Federal Court of Appeal | Cour d'appel fédérale

Date: 20210414

Docket: A-138-20

Citation: 2021 FCA 71

CORAM: **GAUTHIER J.A.**
RIVOALEN J.A.
LOCKE J.A.

BETWEEN:

THE MINISTER OF HEALTH

Appellant

and

GLAXOSMITHKLINE BIOLOGICALS S.A.

Respondent

Heard by online video conference hosted by the Registry on February 10, 2021.

Judgment delivered at Ottawa, Ontario, on April 14, 2021.

REASONS FOR JUDGMENT BY: GAUTHIER J.A.

CONCURRED IN BY: RIVOALEN J.A.
LOCKE J.A.

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REASONS FOR JUDGMENT

GAUTHIER J.A.

[1] This is an appeal from the Federal Court decision (per Barnes J., 2020 FC 397) (FC Decision) setting aside the Minister of Health's decision refusing to issue a Certificate of Supplementary Protection (CSP) to Glaxosmithkline Biologicals S.A. (GSK) in respect of Canadian Patent No. 2,600,905 (905 Patent) and the drug SHINGRIX, a vaccine against shingles.

[2] This is the first time that the Minister's interpretation of the expressions "medicinal ingredient" and "a claim for the medicinal ingredient or combination of all the medicinal ingredients" under subsection 3(2) of the *Certificate of Supplementary Protection Regulations*, S.O.R./2017-165 (*CSP Regulations*) are challenged before this Court.

[3] For the reasons below, I find that the Federal Court erred in concluding that the Minister's interpretation of "medicinal ingredient" under the *CSP Regulations* was unreasonable, that the Minister's decision to refuse the CSP in this case was reasonable and that the appeal should be allowed.

I. General Background

[4] GSK is the owner of the 905 Patent, which relates to a vaccine useful in the prevention or amelioration of shingles. The 905 Patent contains five claims: claim 4 claims an immunogenic composition comprising an antigen, an adjuvant referred to as $AS01_B$ and other non-medicinal ingredients, claims 1 to 3 claim uses of the said composition, and claim 5, a kit comprising the composition components.

[5] It is not disputed that while the antigen induces the immune response in humans to prevent shingles, it could not do so in the absence of the adjuvant, which enhances the immune response to the level necessary for its use in a vaccine to prevent or ameliorate shingles.

[6] The 905 Patent was filed on March 1, 2006; it would normally expire on March 1, 2026. In the CSP application referred to below, it is identified as an eligible patent. The goal of the

CSP regime is to extend the rights under an eligible patent but only with respect to the making, using and selling of the actual drug or pharmaceutical product containing the medicinal ingredient or combination of medicinal ingredients set out in the CSP for a maximum of two years (see sections 115 - 116 of the *Patent Act,* R.S.C., 1985, c. P-4 (*Patent Act*)).

[7] Health Canada issued a Notice of Compliance (NOC) for SHINGRIX on October 13, 2017, which identifies the antigen as the only medicinal ingredient (Appeal Book, Volume 1 at p. 111 (AB), Janet Wagner affidavit, Exhibit A). On the same day, SHINGRIX was listed in the register of innovative drugs where again the antigen is the only medicinal ingredient identified. This listing entitles GSK to benefit from the period of data protection described in subsection C.08.004.1(3) of the *Food and Drug Regulations,* C.R.C., c. 870.

[8] On January 25, 2018, GSK filed its CSP application for the 905 Patent in relation to SHINGRIX and identified the antigen as the single medicinal ingredient (AB, Volume 1 at p. 256, Janet Wagner affidavit, Exhibit F).

[9] On April 10, 2018, the Minister informed GSK that she was of the preliminary view that the 905 Patent did not meet the requirements of subsection 3(2) of the *CSP Regulations* since its claims were directed to a formulation (a composition containing medicinal ingredients and non-medicinal ingredients) and not to "the medicinal ingredient or combination of all the medicinal ingredients" contained in the SHINGRIX vaccine, as contemplated in subsection 3(2) of the *CSP Regulations*. The Minister also noted that the antigen itself was not novel, having been the subject of two prior patents.

[10] On May 24, 2018, GSK submitted written representations, including the affidavit of Dr. Brian Barber, an expert immunologist, in response to the preliminary decision. At this stage, GSK's position was that the adjuvant was itself an active ingredient, in that it had biological activity, and that the 905 Patent was directed to a combination of medicinal ingredients (an immunogenic composition). It argued that the claims at issue were not formulation claims.

[11] On August 3, 2018, the Minister issued the final decision refusing the CSP to GSK. The Minister held that, contrary to paragraph 106(1)(*c*) of the *Patent Act*, and subsection 3(2) of the *CSP Regulations*, the 905 Patent does not include a claim for the approved medicinal ingredient (the antigen) contained in the drug SHINGRIX. The Minister explained that after reviewing various documents referred to by GSK, Health Canada's position is that adjuvants, even those with biological activity, are not medicinal ingredients. This is clearly set out in the Health Canada Guidance Document "Harmonized Requirements for the Licensing of Vaccines and Guidelines for the Preparation of an Application". The Minister also dealt with GSK's submissions regarding various alleged inconsistencies in her position regarding the classification of adjuvants and in other documentation relating to SHINGRIX.

[12] The Minister held that an adjuvant in a vaccine is not responsible for the vaccine's desired effect in the body as it only improved the specific cellular and immune response induced by the antigen itself. This, even if the response without the adjuvant is itself too negligible to be efficient for use in a vaccine. I understand that the Minister meant to apply here the definition of "medicinal ingredient" she normally uses when applying other regulations such as the *Patented*

Medicines (Notice of Compliance) Regulations, S.O.R./93-133 (*PMNOC Regulations*) to the particular facts of this matter.

[13] The Minister found that because the claims are directed at compositions comprising medicinal and non-medicinal ingredients i.e. a formulation, the patent is ineligible for a CSP. Relying on the *CSP Regulations* Regulatory Impact Analysis Statement (RIAS) and the Health Canada Guidance Document on the *CSP Regulations*, the Minister held that her position in that respect is consistent with the *Canada–European Union Comprehensive Economic and Trade Agreement (CETA),* which only requires the protection of a medicinal ingredient or a combination of medicinal ingredients when claimed "as such".

[14] GSK applied for judicial review of this decision, and the Federal Court allowed the application, ordering the matter to be remitted to the Minister for redetermination. In doing so, the Federal Court noted its view that "active ingredient", the term used in CETA, would include an ingredient such as the adjuvant whose biological activity is necessary for the clinical efficacy of the vaccine.

[15] I note that although GSK argued that the Minister failed to consider the objective of the legislation in interpreting the *CSP Regulations*, it never argued before the Minister or before the Federal Court that "active ingredient", the term used in CETA, contemplated biological activity and that therefore, the Minister had failed to interpret the *CSP Regulations* consistently with CETA. GSK's argument was that the Minister had adopted an interpretation of medicinal

ingredient that was not in line with the judicial definition of this term under the *PMNOC Regulations*.

[16] In the reviewing court's view, the Minister adopted administrative tunnel vision by requiring that a medicinal ingredient have an independent desired effect on the body, i.e. in this case, the antigen specific cellular and immune response. The Court also commented that the Minister's interpretation of "claim for the medicinal ingredient" was hard to justify, for nothing other than the RIAS could support the exclusion of formulation claims nor justify excluding novel and useful vaccines, such as SHINGRIX.

II. Legislative Background

[17] As this is the first time that this Court deals with this regulatory scheme, it is worth describing in more detail than is normally expected the background of the particular provisions before us.

[18] CETA covers a large number of subjects including, at Chapter 20, intellectual property. Section A contains the general provisions that apply to the Chapter as a whole. It includes at article 20.1 two general objectives:

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.

[19] Obviously the reference to innovative and creative products is a somewhat general description given that the Chapter deals with a variety of topics such as copyright, protection of technological measures, trademarks and geographical indications, data protection for pharmaceutical products, designs and patents, etc.

[20] At article 20.2, it states that each Party shall be free to determine the appropriate method for implementing CETA's provisions within its own legal system and practice.

[21] Section B includes a definition of "pharmaceutical product" which applies to the most relevant portion of this Chapter in so far as the present matter is concerned, that is sub-section E entitled "Patents" and more particularly article 20.27 which deals with the *sui generis* protection for pharmaceuticals (see the most relevant portions reproduced in Appendix A).

[22] After CETA was signed, the parties issued a Joint Interpretative Instrument dealing with many important subject matters covered. It does not include anything specific about Chapter 20 of CETA dealing with intellectual property. It does however put emphasis on the fact that the Parties preserved their ability to adopt and apply their own laws and regulations that regulate economic activity in the public interest and to achieve legitimate public policy objectives in respect of various issues including public health and social services.

[23] Thereafter, the Canadian government adopted the *Canada–European Union Comprehensive Economic and Trade Agreement Implementation Act*, S.C. 2017, c. 6 (*Implementation Act*). The two most relevant sections of the *Implementation Act* in this case are

sections 3 and 7, which respectively deal with the need for the Canadian legislation to be interpreted in a manner consistent with CETA and its purpose and objectives. The most relevant objective here is set out in paragraph 7(*f*) *viz*:

> (f) [p]rovide adequate and effective protection and enforcement of intellectual property rights in the territory where [CETA] applies.

[24] The Canadian government then issued a Canadian Statement on Implementation (of more than 275 pages) that purports to explain what it understood its rights and obligations to be under CETA. The portion that is most relevant to our purpose here is brief. It is found under the title "Patents" and includes a paragraph dealing expressly with article 20.27 of CETA as follows:

> Article 20.27 requires the Parties to provide a period of additional protection of two to five years for eligible new patented pharmaceutical products. This protection is intended to address a portion of the patent term that is spent in research and development and regulatory review towards the approval of a pharmaceutical product that contains a new active ingredient or a new combination of active ingredients. This protection takes effect after the expiration of the term of the patent on which it is granted and gives the same rights as the patent but only as it pertains to the active ingredient or combination of active ingredients when used in a drug, subject to limitations and conditions. The Article allows for an exception to the protection to enable export of generic versions of products that would otherwise infringe the protection during the period of protection. It also allows the Parties to limit the availability of protection in various ways, such as having deadlines for applying for the protection and limiting the circumstances when the protection can be sought. (My emphasis)

[25] The Canadian legislator thereafter adopted a new section in the *Patent Act* entitled "Supplementary Protection for Inventions — Medicinal Ingredients" which comprises sections 104 to 134. Subsection 106(1) sets out the conditions to obtain a CSP and paragraph 106(1)(*c*) deals with patent eligibility. It is worth reproducing the key elements here (full text in Appendix A):

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;
[…]	[…]
(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;

[26] Under paragraphs 134(1)(*c*) and 12(1)(*h*) of the *Patent Act*, the Governor in Council is given authority to regulate the form and content for CSP applications and to adopt regulations necessary to put into effect the terms of any treaty. The *CSP Regulations* were adopted on the recommendation of the Minister of Industry pursuant to paragraphs 12(1)(*g*), (*h*), (*k*) and subsection 134(1) of the *Patent Act*. They provide among other things for the prescribed

eligibility referred to as a main condition in paragraph 106(1)(*c*) of the *Patent Act*. Subsection 3(2) of the *CSP Regulations* reads as follows:

3(2) For the purpose of paragraph 106(1)(c) of the Act, the prescribed manners in which a patent may pertain to a medicinal ingredient or combination of medicinal ingredients are the following:	**3(2)** Pour l'application de l'alinéa 106(1)c) de la Loi, le brevet est lié à un ingrédient 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.

