Federal Court of Appeal | Cour d'appel fédérale

Date: 20130118

Docket: A-9-12

Citation: 2013 FCA 13

CORAM: **PELLETIER J.A.**
DAWSON J.A.
STRATAS J.A.

BETWEEN:

TAKEDA CANADA INC.

Appellant

and

THE MINISTER OF HEALTH and ATTORNEY GENERAL OF CANADA

Respondents

Heard at Ottawa, Ontario, on June 11, 2012.

Judgment delivered at Ottawa, Ontario, on January 18, 2013.

REASONS FOR JUDGMENT BY: DAWSON J.A.

CONCURRED IN BY: PELLETIER J.A.
DISSENTING REASONS BY: STRATAS J.A.

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REASONS FOR JUDGMENT

STRATAS J.A. (**Dissenting reasons**)

[1] The appellant, Takeda Canada Inc., appeals from the judgment dated September 12, 2011 of the Federal Court (*per* Justice Near): 2011 FC 1444. The Federal Court dismissed Takeda's application for judicial review of a decision of the respondent Minister.

[2] The Minister refused to list Takeda's drug, DEXILANT, on the Register of Innovative Drugs and provide data protection under section C.08.004.1 of the *Food and Drug Regulations*, C.R.C. c. 870, as amended by the *Regulations Amending the Food and Drug Regulations (Data Protection)*, SOR/2006-241.

[3] The Minister refused to list DEXILANT based on her interpretation of the definition of "innovative drug" in subsection C.08.004.1(1) of the Regulations. The Federal Court agreed with the Minister's interpretation, found that DEXILANT was not an "innovative drug" under the subsection, and dismissed Takeda's application for judicial review. Takeda appeals to this Court.

[4] For the reasons set out below, I find that the Minister wrongly interpreted the term "innovative drug" under subsection C.08.004.1(1) of the Regulations. Properly interpreted, the definition of "innovative drug" under the subsection can include a drug such as DEXILANT.

[5] Therefore, I would allow Takeda's appeal, with costs, and remit to the Minister for redetermination the issue whether DEXILIANT is an "innovative drug" entitled to data protection.

A. The data protection regulations: section C.08.004.1 of the Regulations

[6] The provisions contained in Section C.08.004.1 of the Regulations are frequently described as the "data protection regulations." The data protection regulations protect an innovator who submits undisclosed data in support of an application for approval to market certain drugs in certain

circumstances, described below. For a period of time, it prevents others from using the innovator's data in support of their own submissions for drug approval.

[7] Before the enactment of the data protection regulations, one of the impediments to a generic drug manufacturer's ability to obtain approval of the right to market a generic drug was the existence of an unexpired patent. After the enactment of the data protection regulations, generic drug manufacturers cannot obtain approval for their generic drug until the period of market exclusivity of the innovative drug has expired, even where there is no patent protection for that drug.

[8] The data protection regulations read as follows:

C.08.004.1 (1) The following definitions apply in this section.	**C.08.004.1** Les définitions qui suivent s'appliquent au présent article.
"abbreviated new drug submission" includes an abbreviated extraordinary use new drug submission. (*présentation abrégée de drogue nouvelle*)	« drogue innovante » S'entend de toute drogue qui contient un ingrédient médicinal non déjà approuvé dans une drogue par le ministre et qui ne constitue pas une variante d'un ingrédient médicinal déjà approuvé tel un changement de sel, d'ester, d'énantiomère, de solvate ou de polymorphe. (*innovative drug*)
"innovative drug" means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. (*drogue innovante*)	« population pédiatrique » S'entend de chacun des groupes suivants : les bébés prématurés nés avant la 37e semaine de gestation, les bébés menés à terme et âgés de 0 à 27 jours, tous les enfants âgés de 28 jours à deux ans, ceux âgés de deux ans et un jour à 11 ans et ceux âgés de 11 ans et un jour à 18 ans. (*pediatric populations*)
"new drug submission" includes an extraordinary use new drug submission. (*présentation de drogue nouvelle*)	

