admissibilité des brevets pour leur adjonction au registre aux termes du paragraphe (2) :
(a) for the purposes of paragraph (2)(a), a patent that contains a claim for the medicinal ingredient is eligible even if the submission includes, in addition to the medicinal ingredient claimed in the patent, other medicinal ingredients;	**a)** pour l'application de l'alinéa (2)a), un brevet qui contient la revendication de l'ingrédient médicinal est admissible même si la présentation comprend, en plus de l'ingrédient médicinal revendiqué dans le brevet, d'autres ingrédients médicinaux;

(b) for the purposes of paragraph (2)(b), a patent that contains a claim for the formulation is eligible if the submission includes the non-medicinal ingredients specified in the claim, if any are specified, even if the submission contains any additional non-medicinal ingredients; and	**b)** pour l'application de l'alinéa (2)b), un brevet qui contient la revendication de la formulation est admissible si la présentation comprend les ingrédients non médicinaux précisés dans la revendication — si des ingrédients non médicinaux y sont précisés —, même si la présentation contient des ingrédients non médicinaux additionnels;
(c) for the purposes of paragraph (2)(d), a patent that contains a claim for the use of the medicinal ingredient is eligible if the submission includes the use claimed in the patent, even if	**c)** pour l'application de l'alinéa (2)d), un brevet qui contient la revendication de l'utilisation de l'ingrédient médicinal est admissible si la présentation comprend l'utilisation revendiquée dans le brevet, même si :
(i) the submission includes additional medicinal ingredients,	**(i)** la présentation comprend l'utilisation d'ingrédients médicinaux additionnels,
(ii) the submission includes other additional uses of the medicinal ingredient, or	**(ii)** la présentation comprend d'autres utilisations,
(iii) the use that is included in the submission requires the use of the medicinal ingredient in combination with another drug.	**(iii)** l'utilisation comprise dans la présentation requiert l'utilisation de l'ingrédient médicinal en conjonction avec une autre drogue.

FEDERAL COURT

SOLICITORS OF RECORD

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