[27] The RIAS is lengthy and addresses in some detail all the main concepts. I have reproduced in Appendix A the portion dealing with the conditions referred to in subsection

106(1) including particularly patent eligibility. It is worthwhile to quote the first part of the section entitled “Rationale” (full paragraph in Appendix A):

> The Canadian CSP regime is created with the aim of meeting obligations under Article 20.27 of the CETA, which requires Parties to provide an additional period of protection for patent-protected pharmaceutical products, while continuing to balance the interests of stakeholders and the public within the *Patent Act*.

[28] As indicated to the Senate Committee reviewing the bill that would become the *Implementation Act*, it appears that both the text of the *CSP Regulations* and of the RIAS were the subject of intensive consultation with the various players in the pharmaceutical industry (Senate, Standing Committee on Foreign Affairs and International Trade, *Evidence*, 42-1, No. 23 (4 May 2017) (A. Raynell Andreychuk)).

[29] It is important to describe what appears to be the policy that is embodied in article 20.27 of CETA as understood by Canada. For later on in construing the *CSP Regulations*, one will have to determine, among other things, if the text properly reflects this policy.

[30] Although generally, the objective is to grant some “patent-like rights” to compensate for the time lost in obtaining approval of innovative drugs and vaccines, Canada only understood and agreed to a very specific and limited way of doing so.

[31] Indeed, if one only considers the general objective, Canada could have simply agreed to grant such *sui generis* protection for all newly patented innovative drugs (or pharmaceutical products to use the CETA wording). However, this is not the policy described in the various documents issued to explain the Canadian position. It is only those innovative drugs or

pharmaceutical products that contain a new active or medicinal ingredient or a new combination of active or medicinal ingredients that are eligible. Moreover, not all those innovative drugs or pharmaceutical products will be eligible for protection. Indeed, to benefit from this additional period of supplementary protection, the authorization for sale for the pharmaceutical product or drug must be the first issued in Canada with respect to this new active or medicinal ingredient or new combination of active or medicinal ingredients.

[32] Thus, a drug or pharmaceutical product may well be innovative but not have the benefit of a CSP if it is not the first to make actual use of the medicinal ingredient or combination of medicinal ingredients. Further, if a CSP has already been issued for the active or medicinal ingredient, it will not be entitled to the supplementary protection. The policy appears focused on rewarding those that bring to the Canadian market the actual benefit of new medicinal ingredients or new combinations of medicinal ingredients. At the core, it would appear that the goal is to promote research into new medicinal ingredients or new combinations of medicinal ingredients and to give an incentive to put them into practice for the benefit of the public. That incentive is to compensate for part of the time lost in obtaining approval for that first drug or pharmaceutical product.

III. Issues

[33] The issues before us are as follows:

1. Is the Minister's interpretation and application of the term "medicinal ingredient" reasonable?

2. Is the Minister's interpretation and application of the CSP provisions to exclude patent claims directed to a formulation, particularly the one at issue, reasonable?

IV. Standard of Review

[34] It is not disputed that the standard of review chosen by the Federal Court — reasonableness – was the appropriate standard to apply. This is consistent with the *Vavilov* framework, because the presumption of reasonableness applies when no exception calls for derogation from that standard, as in this case (*Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, at para. 17).

V. Analysis

[35] As there is no dispute that the Federal Court applied the appropriate standard of review, our Court's task is simply to assess whether it applied it correctly. In performing this exercise, our Court must focus on the administrative decision rather than the decision of the reviewing court; our Court effectively steps in the shoes of the Federal Court (*Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 SCR 559, at para. 46). As mentioned, I must now assess whether the Minister's construction of the expressions "medicinal ingredient" and "claim for the medicinal ingredient" is reasonable. I will deal first with the expression "medicinal ingredient".

[36] It is trite law that this Court must apply the modern approach to statutory interpretation which calls for reading the words of the statute in their context harmoniously with the scheme

and object of the legislation at issue and the intention of Parliament (*Re Rizzo & Rizzo Shoes Ltd.*, [1998] 1 S.C.R. 27, 154 D.L.R. (4th) 193; *Bell ExpressVu Limited Partnership v. Rex*, 2002 SCC 42, [2002] 2 S.C.R. 559; *Canada Trustco Mortgage Co. v. Canada*, 2005 SCC 54, [2005] 2 S.C.R. 601).

[37] I have already described the scheme and object of the *CSP Regulations* and of the relevant provisions of the *Patent Act* as well as all the information available as to the intention of Parliament. There is no need to repeat it. I have reviewed all the relevant transcripts of debates and found nothing that would be particularly relevant here.

A. *Medicinal Ingredient*

[38] There is no definition of "medicinal ingredient" in the *Patent Act* or any regulations issued under it, even though the expression is used abundantly in the new sections 104 to 112 of the *Patent Act*. As will be mentioned later on, this expression is also used in the *PMNOC Regulations* issued pursuant to section 55.2 of the *Patent Act*. The expression is further found in a few instances in the *Food and Drug Regulations*, Part C, Division 8, C.08.001 "New Drugs" in the definition of "pharmaceutical equivalent" and C.08.004.1(1) in the definition of "innovative drug".

[39] The parties are agreed that the only guiding definition in Canada at this stage is the one used in *Bayer Inc. v. Canada (Health)*, 2009 FC 1171, affirmed in 2010 FCA 161 (*Bayer*), which has since been used in the case law. GSK agrees that, although used in the context of the *PMNOC Regulations*, this definition can and should be used for construing the *CSP Regulations*.

As will be discussed, both sides rely on the same words used in *Bayer* to reach a different conclusion as to what "medicinal ingredient" means in this case. As a matter of first impression, this may indicate that both parties' interpretations may be consistent with the definition used in *Bayer* as applied to the particular facts of this case.

[40] In *Bayer*, the Federal Court had to determine whether a patent including a claim to a formulation containing two medicinal ingredients could be listed under the *PMNOC Regulations* (subsection 4(2)) as it read after the 2006 amendments), in respect of a drug containing a formulation, which only included one of the medicinal ingredients (a combination) claimed.

[41] To better understand the *Bayer* decision, it is worth reproducing the following definitions contained in the *PMNOC Regulations*:

[…]	[…]
claim for the formulation means a claim for a mixture that is composed of medicinal and non-medicinal ingredients, that is contained in a drug and that is administered to a patient in a particular dosage form; (revendication de la formulation)	**revendication de la formulation** Revendication à l'égard d'un mélange formé d'ingrédients médicinaux et non médicinaux qui est contenu dans une drogue et est administré à un patient sous une forme posologique donnée. (claim for the formulation)
claim for the medicinal ingredient includes a claim in the patent for the medicinal ingredient, whether chemical or biological in nature, when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent, or by their obvious chemical equivalents, and also includes a claim for different polymorphs of the medicinal ingredient, but does not include different chemical forms of the	**revendication de l'ingrédient médicinal** S'entend, d'une part, d'une revendication, dans le brevet, de l'ingrédient médicinal — chimique ou biologique — préparé ou produit selon les modes ou procédés de fabrication décrits en détail et revendiqués dans le brevet ou selon leurs équivalents chimiques manifestes, et, d'autre part, d'une revendication pour différents polymorphes de celui-ci, à l'exclusion de ses différentes formes

medicinal ingredient; (revendication de l'ingrédient médicinal)	chimiques. (claim for the medicinal ingredient)
[…]	[…]
claim for the use of the medicinal ingredient means a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms; (revendication de l'utilisation de l'ingrédient médicinal)	**revendication de l'utilisation de l'ingrédient médicinal** Revendication de l'utilisation de l'ingrédient médicinal aux fins du diagnostic, du traitement, de l'atténuation ou de la prévention d'une maladie, d'un désordre, d'un état physique anormal, ou de leurs symptômes. (claim for the use of the medicinal ingredient)
[…]	[…]

[42] It is important to note that there was no dispute in *Bayer* that both ingredients claimed in the formulation were medicinal ingredients (*Bayer* at para. 68), nor was there a dispute as to the meaning of "medicinal ingredient" (*Bayer* at para. 67). The Federal Court had to consider the new definition of "formulation" as this term was introduced for the first time in the 2006 version of the *PMNOC Regulations* in the definition of "claim for the formulation" under section 2 of the said *Regulations*.

[43] It is clear that the Federal Court in *Bayer* relied on the 2006 *PMNOC Regulations* RIAS to say that "medicinal ingredient" refers to the substance in the formulation, which, once administered, is responsible for the drug's desired effect in the body (*Bayer* at paras. 21, 86 and 88).

[44] In the course of its analysis, and while discussing the difference between a compound patent and a formulation patent, the Federal Court described the compound patent as containing a

claim for the approved medicinal ingredient which is the key active part of the drug formulation (*Bayer* at para. 77).

[45] The Minister says that in the case of the SHINGRIX vaccine, the antigen is the only active ingredient that has the desired effect in the body that is, for inducing the antigen specific cellular and humoral immune response against shingles (AB, Volume 1 at p. 57). As mentioned, in the expert opinion of the Minister, the adjuvant does not independently contribute to the proposed therapeutic use of the vaccine. It may have biological activity, but this activity only enhances the efficacy of the antigen, i.e. the medicinal ingredient. It is thus not itself a medicinal ingredient.

[46] For GSK, the key active part of the vaccine can and must include the adjuvant because it is a key biologically active ingredient of the composition claimed in the 905 Patent. Without it, the vaccine would not provide sufficient immunological response to prevent shingles. The whole composition in this case is the medicinal ingredient or combination of medicinal ingredients.

[47] As one can appreciate, *Bayer* is not helpful in determining whether the key active ingredient refers simply to the biological activity necessary for the drug to be clinically useful. We do not know on this record whether there is another adjuvant or composition that could also make the antigen sufficiently effective, albeit offering a different level of protection. Nor does *Bayer* tell us precisely whether the key active ingredient refers to an ingredient that actually produces the therapeutic effect as understood by the regulator. The Court in *Bayer* never had to turn its mind to this particular issue.

[48] The Minister relied on her own scientific expertise to say that her interpretation is in line with the general understanding of what is an active ingredient in the pharmaceutical field and what role the adjuvant plays in this case (as confirmed by Health Canada's Therapeutic Product Directorate in consultation with the Biologics and Genetic Therapies Directorate) (AB, Volume 1 at p. 55). She says that her position in this respect is in line with the understanding of working groups dealing with such issues in the Pan American Network for Drug Regulatory Harmonization and the World Health Organization. The Minister also notes that the composition includes ingredients other than QS21 (adjuvant enhancer) that are indisputably non-medicinal such as cholesterol and dioleoyl phosphatidylcholine (AB, Volume 1 at pgs. 55 and 57).

[49] GSK relies on common sense and logic, saying that it is a logical fallacy to understand that key active ingredient would not include an ingredient that is clinically useful, if not indispensable, because of its biological activity, as found by the Federal Court (Federal Court decision at para. 38). At the hearing before this Court, it also appeared to support the position developed by the Federal Court that "biological activity" was the measure by which CSP relief under CETA was to be made available in Canada (FC decision at para. 35). It is not clear to me whether it continues to support this view after I reviewed its additional submissions filed after the hearing (particularly paragraph 33). Its main argument now seems to be that whatever the meaning of "active ingredient" in the European Union (a subject that I will discuss later on), "medicinal ingredient" as defined in *Bayer* is wider and it does not require that a key ingredient have an independent therapeutic effect.