"pediatric populations" means the following groups: premature babies born before the 37th week of gestation; full-term babies from 0 to 27 days of age; and all children from 28 days to 2 years of age, 2 years plus 1 day to 11 years of age and 11 years plus 1 day to 18 years of age. (*population pédiatrique*)

« présentation abrégée de drogue nouvelle » S'entend également d'une présentation abrégée de drogue nouvelle pour usage exceptionnel. (*abbreviated new drug submission*)

« présentation de drogue nouvelle » S'entend également d'une présentation de drogue nouvelle pour usage exceptionnel. (*new drug submission*)

(2) This section applies to the implementation of Article 1711 of the *North American Free Trade Agreement*, as defined in the definition "Agreement" in subsection 2(1) of the *North American Free Trade Agreement Implementation Act*, and of paragraph 3 of Article 39 of the Agreement on *Trade-related Aspects of Intellectual Property Rights* set out in Annex 1C to the World Trade Organization Agreement, as defined in the definition "Agreement" in subsection 2(1) of the *World Trade Organization Agreement Implementation Act*.

(2) Le présent article s'applique à la mise en œuvre de l'article 1711 de *l'Accord de libre-échange nord-américain*, au sens du terme « Accord » au paragraphe 2(1) de la *Loi de mise en œuvre de l'Accord de libre-échange nord-américain*, et du paragraphe 3 de l'article 39 de *l'Accord sur les aspects des droits de propriété intel*lectuelle qui touchent au commerce figurant à l'annexe 1C de l'Accord sur l'Organisation mondiale du commerce, au sens du terme « Accord » au paragraphe 2(1) de la *Loi de mise en œuvre de l'Accord sur l'Organisation mondiale du commerce*.

(3) If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug,

(3) Lorsque le fabricant demande la délivrance d'un avis de conformité pour une drogue nouvelle sur la base d'une comparaison directe ou indirecte entre celle-ci et la drogue innovante :

(*a*) the manufacturer may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission in respect of the new drug before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug; and

a) le fabricant ne peut déposer pour cette drogue nouvelle de présentation de drogue nouvelle, de présentation abrégée de drogue nouvelle ou de supplément à l'une de ces présentations avant l'expiration d'un délai de six ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante;

(*b*) the Minister shall not approve that submission or supplement and shall not issue a notice of compliance in respect of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.

b) le ministre ne peut approuver une telle présentation ou un tel supplément et ne peut délivrer d'avis de conformité pour cette nouvelle drogue avant l'expiration d'un délai de huit ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante.

(4) The period specified in paragraph (3)(*b*) is lengthened to eight years and six months if

(4) Le délai prévu à l'alinéa (3)*b*) est porté à huit ans et six mois si, à la fois:

(*a*) the innovator provides the Minister with the description and results of clinical trials relating to the use of the innovative drug in relevant pediatric populations in its first new drug submission for the innovative drug or in any supplement to that submission that is filed within five years after the issuance of the first notice of compliance for that innovative drug; and

a) l'innovateur fournit au ministre la description et les résultats des essais cliniques concernant l'utilisation de la drogue innovante dans les populations pédiatriques concernées dans sa première présentation de drogue nouvelle à l'égard de la drogue innovante ou dans tout supplément à une telle présentation déposé au cours des cinq années suivant la délivrance du premier avis de conformité à l'égard de cette drogue innovante;

(*b*) before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug, the Minister determines that the clinical trials were designed and conducted for the purpose of increasing knowledge of the use of the innovative drug in those pediatric populations and this knowledge would thereby provide a health benefit to members of those populations.

b) le ministre conclut, avant l'expiration du délai de six ans qui suit la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante, que les essais cliniques ont été conçus et menés en vue d'élargir les connaissances sur l'utilisation de cette drogue dans les populations pédiatriques visées et que ces connaissances se traduiraient par des avantages pour la santé des membres de celles-ci.

(5) Subsection (3) does not apply if the innovative drug is not being marketed in Canada.

(5) Le paragraphe (3) ne s'applique pas si la drogue innovante n'est pas commercialisée au Canada.

(6) Paragraph (3)(*a*) does not apply to a subsequent manufacturer if the

(6) L'alinéa (3)*a*) ne s'applique pas au fabricant ultérieur dans le cas où

innovator consents to the filing of a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission by the subsequent manufacturer before the end of the period of six years specified in that paragraph.	l'innovateur consent à ce qu'il dépose une présentation de drogue nouvelle, une présentation abrégée de drogue nouvelle ou un supplément à l'une de ces présentations avant l'expiration du délai de six ans prévu à cet alinéa.
(7) Paragraph (3)(*a*) does not apply to a subsequent manufacturer if the manufacturer files an application for authorization to sell its new drug under section C.07.003.	(7) L'alinéa (3)*a*) ne s'applique pas au fabricant ultérieur s'il dépose une demande d'autorisation pour vendre cette drogue nouvelle aux termes de l'article C.07.003.
(8) Paragraph (3)(*b*) does not apply to a subsequent manufacturer if the innovator consents to the issuance of a notice of compliance to the subsequent manufacturer before the end of the period of eight years specified in that paragraph or of eight years and six months specified in subsection (4).	(8) L'alinéa (3)*b*) ne s'applique pas au fabricant ultérieur dans le cas où l'innovateur consent à ce que lui soit délivré un avis de conformité avant l'expiration du délai de huit ans prévu à cet alinéa ou de huit ans et six mois prévu au paragraphe (4).
(9) The Minister shall maintain a register of innovative drugs that includes information relating to the matters specified in subsections (3) and (4).	(9) Le ministre tient un registre des drogues innovantes, lequel contient les renseignements relatifs à l'application des paragraphes (3) et (4).

[9] As the above section shows, data protection is available for "innovative drugs." This term is defined in subsection C.08.004.1(1) of the Regulations.

[10] There are two components to the definition of "innovative drug" in subsection C.08.004.1(1). In order to be an "innovative drug," the drug must:

- "[contain] a medicinal ingredient not previously approved in a drug by the Minister"; and

- not "[be] a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph."

B. The basic facts

[11] DEXILIANT is a "new drug" under Canada's drug approval regulatory regime. It is used in the treatment of gastroesophageal reflux disease, a common, recurring problem affecting 10%-20% of the Canadian population.

[12] The medicinal ingredient in DEXILIANT is dexlansoprazole. The parties agree that dexlansoprazole has not been previously approved in a drug by the Minister.

[13] The dispute between the parties concerns whether dexlansoprazole is a "variation." If it is, it cannot qualify as an "innovative drug."

[14] The parties agree that lansoprazole, a medicinal ingredient previously approved by the Minister, is a racemic mixture of two enantiomers, one of which is dexlansoprazole.

[15] Therefore, the question whether the enantiomer dexlansoprazole is a "variation" boils down to this. Under subsection C.08.004.1(1), is an enantiomer of a medicinal ingredient previously approved by the Minister automatically a "variation"? In her decision under review, and in her

submissions in the Federal Court and in this Court, the Minister answers that question in the affirmative.

C. Takeda's request for data protection and the Minister's decision

[16] On July 16, 2009, Takeda requested data protection for DEXILANT. In support of its request, Takeda advised the Minister that it had to conduct an extensive clinical program to establish DEXILANT's efficacy and safety. According to Takeda, the resulting clinical data, appearing in the new drug submission delivered to the Minister, was generated only as a result of its considerable efforts. In Takeda's view, the granting of data protection for DEXILANT was consistent with the wording of the data protection regulations, the purpose behind the data protection regulations, and Canada's treaty obligations that prompted the enactment of the data protection regulations.

[17] The Minister disagreed. While she granted regulatory approval (a notice of compliance) to DEXILANT, she rejected Takeda's request for data protection. In her view, DEXILANT was not an "innovative drug" because its medicinal ingredient, dexlansoprazole is an enantiomer of lansoprazole. In her view, drugs containing any of the listed variations of a previously approved medicinal ingredient (here an enantiomer) can never be an "innovative drug," regardless of the innovator's effort in developing the drug. Any drug containing a medicinal ingredient that is an enantiomer of a previously approved medicinal ingredient is automatically a "variation."