[50] Be that as it may, it is appropriate as mandated by section 3 of the *Implementation Act* to consider whether the Minister's interpretation is consistent with CETA. In my view, it is appropriate to do so, considering that examining international law may bring to light, and possibly resolve, latent ambiguities in the domestic legislation (*Entertainment Software Association v. Society of Composers, Authors and Music Publishers of Canada*, 2020 FCA 100 at para. 84).

[51] That said, one should be careful not to put aside a regulator's interpretation of a term that is used across the regulatory system dealing with pharmaceutical products, albeit for a variety of purposes, solely because of a seemingly logical alternative interpretation. This is so unless there is some clear indication that the words can and should be construed in a specific manner, at least in the context of the *CSP Regulations*, because of CETA.

[52] As is readily apparent, the expression "medicinal ingredient" is not used in CETA. Instead, the expression "active ingredient or combination of active ingredients of a pharmaceutical product" is used to define "product". I note that the use of the word "product" may lead to some confusion with the defined term "pharmaceutical product" (the actual drug or vaccine, article 20.6 of CETA). They are not the same, and one should be careful in using them indistinctly. For my part, to avoid any confusion, I will use the words "pharmaceutical product" and "active ingredient" as this is what the definition of "product" in CETA refers to (article 20.27(1)).

[53] It is not disputed that the definition of "product" comes from the EU Regulations dealing with Supplementary Protection Certificates, a regime put in place in 1992 (see article 1(b) of the latest version of Regulation 469/2009/EC) (see Appendix A). This will also be discussed later on (in section B) in my analysis of "basic patent" found in CETA at article 20.27. It is also not disputed that Canada was entitled to adapt this wording in its domestic legislation to ensure that the new rules can be applied effectively within its institutional framework of domestic law (Ruth Sullivan on the Construction of Statutes, 6th Edition, Markham, Ontario: Lexis Nexis 2014 at §18.45).

[54] As one can see, the wording in CETA is not particularly illuminating and certainly not more precise than the definition of key active ingredient in the formulation used in *Bayer*. There is nothing in the Joint Statement on CETA that is particularly helpful. I note that in the Canadian Statement on Implementation, the Canadian government uses the words "active ingredient" (as well as the word "drug" when referring to pharmaceutical product) and that there is no indication that the government understood the words "active ingredient" as something other than the term regularly used in its domestic legislation.

[55] I also note that in my experience active pharmaceutical ingredient (API) is a word commonly used by regulators around the world and by IP lawyers in Canada in their memoranda or oral submissions. In fact, the words "active ingredient" were used regularly in the case law when dealing with whether or not a substance was a medicine in the pre 2006 version of the *PMNOC Regulations*. I will discuss this further in examining the second issue before us, but my understanding for this change is that the word "medicine" in "claim for a medicine (*médicament*)

itself" was construed in our case law to include a claim to the drug itself i.e. a formulation of active and non-active ingredients (see for example, *Hoffmann-La Roche Ltd. v. Canada (Minister of National Health & Welfare)* 62 C.P.R. (3d) 58, [1995] F.C.J. No. 985 (F.C.T.D.), aff'd [1995] F.C.J. No. 1775 (F.C.A.), leave to appeal to SCC refused, 25136 (12 September 1996) (*Hoffmann*)). The legislator decided to clarify its intention by removing the reference to medicine and claim to a medicine, and used the words "claim for the medicinal ingredient" to make it clearer that such claim was not a claim to the drug. It did however add a definition for "claim for the formulation" i.e. a mixture of medicinal and non-medicinal ingredients (in other words a drug). In 2015, the legislator added subsection 2(2) of the *PMNOC Regulations*, to clarify that for the purpose of the definition of "claim for the formulation", the claim for the formulation did not need to specify all of the non-medicinal ingredients contained in the drug.

[56] This indicates to me that "active ingredient" and "medicinal ingredient" referred to the same thing in these regulations. I simply cannot discern any other intention of Parliament in respect of CETA or the *CSP Regulations* in that respect.

[57] I ought to mention that the Canadian Generic Pharmaceutical Association had sought leave to intervene in this appeal. However, leave was refused because its main contribution would have been to highlight the similarity of the Minister's interpretation concerning the term "medicinal ingredient" with the interpretation given by the European Court of Justice (ECJ) to "active ingredient" as to whether it encompasses substances that do not have a therapeutic effect on their own.

[58] This similarity in interpretation is relevant to determine the reasonableness of the Minister's decision for, as mentioned, the Canadian case law on the meaning of "medicinal ingredient" had yet to provide a sufficiently precise answer in this respect. I agree with the parties that one must be cautious in using foreign case law, but in this particular case, I find it persuasive based on its reasoning.

[59] I note here that CETA negotiations ended in 2014, the review of the English text was completed in February 2016, and the agreement was signed in October 2016.

[60] During this period, the ECJ, to whom national courts of the members of European Union referred matters of interpretation in respect of the European *SPC Regulations*, had already judicially considered the meaning of "active ingredient" in the definition of "product" in the European Regulation from which the definition in CETA originates. It first did so in 2006 in *Massachusetts Institute of Technology*, case C-431/04, May 4, 2006 (*MIT*), and then in a decision that GSK was presumably aware of, given that it was a party to it and it involved another vaccine comprising an antigen and an adjuvant known as the AS03, which also appear to have been necessary to make the vaccine Prepandrix clinically effective (*Glaxosmithkline Biological S.A. v. Controller General of Patents, Design and Trademarks*, case C-210/13, November 14, 2013 (*Glaxo*)).

[61] In *Glaxo*, the regulatory body in the U.K. (the Patent office which has a similar role to that of the Minister in this respect) refused to issue a supplementary protection certificate because the adjuvant was not an active ingredient within the meaning of the definition of

"product". From my review of this decision, it appears that the adjuvant in question had biological activity and that its mechanism of action was somewhat similar to the one described in the SHINGRIX Product Monograph (see *Glaxosmithkline Biologicals S.A.*, BL O/506/12, December 19, 2012 at paras. 3, 27-31). GSK applied to the Patents Court of England and Wales, who referred the matter to the ECJ. The ECJ first noted that it is "generally accepted in pharmacology that the term active 'ingredient' does not include substances forming part of the medicinal product which do not have an effect of their own on the human or animal body" (*Glaxo* at para. 28). This was the definition adopted by the ECJ in *MIT*. In the ECJ's view, though an excipient such as the one under review in that case could contribute to the pharmaceutical form of the medicinal product, it did not form part of the definition of "product". Therefore, "[w]hether a substance without any therapeutic effect of its own is necessary for the therapeutic efficacy of the active ingredient [could not] be regarded as a sufficiently precise test" (*Glaxo* at para. 29). The ECJ held that the "active ingredient" does not cover a substance that does not have any therapeutic effect on its own (*Glaxo* at para. 30). It also stated at paragraph 32 that the fact "that the substance without any therapeutic effect of its own renders possible a pharmaceutical form of the medicinal product necessary for the therapeutic efficacy of the substance which does not have therapeutic effect cannot invalidate that interpretation" (My emphasis).

[62] The ECJ then concluded at paragraph 45 that "just as an adjuvant does not fall within the definition of 'active ingredient' within the meaning of [article 1(b)], so a combination of two substances, namely an active ingredient having therapeutic effect on its own, and an adjuvant which, while enhancing those therapeutic effects, has no therapeutic effect on its own, does not

fall within the definition of ‘combination of active ingredients’”. This essentially confirmed the definition given to “active ingredient” back in 2006 in MIT.

[63] Although the parties referred to other authorities, I do not consider it necessary to deal with them for I am satisfied that the construction adopted by the Minister is consistent with CETA and with the interpretation of medicinal ingredient applied under our domestic legislation pertaining to pharmaceutical products. I ought to mention that consistency does not mean that the Canadian system must be identical to the system that was already in place in the European Union. Nor should it be inferred from these reasons that foreign case law binds Canadian Courts in any way. This is simply not so.

[64] To conclude on this line of reasoning, given the interpretation adopted by the Federal Court and the arguments put forth by GSK, I am prepared to accept that there is not only one possible reasonable interpretation of the expression “medicinal ingredient”. That said, in such circumstances, it is not for reviewing courts to choose the one they prefer or that they find the most logical from their point of view. This is not what the applicable standard of review calls for.

[65] Although the above goes a long way in dealing with the reasonableness of the Minister’s decision in respect of whether the adjuvant in this matter is a medicinal ingredient, I will deal with the other arguments raised before the Minister by GSK.

[66] I will also say a few words about the view expressed by the Federal Court, which GSK adopted before us, that in this case, the Minister adopted tunnel vision unduly based on

administrative efficiency and a “perceived need for administrative consistency to the exclusion of other highly relevant considerations” (FC Decision at paras. 29-33).

[67] First, there is a definite link in the *CSP Regulations* between the medicinal ingredient listed in the NOC issued by Health Canada for SHINGRIX and the medicinal ingredient referred to at paragraph 106(1)(*c*) of the *Patent Act* (see subsection 106(4)). The medicinal ingredient referred to in the *Patent Act* and *CSP Regulations* is the medicinal ingredient listed in the authorization for sale, i.e. the NOC issued under the *Food and Drug Regulations*, C.08.004 or C.08.004.01.

[68] As mentioned earlier, the NOC for SHINGRIX listed only one medicinal ingredient, the antigen. This is the sole medicinal ingredient for which GSK had applied for a CSP. I therefore see no reviewable error in the Minister’s perceived desire for consistency between the two regimes. It is unfair to characterize her approach as based on unwarranted tunnel vision.

[69] In fact, the Minister had to offer a coherent and consistent treatment of the same subject i.e. what is the “medicinal ingredient” in the drug at issue.

[70] It is obvious that the administrative classification of adjuvants is a non-binding administrative policy; it cannot supplant the words of the legislation. But as mentioned, this is not what has happened here. The Minister adopted a reasonable interpretation of the words “medicinal ingredient” and made a scientific determination that in this case, the adjuvant was not in fact a medicinal ingredient because it had no independent therapeutic effect on the body; thus

the Minister's decision was based on a legal and scientific position backed up by the consistency between the medicinal ingredient listed in the NOC issued under the *Food and Drug Regulations*, the medicinal ingredient referred to in the application for a CSP and the *Patent Act*.

[71] Thus, whether or not in other contexts one regulatory regime may influence another is irrelevant. It all depends on the particular facts of the matter. In this case, there is no doubt that the link between these two regulatory regimes is established.

[72] GSK had raised inconsistencies between the Minister's position on its application and an email received from the Minister, and with the content of the SHINGRIX Product Monograph that the Minister approved. In her reasons, the Minister deals with each of these, and I have not been persuaded that her position on these issues was unreasonable in any respect. In fact, the Minister was responsive to all the concerns expressed by GSK in its submissions before her and it is evident that she considered the scientific opinion and evidence that GSK put forward.