[18] For the Minister, that was the end of the matter: DEXILANT could not qualify as an "innovative drug" and receive data protection.

D. Proceedings in the Federal Court

[19] Takeda sought judicial review of the Minister's decision.

[20] Takeda's submissions focused on the word "variation" in the definition of "innovative drug" in subsection C.08.004.1(1). It submitted that the five categories of substances listed in the subsection – salts, esters, enantiomers, solvates or polymorphs – were only examples of what might be considered to be a "variation."

[21] The Federal Court reviewed the Minister's decision, in particular its interpretation of subsection C.08.004.1(1), on a correctness standard. It dismissed Takeda's judicial review, substantially agreeing with the Minister's interpretation of the subsection.

[22] Takeda notes, however, that the reasons of the Court do contain some ambiguity. At one point, the Federal Court describes the five categories of substances as "presumed" variations (at paragraphs 32 and 36), perhaps implying that they are not automatically excluded from the definition of "innovative drug." But at another point, the Federal Court finds that the five categories of substances are "excluded from the outset" (paragraph 37). Takeda now appeals to this Court.

E. Proceedings in this Court

[23] Before us, the Minister defends her decision, relying upon a literal reading of subsection C.08.004.1(1). To her, the words are clear: the five categories of substances listed in the subsection are automatically excluded, cannot qualify as "innovative drugs," and thus cannot benefit from data protection.

[24] Takeda repeats many of the submissions it made in the Federal Court. In its view, the Minister takes too literal a reading of the text of the subsection. Takeda suggests that the words "variation…such as a[n]…enantiomer" do not mean that all enantiomers are "variations."

[25] Takeda encourages this Court to adopt a contextual and purposive interpretation of the term "variation," one which requires the Minister to assess the nature and extent of the data required to get approval for the drug. In its view, the subsection protects clinical and pre-clinical data necessary for regulatory approval if generating that data required "considerable effort."

F. Analysis

(1) The standard of review

[26] In this Court, both parties agree that the Federal Court adopted the correct standard of review, correctness. I agree that the standard of review is correctness.

[27] This Court has not previously decided the issue of the standard of review of Ministerial interpretations of the data protection provisions under the *Food and Drug Regulations*. The interpretation of subsection C.08.004.1(1) arose in the recent case of *Teva Canada Limited v. Canada (Health)*, 2012 FCA 106. However, this Court did not decide the standard of review issue because the Minister had correctly interpreted the Regulations (at paragraph 9).

[28] The Supreme Court has spoken of a presumption that the standard of review is reasonableness for the legislative interpretations of administrative decision-makers: *Alberta (Information and Privacy Commissioner) v. Alberta Teachers' Association*, 2011 SCC 61, [2011] 3 S.C.R. 654 at paragraph 34. But that is a rebuttable presumption that can be overcome upon an analysis of the four relevant factors discussed in *Dunsmuir*.

[29] In my view, the presumption is overcome. All of the factors relevant to determining the standard of review lean in favour of correctness review. In this case, the nature of the question is purely legal. There is no privative clause. The Minister has no expertise in legal interpretation. There is nothing in the structure of the Act, this regulatory regime or this particular legislative provision that suggests that deference should be accorded to the Minister's decision. This analysis of the factors mirrors that in *Canada (Fisheries and Oceans) v. David Suzuki Foundation*, 2012 FCA 40 at paragraphs 101-105 (sometimes also referred to as "*Georgia Strait*"); *Sheldon Inwentash and Lynn Factor Charitable Foundation v. Canada*, 2012 FCA 136 at paragraphs 18-23.

[30] I am comforted in this conclusion by the application of the correctness standard to Ministerial interpretations of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-

133: *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533 at paragraph 36; *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560; *Purdue Pharma v. Canada (Attorney General)*, 2011 FCA 132 at paragraph 13. Although different regulations are involved in this case, both concern Minister-administered regimes governing the period before drugs are authorized for sale. It would be anomalous if the standards of review differed.

[31] Before leaving the standard of review issue, I wish to address the view of my colleague, Justice Dawson, that *Alberta Teachers' Association* does not apply to this case because of this Court's decision in *Georgia Strait*.

[32] In this case, Parliament empowered the Governor in Council to establish through regulation an administrative scheme that provides for data protection. Parliament could have given this matter to courts, but it did not. Due to this primary indication of Parliamentary intention, the presumption of reasonableness review of administrative decision-makers' decisions in *Alberta Teachers' Association* should apply. However, this presumption can be rebutted in particular cases by examining the normal standard of review factors which shed more light on the matter. This approach, which I shall call the *Alberta Teachers' Association* approach, is the one I have followed.

[33] I am reluctant to carve out administrative decisions from the *Alberta Teachers' Association* approach merely because the administrative decision-maker is a Minister, as is the case here. For one thing, the *Alberta Teachers' Association* approach aptly handles the breadth of Ministerial decision-making, which comes in all shapes and sizes, and arises in different contexts for different

purposes. In addition, Ministerial decision-making power is commonly delegated, as happened here. It would be arbitrary to apply the *Alberta Teachers' Association* approach to decisions of administrative board members appointed by a Minister (or, practically speaking, a group of Ministers in the form of the Governor in Council), but apply the *Georgia Strait* approach to decisions of delegates chosen by a Minister. Finally, although this Court's decision in *Georgia Strait* postdates that of the Supreme Court in *Alberta Teachers' Association*, I consider myself bound by the latter absent further direction from the Supreme Court: see *Canada v. Craig*, 2012 SCC 43 at paragraphs 18-23; see also earlier expressions of uncertainty concerning the standard of review of Ministerial decision-making in *Global Wireless Management v. Public Mobile Inc.*, 2011 FCA 194, [2011] 3 F.C.R. 344 at paragraph 35 (leave denied, April 26, 2012) and *Toussaint v. Canada (Attorney General)*, 2011 FCA 213, 420 N.R. 213 at paragraph 19 (leave denied, April 5, 2012).

[34] In any event, I do not see the *Alberta Teachers' Association* approach as being much different from the approach actually followed in *Georgia Strait*. Indeed, in this case, the two lead to the same result, as I agree with my colleague that the standard of review in this case is correctness.

(2) The interpretation issue

[35] For the reasons set out below, Takeda's interpretation of subsection C.08.004.1(1) is to be preferred. The Minister's interpretation is too literal and runs counter to the context surrounding and the purpose underlying the data protection regulations.

[36] In brief, my interpretation of subsection C.08.004.1(1) is as follows.

[37] A drug that contains an enantiomer of a previously approved medicinal ingredient is not automatically excluded from data protection under subsection C.08.004.1(1) of the Regulations. The listed substances in the definition of "innovative drug" – salts, esters, enantiomers, solvates or polymorphs – are examples of substances that may be "variations," depending on the circumstances, and invite special scrutiny.

[38] Whether an enantiomer is a "variation" of a previously approved medicinal ingredient depends on the circumstances surrounding the data that had to be submitted to get regulatory approval. In particular, if regulatory approval for the drug required the submission of confidential data generated by considerable effort – *e.g.*, new and significant evidence bearing upon the safety and efficacy of the drug – and the medicinal ingredient in the drug is "new" in the sense that it has qualities of safety and efficacy materially different from a previously approved medicinal ingredient, then it is not a "variation" of that previously approved medicinal ingredient.

[39] I offer several reasons for my conclusion. I begin first with a discussion of principles pertaining to the textual, contextual and purposive approach to legislative interpretation. Then I examine the textual, contextual and purposive considerations in this case. Some of these considerations, such as the text of the subsection, are merely consistent with the conclusion I have reached. Others, such as the implementation of Canada's international obligations, more strongly point in favour of the conclusion I have reached. But, taken together, they confirm that subsection C.08.004.1(1) should be interpreted in the way I have suggested.