[73] I find the following passage from *Vavilov* especially instructive as to inform a reviewing court on the manner it should approach a situation like the one before us:

> [93] An administrative decision maker may demonstrate through its reasons that a given decision was made by bringing that institutional expertise and experience to bear: see *Dunsmuir*, at para. 49. In conducting reasonableness review, judges should be attentive to the application by decision makers of specialized knowledge, as demonstrated by their reasons. Respectful attention to a decision maker's demonstrated expertise may reveal to a reviewing court that an outcome that might be puzzling or counterintuitive on its face nevertheless accords with the purposes and practical realities of the relevant administrative regime and represents a reasonable approach given the consequences and the operational impact of the decision. This demonstrated experience and expertise may also explain why a given issue is treated in less detail.

[74] This leads me to the next point; that is, that the Minister's decision was unreasonable because it does not address specifically the consistency of her interpretation with CETA, particularly the meaning of "active ingredient" and the general purpose of the *CSP Regulations*.

[75] As mentioned earlier, GSK never raised expressly the issue of "active ingredient" in CETA being different from "medicinal ingredient" in the CSP Regulations. It simply referred generally to the overall purpose of article 20.27 and of the *CSP Regulations*. Thus, there was no express need to discuss this in the Minister's reasons with respect to what was (were) the medicinal ingredient(s) in SHINGRIX other than to respect the criteria of justification discussed in *Vavilov*. As noted in *Vavilov* at paragraphs 119 and 120, although the merits of an administrative decision maker's interpretation must be consistent with the text, context and purpose of the legislative provisions, he or she is not required to engage in a formalistic statutory interpretation exercise in every case. In fact, as mentioned by the Supreme Court, like other aspects of the reasonableness review, the key question remains whether the omitted aspect of the analysis causes the reviewing court to lose confidence in the outcome reached by the decision maker (*Vavilov* at para. 122).

[76] In this particular case, the lack of an express reference to CETA with regard to her interpretation of medicinal ingredient does not make me lose confidence in the reasoning of the Minister and the conclusion she reached. This is especially so considering that, as will be discussed in the next section of my analysis, she did refer to the RIAS and was thus clearly aware of the objective and rationale spelled out in it.

[77] Before addressing the second question before us, I wish to note that the present case may be quite different from the one before the Federal Court in *ViiV Healthcare ULC v. Canada (Health)*, 2020 FC 756, which GSK relies on. In that case, it appears that the Minister failed to grapple with quite specific submissions made before her on the issues referred to in paragraph 26 to 28 of the reviewing court's decision. In addition, I have a specific concern, similar to that mentioned in paragraph 52 above, regarding the use of terminology in that case. It is not clear to me that the reviewing court was as careful as it should have been in its choice of words. At paragraph 26 of its decision (see also paragraph 18), it stated that it was persuaded by the view that the patent at issue "protects the product (i.e. JULUCA) as such" and that this view "is not inconsistent on its face with CETA". However, JULUCA was the drug or pharmaceutical product and not the *product* i.e. medicinal ingredient or combination of the medicinal ingredients in this drug or pharmaceutical product. As this matter is not before us, I will not comment on whether or not this wording resulted from a misunderstanding or was simply a lack of precision in the wording used. Moving forward, reviewing courts must be careful as these kinds of errors can have serious consequences and distort the meaning intended by Parliament.

[78] At this stage, I have not identified any reviewable error that would justify our intervention. I will therefore examine the second issue before us.

B. *Subsection 3(2) of the CSP Regulations and the formulation in the 905 Patent*

[79] The second reason given by the Minister for refusing the issuance of a CSP was that the 905 Patent did not pertain to the antigen, i.e. the medicinal ingredient, within the meaning of subsection 3(2) of the *CSP Regulations*.

[80] GSK described this as a core issue in its oral arguments before us. However, its arguments before the Minister in that respect were quite limited and mostly interconnected with those advanced with respect to what a "medicinal ingredient" is within the meaning of the *CSP Regulations*.

[81] This is especially so considering that, having received the preliminary decision of the Minister on April 10, 2018 (AB, Volume 1 at pgs. 261-267), GSK was fully aware that:

i) The Minister considered its claim as directed to a formulation; i.e. a mixture composed of medicinal and non-medicinal ingredients;

ii) The only medicinal ingredient described on its NOC, the antigen, was not claimed as such under the 905 Patent as it was disclosed in EP0405867 and EP192902 (see description in the 905 Patent, AB, Volume 1 at pgs. 186-187 and 266).

[82] In its written representations to the Minister, as mentioned, GSK submitted that the 905 Patent did not claim a formulation, but rather a composition that was itself a combination of medicinal ingredients. Its claims did not include non-medicinal ingredients, as both the antigen and its proprietary adjuvant system (a single structure) were medicinal ingredients (AB, Volume 5 at pgs. 1046-1047).

[83] It argued that there was nothing in the grammatical and ordinary sense of the words in subsection 3(2) of the *CSP Regulations* that excluded claim 1 of the 905 Patent. For GSK, it qualified as a claim for the medicinal ingredient or a combination of medicinal ingredients. Also, other claims could be viewed as for the use of such medicinal ingredient in the preparation of a medicament against shingles for people of 50 years of age or older, and those with an

immunocompromised system (AB, Volume 5 at p. 1049). According to GSK, this interpretation is consistent "with the object and purpose of the CSP Regulations to provide an additional period of protection for drugs containing new medicinal ingredients, like SHINGRIX, in order to compensate for the time such drugs spend in research and development and obtaining marketing authorization" (my emphasis). GSK did not dispute that the antigen had already been disclosed and could not therefore be claimed as a compound.

[84] In the circumstances, it is not surprising that the Minister did not go into an elaborate statutory analysis of the wording of subsection 3(2) in her decision. In my view, on a fair reading of the decision, she did consider all the arguments put forth by GSK, even though they are not all grouped under the same heading given their interconnection with the determination of what was the medicinal ingredient in SHINGRIX.

[85] First, as already mentioned, the Minister made it clear that the claims included many non-medicinal ingredients. Apart from the adjuvant enhancers *per se* — QS21 and 3D-MPL, there were other non-medicinal ingredients such as cholesterol (see last paragraph in AB, Volume 1 at p. 57 and at paragraph 48 above). She then clearly found that the claim at issue was for a formulation within the generally understood meaning of such claims i.e. a mixture of medicinal and non medicinal ingredients. The use claims were directed to such formulations only. As will be explained later on, previous case law used this definition of formulation before it was included in the definitions of the 2006 version of the *PMNOC Regulations* (see paragraph 41 above). In fact, GSK itself had made reference to one of those decisions, *Hoffmann*, in its

submissions (see AB, Volume 7 at p. 1687, footnote 15). In the Minister's view, there was no provision in subsection 3(2) that made claims for a formulation sufficient to be eligible.

[86] With respect to GSK's argument that there was no legislative reference to exclude certain types of claims from CSP eligibility, the Minister expressly states that she disagrees and that her reading of subsection 3(2) was confirmed by the RIAS. The Minister also relied on a clear passage to that effect in the Health Canada Guidance Document dealing with the *CSP Regulations* at page 17, which confirmed her understanding. She finally noted, quoting the RIAS, that this was understood to be consistent with the wording in CETA which includes the expression "as such".

[87] I have already summarized the legislative background and will not repeat it at length here.

[88] The word "claim" has many ordinary meanings. Among its dictionary definitions, the most appropriate here is "a right or title to something" (*Oxford English Dictionary Online*, Oxford University Press, *sub verbo* "claim").

[89] Obviously, when one construes the words used, one has to consider their particular context. Here, subsection 27(4) of the *Patent Act* provides that claims in a patent are meant to define distinctly and in explicit terms "the subject matter of the invention" for which an exclusive privilege or property is claimed.

[90] The *CSP Regulations* prescribe the criteria to determine whether a patent pertains to the medicinal ingredient or the combination of medicinal ingredients as required at paragraph 106(1)(*c*) of the *Patent Act*. It is important here to recall that this new section of the *Patent Act* is entitled "Supplementary Protection for Inventions — Medicinal Ingredient" (my emphasis).

[91] In this context, the following patent law concepts are well understood and have been often used in the case law: product claims, product-by-process claims, formulation or composition claims and use claims. Today, there is rarely a need for one to explain what one means when referring to those expressions. This was so, even before the Governor in Council included definitions of "claim for medicine itself " or "claim for use of the medicine" in the 1993 version of the *PMNOC Regulations* and "claim for the formulation", as well as "claim for the medicinal ingredient" in the 2006 version of the said *Regulations*; but when it did so, it gave rise to many judicial decisions which helped the Governor in Council refine those expressions. As will be explained, this case law can to a certain extent be useful here – just as *Bayer* was useful in providing a definition of active or medicinal ingredient. The object of these regulations may be different but they have a link (see the numerous references to CSPs added to the *PMNOC Regulations* as part of the implementation of CETA).

[92] In this context, it would appear somewhat straightforward to say that a claim for a medicinal ingredient or a combination of all the medicinal ingredients would normally be understood as a claim for these compounds (products claims). Or they could be understood, given the particular history of medicines which were the subject of restrictions as to how they could be claimed under the *Patent Act* in the past, as including product-by-process claims (see

for example section 41 of the *Patent Act*, R.C.S. 1952 c. 203 as discussed in *Farbwerke Hoechst A.G. vormals Meister Lucius & Bruning v. Canada (Commissioner of Patents)*, [1964] S.C.R. 49, 41 C.P.R. 9). In such claims, the "medicinal substance" (wording from *Farbwerke*) had to be defined in terms of the process by which they were made.

[93] When paragraph 3(2)(*a*) is read alongside 3(2)(*b*) and (*c*), one would conclude that paragraph 3(2)(*a*) does not include a product-by-process claim for the medicinal ingredients for these are expressly covered by paragraph (*b*).

[94] A claim for the use of a medicinal ingredient or a combination of all medicinal ingredients is also a well-understood concept. They include Swiss-type claims and are particularly helpful when the compounds are already known and the subject matter of the invention is the new use.

[95] Given this enumeration at subsection 3(2), and the fact that unless listed, another specific type of claim will not be sufficient to qualify a patent in the prescribed manner, I do not believe that it was incumbent on the legislator to exclude expressly from eligibility patent claims directed to a formulation. It would have certainly been easier for our statutory analysis, but it is not a sufficient reason in itself to find that the Minister's conclusion is unreasonable or to disregard the explanations in the RIAS as evidence of the legislative intent (FC Decision at para. 44).

[96] Courts have been quite capable of excluding pure process claims or other types of claims (such as claims for intermediate compounds) from the definition of "claims for the medicine" without the need for express exclusions (see for example *Deprenyl Research Ltd. v. Apotex Inc.*, 55 C.P.R. (3d) 171, [1994] F.C.J. No. 542 (F.C.T.D.), aff'd 60 C.P.R. (3d) 501, [1995] F.C.J. No. 532 (F.C.A.) and *Hoffmann* at page 74 e).

[97] Courts have also been capable of including compositions or formulation claims when the wording of the subject matter of the claim enabled them to do so.

[98] This is exactly what happened in *Hoffmann* when the Federal Court (confirmed by our Court) had to determine whether a claim for a composition of active and non-active ingredients in an approved drug was a "claim for the medicine itself".

[99] I will start by noting that in *Hoffmann* the expressions "formulation claim" and "composition claim" were used interchangeably. There was no issue that both expressions referred to a claim for a mixture of active and non-active ingredients (*Hoffmann* at page 72 g). What mattered was whether the claim was <u>for</u> the medicine (*médicament*). Using the modern approach to statutory interpretation, Noël J. (as he then was) concluded that "medicine" was not used in contradistinction to "drug". Rather, the word medicine was used to exclude a disinfectant, which would be included in the definition of drug at section 2 of the *Food and Drug Regulations* (*Hoffmann* at pgs. 69, 74). As the word "medicine" could refer either to the active ingredient itself or to the approved drug containing it, a claim to the formulation or composition,

i.e. the mixture of active and inactive ingredients included in the approved drug, was a claim for the medicine.