– I –

[40] Our starting point is the now classic approach to the interpretation of legislative provisions. This approach requires careful attention to the text, context and purpose surrounding the provisions:

> Today there is only one principle or approach, namely, the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament.

(*Bell ExpressVu Limited Partnership v. Rex*, 2002 SCC 42, [2002] 2 S.C.R. 559 at paragraph 26, citing Elmer Driedger, *Construction of Statutes* (2nd ed. 1983) at page 87. See also *Rizzo & Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27 at paragraphs 20-23, and in the area of pharmaceutical legislation, see *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560 at paragraph 26.)

[41] In interpreting subsection C.08.004.1(1), this Court has followed this approach to statutory interpretation: *Teva Canada*, *supra*. Further, in the seminal case of *Bayer Inc. v. Canada (Attorney General)*, [1999] 1 F.C. 553 (approved by this Court on this point at (1999), 87 C.P.R. (3d) 293), Evans J. (as he then was) went beyond the literal wording of subsection C.08.004.1(1), examining, as he was bound by the authorities to do, "the context of the overall scheme" and the "overall purposes of the statutory scheme."

[42] In the Federal Court and in this Court, the Minister's submissions are founded upon what it considers to be clear text. In addressing the Minister's submissions, it is apposite to examine the impact in the interpretive exercise of apparently clear text.

[43] If the words of the legislative provision are truly clear, they will predominate in the interpretive exercise. As the Supreme Court has said,

> When the words of a provision are precise and unequivocal, the ordinary meaning of the words plays a dominant role in the interpretive process. On the other hand, where the words can support more than one reasonable meaning, the ordinary meaning of the words plays a lesser role.

(*Canada Trustco Mortgage Co. v. Canada*, 2005 SCC 54, [2005] 2 S.C.R. 601 at paragraph 10.)

[44] In some cases, however, "[e]ven where the meaning of particular provisions may not appear to be ambiguous at first glance, statutory context and purpose may reveal or resolve latent ambiguities": *Canada Trustco*, *supra* at paragraph 47; *Placer Dome Canada Ltd. v. Ontario (Minister of Finance)*, 2006 SCC 20, [2006] 1 S.C.R. 715 at paragraph 22. So even where the text has some clarity, as the Minister emphasizes here, regard must still be paid to context and purpose, "reading the provisions of [the] Act as a harmonious whole": *Canada Trustco*, *supra* at paragraph 10.

– II –

[45] Turning to the text of subsection C.08.004.1(1), the Minister submits that the wording of the subsection is perfectly clear.

[46] That is not the case.

[47] Subsection C.08.004.1(1) does not define "variation" precisely or exhaustively. Instead, the subsection offers only a loose definition, described by five listed categories of substances: "a salt, ester, enantiomer, solvate or polymorph."

[48] Are all substances falling within these categories automatically "variations"?

[49] The words of subsection C.08.004.1(1) do not answer that question clearly. In particular, the words "*such as* a salt, ester, enantiomer, solvate or polymorph" [my emphasis] inject uncertainty into the matter.

[50] If it were intended that all substances falling within those five categories are automatically "variations," "variations" would have been defined as "*any* salt, ester, enantiomer, solvate or polymorph" or "*all* salts, esters, enantiomers, solvates or polymorphs."

[51] Instead, subsection C.08.004.1(1) uses the words "such as" – words that differ from "any" or "all," and lend a more open meaning to the subsection.

[52] The more open meaning imported by the words "such as" can be shown by an example. Suppose a particular regulation is aimed at reducing emissions that pollute. The regulation applies to "vehicles such as cars, trucks and buses." Are all cars caught by the regulation? It may be that

electric cars or hybrid cars are not covered by the regulation. Although they are literally "cars," they may not be "vehicles" for the purposes of the emissions regulation because they do not emit pollution or emit much less pollution than other cars.