[100] This interpretation was adopted in all cases until 2006, when as mentioned earlier, the *PMNOC Regulations* were amended to clarify certain matters. Among those was the acknowledgment of the distinction between a claim for a medicinal ingredient (i.e. as explained, the active ingredient in a drug or pharmaceutical product) and a claim for a formulation, i.e. a mixture composed of medicinal and non-medicinal ingredients in an approved drug. This even though the legislator agreed to keep both types of claims within the scope of the *PMNOC Regulations*. It is clear from the relevant RIAS that the new definitions were intended to bear their established meaning under the extensive body of case law interpreting "claim for the medicine itself" (RIAS S.O.R./2006-242, Canada Gazette, Vol. 140, No. 21 at p. 1516).

[101] Thus, given that I have already determined that it was reasonable for the Minister to conclude that the only medicinal ingredient here is the antigen, it also appears reasonable at this stage of the analysis (words read in context) to conclude that a claim for the medicinal ingredient refers only to a claim for the antigen and not a mixture of ingredients in an approved drug.

[102] The object and purpose of the *CSP Regulations* is not really in dispute. Nor is the purpose of the new section in the *Patent Act*. Those are clearly spelled out in the RIAS to which the Minister refers in her decision. It would be difficult, if not improper to presume that the Minister did not consider the RIAS because she does not recite it at length. The said RIAS starts by stating the following:

Issues

The *Certificate of Supplementary Protection Regulations* (the Regulations) are required, in conjunction with amendments to the *Patent Act* in the *Canada-European Union Comprehensive Economic and Trade Agreement Implementation Act*, to establish an additional period of protection for drugs containing a new medicinal ingredient, or a new combination of medicinal ingredients, protected by an eligible patent. The legislative and regulatory changes are required to meet Canada's commitment under the Canada-European Union Comprehensive Economic and Trade Agreement (CETA).

Enjeux

Le *Règlement sur les certificats de protection supplémentaire* (le Règlement) doit, en conjonction avec les modifications apportées à la *Loi sur les brevets* dans la *Loi de mise en œuvre de l'Accord économique et commercial global entre le Canada et l'Union européenne,* établir une période de protection supplémentaire pour les médicaments contenant un nouvel ingrédient médicinal, ou une nouvelle combinaison d'ingrédients médicinaux, protégés par un brevet admissible. Les modifications législatives et réglementaires sont requises afin que le Canada respecte les engagements pris dans le cadre de l'Accord économique et commercial global (AECG) entre le Canada et l'Union européenne.

Background

In order to meet Canada's CETA obligations, the *Patent Act* (the Act) was amended to create a framework for the issuance and administration of certificates of supplementary protection (CSP), for which patentees with patents relating to human and veterinary drugs may apply. As set out in the Act, the new CSP regime, which will be administered by the Minister of Health (Minister), will provide additional protection from the date of the expiry of the eligible pharmaceutical patent based on the first authorization for sale of a drug containing a new medicinal ingredient or combination of medicinal ingredients in Canada. This new protection, which is intended to partly compensate for time spent in research and obtaining marketing authorization, provides patent-like rights in respect of drugs containing

Contexte

Afin de remplir les obligations du Canada à l'égard de l'AECG, la *Loi sur les brevets* (la Loi) a été modifiée afin de créer un cadre pour la délivrance et l'administration des certificats de protection supplémentaires (CPS) pour lesquels les titulaires de brevets liés aux drogues à usage humain et à usage vétérinaire peuvent déposer une demande. Comme le prévoit la Loi, le nouveau régime de CPS, qui sera administré par la ministre de la Santé (la ministre), fournira une protection additionnelle à compter de la date d'expiration du brevet pharmaceutique admissible en fonction de la première autorisation de vente d'une drogue contenant un nouvel ingrédient médicinal ou une nouvelle combinaison d'ingrédients médicinaux au Canada. Cette nouvelle protection, qui vise en partie

the same medicinal ingredient or combination. The scope of protection can be no broader than the scope of protection afforded by the patent set out in the CSP, and is subject to the same limitations and exceptions as the patent.	à compenser le temps consacré à la recherche et à l'obtention d'une autorisation de mise en marché, fournit des droits similaires à ceux des brevets relativement aux drogues contenant le même ingrédient médicinal ou la même combinaison d'ingrédients médicinaux. La portée de la protection ne peut être plus vaste que la protection conférée par le brevet mentionné dans le CPS, et elle est assujettie aux mêmes limites et exceptions que le brevet.

[103] In its submissions to the Minister, GSK only referred to the RIAS to argue that its interpretation was consistent with the object and purpose pertinent to construing subsection 3(2) (AB, Volume 7 at p. 1685).

[104] What the Minister expressly referred to as evidencing the intention of the legislator (here the Governor in Council) is the section of the RIAS dealing with patent eligibility which deals more specifically with the issue before her.

[105] In this section, the RIAS makes it clear that there is no need for the patent to protect the medicinal ingredient that was approved, but only that it protect what is described as "the same medicinal ingredient" in the RIAS (AB, Volume 7 at p. 1472, section 105 of the *Patent Act*, and section 2 of the *CSP Regulations*).

[106] I understand this to mean that, as explained at page 8 of the RIAS (see AB, Volume 7 at p. 1470) under the section entitled "Same medicinal ingredients", if the approved medicinal ingredient only differs from the claimed medicinal ingredient with respect to a minor variation

such as an enantiomer or an appendage (e.g. ester or salt) within a particular molecular structure, it is nevertheless eligible for a CSP. The same concept applies to use claims and product-by-process claims. I need not discuss the comments made in respect of combinations of medicinal ingredients as they are not relevant here.

[107] The RIAS also mentions that pure process claims do not make the patent eligible, as they do not protect "the product" — which, as discussed above, means the "active ingredient or combination of active ingredients" under CETA. This is an understanding that would also be derived from case law mentioned earlier.

[108] The RIAS then states:

Also, claims that are directed to a formulation containing the medicinal ingredient, including compositions, preparations or similar claim types, do not make a patent eligible for a CSP. A claim to a formulation does not protect the medicinal ingredient or combination of medicinal ingredients per se. A claim to a formulation may be directed, for example, to the improvement of the stability of medicinal ingredients. This is consistent with CETA, which only requires the protection of the medicinal ingredient or combination of medicinal ingredients when claimed "as such."	De plus, les revendications qui visent une formulation contenant l'ingrédient médicinal, y compris les compositions, les préparations ou des revendications similaires, ne rendent pas un brevet admissible à un CPS. Une revendication relative à une formulation ne protège pas l'ingrédient médicinal ou la combinaison d'ingrédients médicinaux en soit. Par exemple, une revendication à l'égard d'une formulation peut être orientée vers l'amélioration de la stabilité des ingrédients médicinaux. Cela est conforme avec l'AECG, qui ne requiert que la protection de l'ingrédient médicinal ou de la combinaison d'ingrédients médicinaux lorsqu'ils sont revendiqués « comme tels ».

[109] The first sentence expresses very clearly a legislative intention in line with the meaning derived from the words used in subsection 3(2) read in their context.

[110] I note that the Federal Court appears to somewhat criticize the use of the words "*per se*" in this section of the RIAS stating that there are no such express words in the statutory provisions themselves (FC Decision at para. 26). First, as mentioned, the generally understood meaning of the words "a claim for the medicinal ingredient" read in their context offers sufficient support for saying that such a claim would cover the medicinal ingredient *per se*. Second, generally and unless one has poor claim drafting skills, when the subject of the invention is a medicinal ingredient, it would not be claimed solely through a formulation, as this would offer very limited protection for such an invention. Such a claim may well be in the cascade of claims in a patent. There is no limitation on what a patent as a whole may include and some may include a claim to the formulation of the approved drug (complete or not) while some may not. This is the point here — however many and diverse claims a patent may include, it must have at least one of the three type of claims described in subsection 3(2).

[111] The example used in the RIAS regarding a formulation that would improve stability indicates that the legislator did not intend to protect a simple improvement to a known medicinal ingredient. I do not agree that this example necessarily refers to a minor improvement (FC Decision at para. 44). Stability issues can be quite serious and if a claim was granted it benefits from the presumption that it is directed to a novel and useful invention. Be that as it may, the example does not limit the general statement.

[112] In fact, this example is not very far from what appears to be the present situation. The antigen in this case was known for use in a vaccine against the VZV virus, which causes chicken pox and shingles (see paragraph 81 above). Its mixture with the patented non-medicinal ingredients in the 905 Patent (the so-called proprietary adjuvant system) resulted in an improved vaccine for the same indication, i.e. shingles. All the claims in this patent are directed to this combination.

[113] The last sentence of the RIAS quoted above brings me to CETA, which the RIAS refers to when quoting the words “as such”, and the definition of “basic patent”.

[114] In my view, on a fair reading of the RIAS, one could reasonably conclude that the legislator endeavoured to adopt a text that would be consistent with the definition of “basic patent” at article 20.27 of CETA while adapting it to the language used and understood in its domestic patent legislation. Under article 20.27(1), “basic patent means a patent which protects a product as such, a process to obtain a product or an application of a product […]”. There is no dispute before us that the word “application” means “use”.

[115] At this stage, I see no reason to conclude that subsection 3(2) as it was intended to be read and applied by the legislator is inconsistent with Canada’s obligation under Article 20.27.

[116] The RIAS indicates that the European Union was consulted on the wording of the *CSP Regulations* (see AB, Volume 7 at p. 1475).

[117] I further note that if the Canadian understanding of CETA, as set out in the Canadian Statement on Implementation or in the *CSP Regulations* is not consistent with CETA, the said agreement provides for a complete mechanism to deal with such issues (Chapter 29) and that there is a CETA Joint Committee with specialized subcommittees in place. We have no evidence that the European Union considers the Canadian government's implementation of CETA to be inconsistent with its obligations.

[118] As a last point before concluding on whether the Minister's decision was reasonable, I will address a submission made by GSK in its additional written submissions in respect of ECJ case law dealing with the meaning of "basic patent".

[119] GSK noted that the word "protects" was construed in the European regulations as meaning that the active ingredient or combination of active ingredients is identified or identifiable in the claims when one reads them with the description of the patent and considers the general knowledge at the time of filing of the patent. Thus, any formulation claims specifying the active ingredient like those in the 905 Patent would be sufficient to meet the test.

[120] I have considered the authorities referred to, including the Minister's submissions that the European case law on this point is of limited assistance because of the particularities of the EU and its members' dual patent legal system and the precise wording used in the Canadian statutory provisions.

[121] I ought to mention that the ECJ has no jurisdiction on the application of national patent law and its interpretation by their national courts or the European Patent Convention and its interpretation. Looking at the ECJ case law, it becomes evident that the ECJ struggled over many years to find a workable interpretation for all its members. As noted by an author cited by the Minister it appears that the words "protected by" have been the subject of more referrals than any other provision of the said regulations and this since the 1990s (Alexa von Uexküll & Oswin Ridderbusch, *European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe* (Wolters Kluwer, 2018) at p. 58).