[53] In my view, the case before us is exactly like this example. Recourse must be had to context and purpose in order to understand what qualifies as a "variation" because the wording of the subsection is not perfectly clear: *Canada Trustco*, *supra* at paragraph 47. The plain text of the subsection opens up the possibility that only some salts, esters, enantiomers, solvates or polymorphs can qualify as "variations" in a particular case, or that some substances falling into categories other than the five listed categories of substances might constitute a variation. It is necessary to examine the context and purpose of the data protection regulations in order to see whether this possibility is a reality. Before examining the context and purpose of the data protection regulations, however, further observations about the plain text of the subsection need to be made.

– III –

[54] The somewhat open-ended nature of the plain text of the subsection is confirmed by the Regulatory Impact Analysis Statement issued concurrently with the data protection regulation.

[55] As the Supreme Court has acknowledged, such statements are commonly used as an aid in the interpretation of regulatory provisions:

> …a Regulatory Impact Analysis Statement, which accompanies but does not form part of the regulations, reveals the intention of the government and contains "…information as to the purpose and effect of the proposed regulation."

(*Bristol-Myers Squibb Co., supra* at paragraph 156, citing McGillis J. in *Merck & Co. v. Canada (Attorney General)* (1999), 176 F.T.R. 21 at paragraph 51 (T.D.), aff'd (2000), 5 C.P.R. (4th) 138 (F.C.A.). See also *Bayer Inc. v. Canada (Attorney General)* (1999), 87 C.P.R. (3d) 293 at paragraph 10 (F.C.A.).)

[56] In this case, the Regulatory Impact Analysis Statement envisages that some substances falling into other categories of substances might constitute a variation. In particular, it confirms that the five categories of substances in the subsection are "not exhaustive": *Canada Gazette*, Part II, vol. 140, no. 21, page 1496. Elsewhere, the RIAS concedes that whether or not "arguable variations" outside of the five express categories of substances fall within the definition of "innovative drug" depends on whether approval for the "arguable variations" is "being sought primarily on the basis of previous submitted clinical data" or "new and significant clinical data": *ibid*. This shows that "variations" are not defined solely by the five categories that follow, namely "salt, ester, enantiomer, solvate or polymorph."

[57] While the RIAS does state that the five categories "give examples of the types of variations not considered for protection," the Minister herself has declined to apply the five categories in a closed-minded way, preferring instead to see "variation" as the controlling idea in the subsection. This is seen in her treatment of certain drugs that contain medicinal ingredients that are esters or enantiomers, such as TORISEL, PRECEDEX and AVAMYS. The Minister has regarded these as qualifying or potentially qualifying as "innovative drugs" under subsection C.08.004.1(1): see Appeal Book, Tabs 10-12.

[58] This shows that in practice the Minister interprets the five categories in the subsection as identifying substances that will normally regarded as variations. But even in the case of those substances, the Minister can go on to consider whether, in fact, the substance is more than a "variation" and, thus, eligible for data protection under the subsection.

[59] The Minister's particular interpretations of the subsection in other cases are not determinative. Indeed, under a correctness standard of review, courts have the final word and can impose their interpretation of the subsection over that of the Minister. But the Minister, like the courts, is responsible for interpreting the subsection and her interpretations can sometimes provide confirmation of a court's view of the subsection, if not direct guidance. The Minister's interpretations of the subsection in the cases of TORISEL, PRECEDEX and AVAMYS confirm the view, expressed above, that the subsection is somewhat open-ended and that the controlling idea in the subsection is whether or not a medicinal ingredient is a "variation," not whether the medicinal ingredient falls within the five categories of substance.

– IV –

[60] So what, then, is a "variation"?

[61] Neither subsection C.08.004.1(1) nor the data protection regulations define the term "variation" precisely. There is expert evidence that "variation" does not have a specific scientific meaning: Jubran cross-examination, Q. 216; Appeal Book, page 475.

[62] "Variation" is a common word with a common meaning. Its dictionary definition is a "minor change" or a "slight difference": *Oxford English Dictionary* (New York: Oxford University Press, 2004), 11th ed., at page 1599, cited by the Federal Court at paragraph 33 of its reasons.