[122] GSK relies on paragraph 40 of *Glaxo*, to demonstrate that in the case of a patent like the 905 Patent, the ECJ found that a formulation claim protects the antigen "as such", and is therefore eligible for protection. This passage is not persuasive as the issue was not raised by the referring Court, and the basis for such statement is not really explained. We do not even know to which claim in this patent the statement relates. As mentioned, foreign case law is only useful insofar as its reasoning is persuasive. In fact, the only case before us where the ECJ turned its mind to the words "as such" is in *Actavis Group PTC EHF, et al v. Boehringer Ingelheim Pharma GmbH & Co. KG*, Case C-577/13, March 12, 2015 at paragraphs 28 to 38. The interpretation and reasoning in this decision does not persuade me that the interpretation of the Canadian government is inconsistent with its obligation under CETA. The fierce and prolonged debate under the European regulations indicates that there may be more than one possible interpretation of the relevant wording in CETA depending on one's own patent law and jurisprudence.

[123] A patent that protects the product (i.e. the active ingredient) as such is consistent with the requirement that there be a claim for the medicinal ingredient; that is, a claim which defines the subject matter of the invention as the medicinal ingredient or the combination of medicinal ingredients.

[124] If the general objectives described in article 20.1 of CETA mandated a policy broader than the one understood by Canada, the parties could have easily said that any claim that identified the subject of the invention as all active ingredients in a pharmaceutical product combined with any thing else is a basic patent. Why would the parties only refer to combinations of active ingredients?

[125] I conclude by reiterating the obvious. It is not for judges to rewrite government policies when they are of the view that such policies are not fair or broad enough to cover, as in this case, a vaccine that they believe to be a welcome improvement (FC Decision at para. 45). Like many other persons over 55, I know that the SHINGRIX vaccine is more efficient than previous vaccines for shingles, but according to the current Canadian government policy, this is not enough to make it eligible for a CSP in respect of a patent essentially covering this improved vaccine or pharmaceutical product which does not include the type of claims prescribed by the Canadian legislator.

VI. Conclusion

[126] Considering the submissions before her, and her reasoning, I conclude that the Minister's decision was reasonable. Therefore, the Federal Court did not apply the applicable standard of review correctly, and I propose that the appeal be allowed. Neither party requested costs.

"Johanne Gauthier"
J.A.

"I agree
Marianne Rivoalen J.A."

"I agree
George R. Locke J.A."

APPENDIX A

Canada–European Union Comprehensive Economic and Trade Agreement Implementation Act

S.C. 2017, c. 6

[…]	[…]
Interpretation	**Définitions et interprétation**
Definitions	**Définitions**
[…]	[…]
Interpretation consistent with Agreement	**Interprétation compatible**
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 œuvre 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.
[…]	[…]
Purpose	**Objet**
Purpose	**Objet**
7 The purpose of this Act is to implement the Agreement, the objectives of which, as elaborated more specifically through its provisions, are to	**7** La présente loi a pour objet la mise en œuvre de l'Accord dont les objectifs — définis de façon plus précise dans ses dispositions — sont les suivants :
[…]	[…]
(f) provide adequate and effective protection and enforcement of intellectual property rights in the territory where the Agreement applies;	**f)** assurer de façon efficace et suffisante la protection et le respect des droits de propriété intellectuelle sur le territoire auquel l'Accord s'applique;
[…]	[…]

Certificate of Supplementary Protection Regulations

SOR/2017-165

[…]

Variations

2 For the purposes of subsections 105(3) and (4) of the Act, the prescribed variations are

(a) a variation in any appendage within the molecular structure of a medicinal ingredient that causes it to be an ester, salt, complex, chelate, clathrate or any non-covalent derivative;

(b) a variation that is an enantiomer, or a mixture of enantiomers, of a medicinal ingredient;

(c) a variation that is a solvate or polymorph of a medicinal ingredient;

(d) an in vivo or in vitro post-translational modification of a medicinal ingredient; and

(e) any combination of the variations set out in paragraphs (a) to (d).

[…]

Content of application

6(3) An application for a certificate of supplementary protection must contain

[…]

(d) the applicant's attestation that

(i) when the application was filed for the authorization for sale referred to in paragraph 106(1)(c) of the Act, no application for a marketing approval, equivalent to an authorization for

[…]

Variations

2 Pour l'application des paragraphes 105(3) et (4) de la Loi, sont des variations :

a) la variation de tout appendice dans la structure moléculaire de l'ingrédient médicinal qui en fait un ester, un sel, un complexe, un chélate, un clathrate ou un dérivé non covalent;

b) la variation qui est un énantiomère, ou un mélange d'énantiomères, d'un ingrédient médicinal;

c) la variation qui est un solvate ou un polymorphe d'un ingrédient médicinal;

d) toute modification post-traductionnelle in vivo ou in vitro d'un ingrédient médicinal;

e) toute combinaison des variations visées aux alinéas a) à d).

[…]

Contenu de la demande

6(3) Toute demande de certificat de protection supplémentaire contient ce qui suit :

[…]

d) l'attestation du demandeur portant que :

(i) au moment du dépôt de la demande d'autorisation de mise en marché visée à l'alinéa 106(1)c) de la Loi, aucune demande pour une autorisation de vente équivalant à une

sale, with respect to the medicinal ingredient or combination of medicinal ingredients, as the case may be, set out in the application for the certificate of supplementary protection had been submitted in a country prescribed by paragraph (1)(a), or

autorisation de mise en marché, relativement à l'ingrédient médicinal ou à la combinaison d'ingrédients médicinaux, selon le cas, mentionné dans la demande de certificat de protection supplémentaire, n'avait été présentée auprès d'un des pays visés à l'alinéa (1)a),

(ii) if one or more of those applications for a marketing approval had been submitted in one or more of those countries, the application for the authorization for sale referred to in paragraph 106(1)(c) of the Act was filed before the end of the prescribed period referred to in paragraph (1)(b) that begins on the day of submission of the first of those marketing approval applications; and

(ii) si une ou plusieurs de ces demandes d'autorisation de vente avaient été présentées auprès d'un ou de plusieurs de ces pays, la demande d'autorisation de mise en marché visée à l'alinéa 106(1)c) de la Loi a été déposée avant la fin du délai prévu à l'alinéa (1)b) qui commence à la date de présentation de la première de ces demandes d'autorisation de vente;

Patent Act

R.S.C., 1985, c. P-4

[…]

Supplementary Protection for Inventions — Medicinal Ingredients

Interpretation

Definitions

104 The following definitions apply in this section and in sections 105 to 134.

authorization for sale has the meaning assigned by regulations. (autorisation de mise en marché)

drug means a substance or a mixture of substances manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; or

(b) restoring, correcting or modifying organic functions in human beings or animals. (drogue)

[…]

Interpretation

105 (1) For the purposes of this section and sections 106 to 134, if a patent is reissued under section 47, it is deemed to have been granted on the day on which the original patent was granted and its application filing date is deemed to be the day on which the application for the original patent was filed.

[…]

Protection supplémentaire pour les inventions — ingrédients médicinaux

Définitions et interprétation

Définitions

104 Les définitions qui suivent s'appliquent au présent article et aux articles 105 à 134.

autorisation de mise en marché S'entend au sens des règlements. (authorization for sale)

drogue Substance ou mélange de substances qui est fabriqué, vendu ou présenté comme pouvant servir à l'une des fins suivantes :

a) le diagnostic, le traitement, l'atténuation, la prévention d'une maladie, d'un désordre, d'un état physique anormal ou de leurs symptômes, chez l'être humain ou les animaux;
b) la restauration, la correction ou la modification des fonctions organiques chez l'être humain ou les animaux. (drug)

[…]

Interprétation

105 (1) Pour l'application du présent article et des articles 106 à 134, dans le cas où un brevet est redélivré en vertu de l'article 47, la date de dépôt de la demande de brevet est réputée être celle de la demande du brevet original et la date d'octroi du nouveau brevet est réputée être celle du brevet original.

[…]

Same medicinal ingredient — human use

(3) If medicinal ingredients contained in drugs authorized for human use differ from each other only with respect to a prescribed variation, they are to be treated as the same medicinal ingredient for the purposes of this section and sections 106 to 134.

[…]

Same combination — human use

(5) If combinations of medicinal ingredients contained in drugs authorized for human use differ from each other only with respect to a variation in the ratio between those ingredients, they are to be treated as the same combination of medicinal ingredients for the purposes of this section and sections 106 to 134.

[…]

Application for Certificate of Supplementary Protection

Application

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:

(a) the patent is not void and it meets any prescribed requirements;

[…]

Même ingrédient médicinal — usage humain

(3) Pour l'application du présent article et des articles 106 à 134, lorsque des ingrédients médicinaux contenus dans des drogues autorisées pour un usage humain ne diffèrent entre eux que par une variation prévue par règlement, ils sont considérés comme le même ingrédient.

[…]

Même combinaison — usage humain

(5) Pour l'application du présent article et des articles 106 à 134, lorsque des combinaisons d'ingrédients médicinaux contenues dans des drogues autorisées pour un usage humain ne diffèrent entre elles que par une variation dans la proportion des ingrédients qu'elles contiennent, elles sont considérées comme la même combinaison.

[…]

Demande de certificat de protection supplémentaire

Demande

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) 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.

Comprehensive Economic and Trade Agreement

[…]	[…]
Chapter twenty: Intellectual property	**Chapitre vingt : Propriété intellectuelle**
Section A – General Provisions	**Section A – Dispositions générales**
Article 20.1 – Objectives	**Article 20.1 – Objectifs**
The objectives of this Chapter are to:	Les objectifs du présent chapitre sont les suivants :
a. facilitate the production and commercialisation of innovative and creative products, and the provision of services, between the Parties; and	a. faciliter la production et la commercialisation de produits novateurs et créatifs et la prestation de services entre les Parties;
b. achieve an adequate and effective level of protection and enforcement of intellectual property rights.	b. atteindre un niveau approprié et efficace de protection et de mise en œuvre des droits de propriété intellectuelle.
Article 20.2 – Nature and scope of obligations	**Article 20.2 – Nature et portée des obligations**
1. The provisions of this Chapter complement the rights and obligations between the Parties under the TRIPS Agreement.	1. Les dispositions du présent chapitre complètent les droits et obligations réciproques des Parties au titre de l'Accord sur les ADPIC.
2. Each Party shall be free to determine the appropriate method of implementing the provisions of this Agreement within its own legal system and practice.	2. Chaque Partie est libre de déterminer la méthode appropriée pour mettre en œuvre les dispositions du présent accord dans le cadre de son système et de ses pratiques juridiques.
3. This Agreement does not create any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and enforcement of law in general.	3. Le présent accord ne crée aucune obligation en ce qui concerne la répartition des ressources entre les moyens de faire respecter les droits de propriété intellectuelle et les moyens de faire respecter le droit en général.
[…]	[…]
Section B – Standards Concerning Intellectual Property Rights	**Section B – Normes concernant les droits de propriété intellectuelle**

Article 20.6 – Definition	**Article 20.6 - Définition**
For the purposes of this Section:	Pour l'application de la présente section :
pharmaceutical product means a product including a chemical drug, biologic drug, vaccine or radiopharmaceutical, that is manufactured, sold or represented for use in:	**produit pharmaceutique** désigne un produit, y compris un médicament chimique, un médicament biologique, un vaccin ou un médicament radiopharmaceutique, qui est fabriqué, vendu ou présenté pour servir, selon le cas :
a. making a medical diagnosis, treating, mitigating or preventing disease, disorder, or abnormal physical state, or its symptoms, or	a. au diagnostic médical, au traitement, à l'atténuation ou à la prévention d'une maladie, d'un trouble, d'un état physique anormal ou de leurs symptômes;
b. restoring, correcting, or modifying physiological functions.	b. à la restauration, à la correction ou à la modification de fonctions physiologiques.
[…]	[…]
Sub-section E – Patents	**Sous-section E – Brevets**
[…]	[…]
Article 20.27 – Sui generis protection for pharmaceuticals	**Article 20.27 – Protection sui generis des produits pharmaceutiques**
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	2. Chaque Partie prévoit une période de protection sui generis à l'égard d'un produit qui est protégé par un

patent in force at the request of the holder of the patent or his successor in title, provided the following conditions have been met:

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);

b. the product has not already been the subject of a period of sui generis protection; and

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.

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. 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. le produit n'a pas déjà fait l'objet d'une période de protection sui generis;

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.

CSP REGULATIONS REGULATORY IMPACT ANALYSIS STATEMENT

Issues

The *Certificate of Supplementary Protection Regulations* (the Regulations) are required, in conjunction with amendments to the *Patent Act* in the *Canada-European Union Comprehensive Economic and Trade Agreement Implementation Act*, to establish an additional period of protection for drugs containing a new medicinal ingredient, or a new combination of medicinal ingredients, protected by an eligible patent. The legislative and regulatory changes are required to meet Canada's commitment under the Canada-European Union Comprehensive Economic and Trade Agreement (CETA).

Enjeux

Le *Règlement sur les certificats de protection supplémentaire* (le Règlement) doit, en conjonction avec les modifications apportées à la *Loi sur les brevets* dans la *Loi de mise en œuvre de l'Accord économique et commercial global entre le Canada et l'Union européenne,* établir une période de protection supplémentaire pour les médicaments contenant un nouvel ingrédient médicinal, ou une nouvelle combinaison d'ingrédients médicinaux, protégés par un brevet admissible. Les modifications législatives et réglementaires sont requises afin que le Canada respecte les engagements pris dans le cadre de l'Accord économique et commercial global (AECG) entre le Canada et l'Union européenne.

Background

In order to meet Canada's CETA obligations, the Patent Act (the Act) was amended to create a framework for the issuance and administration of certificates of supplementary protection (CSP), for which patentees with patents relating to human and veterinary drugs may apply. As set out in the Act, the new CSP regime, which will be administered by the Minister of Health (Minister), will provide additional protection from the date of the expiry of the eligible pharmaceutical patent based on the first authorization for sale of a drug containing a new medicinal ingredient or combination of medicinal ingredients in Canada. This new protection, which is intended to partly compensate for time spent in research and obtaining marketing

Contexte

Afin de remplir les obligations du Canada à l'égard de l'AECG, la Loi sur les brevets (la Loi) a été modifiée afin de créer un cadre pour la délivrance et l'administration des certificats de protection supplémentaires (CPS) pour lesquels les titulaires de brevets liés aux drogues à usage humain et à usage vétérinaire peuvent déposer une demande. Comme le prévoit la Loi, le nouveau régime de CPS, qui sera administré par la ministre de la Santé (la ministre), fournira une protection additionnelle à compter de la date d'expiration du brevet pharmaceutique admissible en fonction de la première autorisation de vente d'une drogue contenant un nouvel ingrédient médicinal ou une nouvelle combinaison d'ingrédients

authorization, provides patent-like rights in respect of drugs containing the same medicinal ingredient or combination. The scope of protection can be no broader than the scope of protection afforded by the patent set out in the CSP, and is subject to the same limitations and exceptions as the patent.

médicinaux au Canada. Cette nouvelle protection, qui vise en partie à compenser le temps consacré à la recherche et à l'obtention d'une autorisation de mise en marché, fournit des droits similaires à ceux des brevets relativement aux drogues contenant le même ingrédient médicinal ou la même combinaison d'ingrédients médicinaux. La portée de la protection ne peut être plus vaste que la protection conférée par le brevet mentionné dans le CPS, et elle est assujettie aux mêmes limites et exceptions que le brevet.

The term of a CSP is the difference between the date of the filing of the application for the patent and the date of issuance of the authorization for sale, reduced by five years, and capped at two years (i.e. CSP term = [Notice of Compliance date – Patent filing date] – five years, with a cap of two years).

La durée du CPS représente la différence entre la date de dépôt de la demande de brevet et la date d'émission de l'autorisation de mise en marché, réduite de cinq ans, et plafonnée à deux ans (c'est-à-dire durée du CPS = [date de l'avis de conformité – date de dépôt du brevet] – cinq ans, avec un plafond de deux ans).

The Act allows CSP applications to be submitted within a prescribed timeframe from (i) the authorization for sale of a drug; or (ii) the subsequent grant of an eligible patent that occurs after the authorization for sale of the drug. To be eligible, the application for authorization to sell a drug containing a medicinal ingredient or combination must be filed with the Minister before, or within a reasonable amount of time from, when the approval of a drug containing the same medicinal ingredient or combination was first sought in any comparable jurisdictions (the timely submission requirement). For a medicinal ingredient or combination to be eligible for a CSP, a drug containing it must not have been previously

La Loi prévoit que les demandes de CPS peuvent être présentées dans un délai prescrit à partir : (i) de l'autorisation de mise en marché d'une drogue; ou (ii) de la délivrance subséquente d'un brevet admissible qui a lieu après l'autorisation de mise en marché de la drogue. Pour être admissible, la demande d'autorisation de mise en marché d'une drogue contenant un ingrédient médicinal ou une combinaison d'ingrédients médicinaux doit être présentée au ministre avant que, ou dans un délai raisonnable à partir du moment où, la première demande visant une approbation d'une drogue contenant le même ingrédient médicinal ou la même combinaison d'ingrédients médicinaux a été déposée dans une des juridictions comparables

authorized for sale (as that phrase is defined) in Canada.	(l'exigence de dépôt en temps opportun). Pour qu'un ingrédient médicinal ou une combinaison d'ingrédients médicinaux soit admissible à un CPS, la vente de la drogue qui contient l'ingrédient visé ne doit pas avoir été autorisée précédemment (au sens du projet de règlement) au Canada.
This regime is substantially defined in the amendments to the Act. The Regulations specify the various timelines and requirements necessary for the purpose of the regime.	Ce régime est essentiellement défini dans les modifications apportées à la Loi. Le Règlement précise les différents délais ainsi que les exigences nécessaires aux fins du régime.
[…]	[…]
Objectives	Objectifs
The Regulations accompany the Act amendments which establish the CSP regime. This regime implements Canada's commitment in the CETA by providing for an additional period of patent-like protection for drugs containing new medicinal ingredients and new combinations of medicinal ingredients.	Le Règlement accompagne les modifications apportées à la Loi, qui établissent le régime de CPS. Ce régime met en œuvre l'engagement du Canada à l'égard de l'AECG en prévoyant une période additionnelle de protection similaire à celle des brevets pour les drogues contenant de nouveaux ingrédients médicinaux et de nouvelles combinaisons d'ingrédients médicinaux.
The Regulations provide for various timelines, requirements and procedures needed to carry out the CSP regime defined in sections 104–134 of the Act.	Le Règlement prévoit plusieurs délais, exigences et procédures nécessaires afin de mettre en œuvre le régime de CPS défini aux articles 104 à 134 de la Loi.
Description	Description
The following describes the various specific elements of the CSP regime prescribed in the Regulations.	La partie qui suit décrit les différents éléments spécifiques du régime de CPS prévu par le Règlement.
(a) Same medicinal ingredients	a) Mêmes ingrédients médicinaux
In order to ensure that relatively minor variations in medicinal ingredients or combinations of medicinal ingredients cannot be used to circumvent the scope of protection	Afin de veiller à ce que des variations relativement mineures d'ingrédients médicinaux ou de combinaisons d'ingrédients médicinaux ne puissent être utilisées pour contourner la

granted by an issued CSP, or the eligibility requirements relating to the first authorization or timely submission, the Regulations prescribe the variations in medicinal ingredients that would lead to the medicinal ingredients being considered the same.

portée de la protection que confère un CPS, ou les exigences en matière d'admissibilité liées à la première autorisation ou le dépôt en temps opportun, le Règlement prévoit les variations d'ingrédients médicinaux qui pourraient faire en sorte que des ingrédients médicinaux soient considérés comme les mêmes.

Subject to subsection 105(2) of the Act regarding human and veterinary uses, if medicinal ingredients only differ from one another with respect to one or more of the following prescribed variations in any appendage within the molecular structure: an ester, salt, complex, chelate, clathrate or non-covalent derivative, then the medicinal ingredients are considered to be the same. The word "appendage" in the context of medicinal ingredients is intended to refer to a portion of the molecule that is connected or joined to a larger or more important part. It is meant to signify the non-principal part of the molecule which is not principally responsible for the mechanism of action of the medicinal ingredient. Also, if the medicinal ingredients only differ from one another with respect to a variation that is an enantiomer, mixture of enantiomers, solvate or polymorph, they are treated as the same medicinal ingredients. Medicinal ingredients that only differ from one another due to post-translational modifications which are done within a living cell (in vivo) or outside of it (in vitro) (e.g. PEGylation) are also treated as the same. Lastly, any differences that arise solely due to combining any of the prescribed variations would also render the medicinal ingredients to be the same.

Sous réserve du paragraphe 105(2) de la Loi concernant les usages humains et les usages vétérinaires, si les ingrédients médicinaux ne diffèrent entre eux que par une ou plusieurs des variations prescrites de tout appendice dans la structure moléculaire (c'est-à-dire un ester, un sel, un complexe, un chélate, un clathrate ou un dérivé non covalent), alors les ingrédients médicinaux sont considérés les mêmes. Le terme « appendice », dans le contexte des ingrédients médicinaux, vise à faire référence à une portion de la molécule qui est rattachée ou jointe à une partie plus large ou plus importante. Il désigne la partie non principale de la molécule qui n'est pas essentiellement responsable du mécanisme de l'action de l'ingrédient médicinal. De plus, si les ingrédients médicinaux ne diffèrent entre eux que par la variation qui est un énantiomère, un mélange d'énantiomères, un solvate ou un polymorphe, ils sont traités comme les mêmes ingrédients médicinaux. Les ingrédients médicinaux qui ne diffèrent entre eux qu'en raison de modifications post-traductionnelles qui sont effectuées dans une cellule vivante (in vivo) ou à l'extérieur de celle-ci (in vitro) (par exemple pégylation) sont également traités comme les mêmes. Enfin, toute différence qui survient uniquement en

raison de la combinaison de l'une des variations prescrites rendra aussi les ingrédients médicinaux les mêmes.

It should be noted that two combinations, where the individual medicinal ingredients in one combination are prescribed variations of those in the other combination, are considered to be the same combination [e.g. Combo 1 (A+B) is the same as Combo 2 (A'+B') wherein A' and A are prescribed variations of one another, and B' and B are also prescribed variations of one another]. It should also be noted that where differences between two combinations lie only in the proportion of two or more medicinal ingredients that are to be treated as the same, the Act provides that the two combinations are considered to be the same combination of medicinal ingredients. For example, combination 1, containing 0.5 g of medicinal ingredient A and 0.5 g of medicinal ingredient B, would be considered the same combination as combination 2, containing 0.4 g of medicinal ingredient A and 0.6 g of medicinal ingredient B (i.e. changing the medicinal ingredient dose/strength in a combination does not make it a new medicinal ingredient or combination).

Il convient de noter que deux combinaisons, où les ingrédients médicinaux individuels dans une combinaison sont des variations prescrites de celles de l'autre combinaison, sont considérées être la même combinaison [par exemple Combo 1 (A+B) est la même que Combo 2 (A'+B') où A' et A sont des variations prescrites l'une de l'autre, et B' et B sont également des variations prescrites l'une de l'autre]. Il convient aussi de noter que lorsque les différences entre les deux combinaisons ne résident que dans la proportion de deux ou plusieurs ingrédients médicinaux qui doivent être traités comme étant les mêmes, la Loi prévoit que les deux combinaisons sont considérées être la même combinaison d'ingrédients médicinaux. Par exemple, la combinaison 1, contenant 0,5 g de l'ingrédient médicinal A et 0,5 g de l'ingrédient médicinal B, serait considérée comme la même combinaison que la combinaison 2, contenant 0,4 g de l'ingrédient médicinal A et 0,6 g de l'ingrédient médicinal B (c'est-à-dire changer la dose/la force de l'ingrédient médicinal d'une combinaison n'en fait pas un nouvel ingrédient médicinal ou une nouvelle combinaison).

(b) Authorizations for sale

b) Autorisations de mise en marché

To be eligible, the medicinal ingredient or combination cannot have been the sole medicinal ingredient or the combination of all medicinal ingredients in a drug previously authorized for regular sale

Pour être admissible, l'ingrédient médicinal ou la combinaison ne peut avoir été le seul ingrédient médicinal ou la seule combinaison de tous les ingrédients médicinaux d'une drogue dont la mise en marché régulière a été

in Canada (e.g. by way of a Notice of Compliance, Drug Identification Number, Natural Health Product Number). Limited purpose authorizations and interim orders permitting drug sales do not prohibit a medicinal ingredient or combination of medicinal ingredients contained therein from eligibility for a CSP, if a drug containing that medicinal ingredient or combination is subsequently approved by way of a Notice of Compliance (NOC).

autorisée précédemment au Canada (par exemple au moyen d'un avis de conformité, d'un numéro d'identification de la drogue, d'un numéro de produit naturel). Les autorisations en vue d'un usage restreint et les ordonnances intérimaires autorisant la mise en marché de drogues n'empêchent pas qu'un ingrédient médicinal ou une combinaison d'ingrédients médicinaux soient admissibles à un CPS, pour autant que la drogue contenant cet ingrédient médicinal ou une combinaison soit approuvé subséquemment au moyen d'un avis de conformité (AC).

The 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. The Regulations prescribe the current authorization for sale which renders the medicinal ingredient eligible for a CSP as the NOC (section 4).

La Loi prévoit également que pour qu'un ingrédient médicinal ou une combinaison d'ingrédients médicinaux soit admissible à un CPS, il faut que l'ingrédient médicinal ou la combinaison de tous les ingrédients médicinaux soit contenu dans une drogue visée par une autorisation de mise en marché au Canada. Le Règlement prévoit que l'autorisation de mise en marché actuelle qui rend l'ingrédient médicinal admissible à un CPS est un AC (article 4).

(c) Patent eligibility

c) Admissibilité du brevet

The Regulations prescribe that a patent must be in force, which is a condition that applies at the time of filing a CSP application and at the time of the issuance of a CSP by the Minister.

Le Règlement prévoit qu'un brevet doit être en vigueur, une condition qui s'applique au moment du dépôt d'une demande de CPS ainsi qu'au moment de la délivrance d'un CPS par la ministre.

To be eligible for a CSP, the patent claims must pertain, in the case of a drug containing one medicinal ingredient, to the one medicinal ingredient, or, in the case of a drug containing two or more medicinal

Afin d'être admissibles à un CPS, les revendications du brevet doivent, dans le cas d'une drogue contenant un ingrédient médicinal, être liées à un ingrédient médicinal ou, dans le cas d'une drogue contenant deux ou plusieurs ingrédients médicinaux, être

ingredients, to the combination of all medicinal ingredients.

liées à la combinaison de tous les ingrédients médicinaux.

With the intention that the eligibility of a patent for a CSP will mirror the scope of protection of the resulting CSP, an eligible patent need not protect the approved medicinal ingredient but must pertain to the same medicinal ingredient [see (a) above] as contained in the drug for which the authorization for sale specified on the CSP application was issued. To pertain to the same medicinal ingredient, the patent must include at least one claim that is directed at

De façon à ce que l'admissibilité d'un brevet à un CPS reflète la portée de la protection résultant du CPS, un brevet admissible n'a pas à protéger l'ingrédient médicinal approuvé, mais doit viser le même ingrédient médicinal [voir a) ci-dessus] tel qu'il figure dans la drogue pour laquelle l'autorisation de mise en marché précisée dans la demande de CPS a été délivrée. Afin de viser le même ingrédient médicinal, le brevet doit contenir au moins une revendication visant :

•the same medicinal ingredient;

•le même ingrédient médicinal;

•any use of the same medicinal ingredient; or

•toute utilisation du même ingrédient médicinal;

•the same medicinal ingredient as produced by a defined process (product-by-process).

•le même ingrédient médicinal tel qu'il est obtenu au moyen d'un procédé déterminé (produit-par-procédé).

Where the authorization is for a drug that contains a combination of medicinal ingredients, the eligible patent need not protect the approved combination of medicinal ingredients but it must pertain to the same combination of the same medicinal ingredients. To pertain to the same combination of the same medicinal ingredients, the patent must include at least one claim directed at

Lorsque l'autorisation vise une drogue qui contient une combinaison d'ingrédients médicinaux, le brevet admissible n'a pas à protéger la combinaison approuvée d'ingrédients médicinaux, mais il doit viser la même combinaison des mêmes ingrédients médicinaux. Afin de viser la même combinaison des mêmes ingrédients médicinaux, le brevet doit inclure au moins une revendication visant :

•the same combination of the same medicinal ingredients;

•la même combinaison des mêmes ingrédients médicinaux;

•any use of the same combination of the same medicinal ingredients; or

•toute utilisation de la même combinaison des mêmes ingrédients médicinaux;

•the same combination of the same medicinal ingredients as produced by

•la même combinaison des mêmes ingrédients médicinaux tels qu'ils

a defined process (product-by-process).	sont obtenus au moyen d'un procédé déterminé (produit-par-procédé).
A patent which protects more than one medicinal ingredient or more than one combination of medicinal ingredients, subject to the rules on variations and combinations, would be eligible to support a CSP application in respect of each of those medicinal ingredients or combinations, as the case may be. However, pure process claims do not protect the product and therefore do not render a patent eligible for a CSP.	Un brevet qui protège plus d'un ingrédient médicinal ou plus d'une combinaison d'ingrédients médicinaux, sous réserve des règles relatives aux variations et aux combinaisons, serait admissible au soutien d'une demande de CPS relativement, selon le cas, à chacun des ingrédients médicinaux ou à chacune des combinaisons d'ingrédients médicinaux. Cependant, les revendications au titre d'un processus pur ne protègent pas le produit et, par conséquent, ne rendent pas un brevet admissible à un CPS.
Also, claims that are directed to a formulation containing the medicinal ingredient, including compositions, preparations or similar claim types, do not make a patent eligible for a CSP. A claim to a formulation does not protect the medicinal ingredient or combination of medicinal ingredients per se. A claim to a formulation may be directed, for example, to the improvement of the stability of medicinal ingredients. This is consistent with CETA, which only requires the protection of the medicinal ingredient or combination of medicinal ingredients when claimed "as such."	De plus, les revendications qui visent une formulation contenant l'ingrédient médicinal, y compris les compositions, les préparations ou des revendications similaires, ne rendent pas un brevet admissible à un CPS. Une revendication relative à une formulation ne protège pas l'ingrédient médicinal ou la combinaison d'ingrédients médicinaux en soit. Par exemple, une revendication à l'égard d'une formulation peut être orientée vers l'amélioration de la stabilité des ingrédients médicinaux. Cela est conforme avec l'AECG, qui ne requiert que la protection de l'ingrédient médicinal ou de la combinaison d'ingrédients médicinaux lorsqu'ils sont revendiqués « comme tels ».
[…]	[…]
Rationale	Justification
The Canadian CSP regime is created with the aim of meeting obligations under Article 20.27 of the CETA, which requires Parties to provide an	Le régime canadien de CPS a pour objet de respecter les obligations prévues à l'article 20.27 de l'AECG, selon lequel les Parties doivent

additional period of protection for patent-protected pharmaceutical products, while continuing to balance the interests of stakeholders and the public within the Patent Act. In determining if requirements should be defined by regulations and not the Act, the main consideration was that regulations can be more responsive to changes. Definitions and meanings that refer to other legislation and regulations (i.e. the Food and Drug Regulations) were inserted in the Regulations, given that it would be easier to amend the relevant reference in case of a change in said related instruments. Elements (timelines, etc.) that are dependent on procedures currently in place at either Health Canada or other regulatory agencies were also defined in the Regulations, given that they might need to be readily changed if or when these procedures are altered. Also, elements of a technical, industrial, scientific or litigious nature, which will evolve according to advancements in the field and will therefore need to be easily amended accordingly, were placed in the Regulations.

prévoir une protection supplémentaire à l'égard des produits pharmaceutiques protégés par brevet, tout en conciliant les intérêts des intervenants et du public au sens de la Loi sur les brevets. Afin de déterminer si les exigences devraient être définies par règlement et non par la Loi, le principal facteur était qu'un règlement peut plus facilement refléter les changements. Les définitions et les explications qui renvoient à d'autres dispositions législatives et réglementaires (c'est-à-dire le Règlement sur les aliments et drogues) ont été insérées dans le Règlement, puisqu'il serait plus facile de modifier la référence pertinente si un changement était apporté aux dispositions visées. Les éléments (délais, etc.) qui dépendent des procédures actuelles soit à Santé Canada ou dans d'autres organismes de réglementation ont aussi été définis dans le Règlement, puisqu'ils pourraient être nécessaire de les modifier rapidement lorsque des changements sont apportés à ces procédures. De plus, les éléments de nature technique, industrielle, scientifique ou litigieuse, qui évolueront au fil des avancées dans le domaine et qui, par conséquent, devront être faciles à modifier, ont été inclus dans le Règlement.

REGULATION (EC) No 469/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 concerning the supplementary protection certificate for medicinal products

Article 1 **Definitions**	*Article premier* **Définitions**
For the purposes of this Regulation, the following definitions shall apply:	Aux fins du présent règlement, on entend par:
[…]	[…]
(b) ‘product’ means the active ingredient or combination of active ingredients of a medicinal product;	b) «produit»: le principe actif ou la composition de principes actifs d’un médicament;
(c) ‘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 is designated by its holder for the purpose of the procedure for grant of a certificate;	c) «brevet de base»: 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 son titulaire aux fins de la procédure d’obtention d’un certificat;

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE BARNES DATED APRIL 7, 2020, NO. T-1603-18

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PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	FEBRUARY 10, 2021
REASONS FOR JUDGMENT BY:	GAUTHIER J.A.
CONCURRED IN BY:	RIVOALEN J.A. LOCKE J.A.
DATED:	APRIL 14, 2021

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