[63] Here again, the Regulatory Impact Analysis Statement is useful. The RIAS confirms that "variations" of previously approved medicinal ingredients are excluded from the definition of "innovative drugs" in order to prevent "the granting of an additional eight years of protection where an innovator seeks approval for a *minor* change to a drug [my emphasis]": *Canada Gazette*, Part II, vol. 140, no. 21, page 1496.

[64] The Federal Court found that salts, esters, and the other listed items "are widely recognized chemical variations" (at paragraph 37). This suggests that salts, esters, and the other listed items are automatically minor changes and, thus, excluded from data protection. But there is no evidence in the record to support this finding. As mentioned above, "variation" does not have a specific scientific meaning.

[65] Indeed, there is some scientific evidence to show that some enantiomers are quite different. This is an important element of context that assists our interpretive task. According to the Minister, some enantiomers, although just mirror images of other substances, can sometimes significantly differ from those substances in terms of pharmacokinetics, pharmacodynamics, toxicity, and protein binding: Health Canada, *Guidance for Industry: Stereochemical Issues in Chiral Drug Development*

(February 14, 2000), at page 2; Appeal Book, page 84. These are all characteristics that can potentially bear upon the safety and efficacy of a drug.

[66] For example, different enantiomers of thalidomide differ significantly in their safety: Jubran cross-examination, QQ. 107-110; Appeal Book, page 468. One causes birth defects, the other does not.

[67] Thus, from the standpoint of safety and efficacy, enantiomers which comprise a racemic mixture may differ from one another or from the racemic mixture. Often, others may be similar, hence the listing of enantiomers as an example of a substance that may be a variation. Because of the possibility they may be different, Health Canada takes the position that the drug submission requirements for a single enantiomer of a marketed racemate are the same as those for any new active substance. Testing must be done.

[68] If the safety and efficacy of an enantiomer is established after only a little testing, there is a sense in which it is not all that different from the previously approved medicinal ingredient. If, on the other hand, much testing has to be done, there is a sense in which it is quite different or new when compared with the previously approved medicinal ingredient. These concepts – considerable effort in testing and difference/newness – lie at the heart of the concept of what is and is not a minor variation under subsection C.08.004.1(1).

[69] This, and my earlier conclusion that the plain text is somewhat open-ended, is confirmed by the purpose behind the data protection regulations, a matter to which I now turn.

– V –

[70] So what is the purpose of the data protection regulations?

[71] As this Court noted in *Apotex Inc. v. Canada (Minister of Health)*, 2010 FCA 334 at paragraph 114, the background to the data protection regulations is key to understanding their purpose. The data protection regulations were prompted by two international obligations accepted by Canada: Article 1711 of the *North American Free Trade Agreement*, 17 December 1992, Can. T.S. 1994 No. 2, 32 I.L.M. 289 (entered into force 1 January 1994) and paragraph 3 of Article 39 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* as set out in Annex 1C to the *Marrakesh Agreement Establishing the World Trade Organization*, 15 April 1994, 1867 U.N.T.S. 154, 33 I.L.M. 1144 (entered into force 1 January 1996).

[72] Article 1711 of the *North American Free Trade Agreement* provides as follows:

1. Each Party shall provide the legal means for any person to prevent trade secrets from being disclosed to, acquired by, or used by others without the consent of the person lawfully in control of the information in a manner contrary to honest commercial practices, in so far as:	1. Chacune des Parties assurera à toute personne les moyens juridiques d'empêcher que des secrets commerciaux ne soient divulgués à des tiers, acquis ou utilisés par eux, sans le consentement de la personne licitement en possession de ces renseignements et d'une manière contraire aux pratiques commerciales honnêtes, dans la mesure où :
(a) the information is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons that	a) les renseignements sont secrets, en ce sens que, dans leur globalité ou dans la configuration et l'assemblage exacts de leurs éléments, ils ne sont pas généralement connus de personnes

normally deal with the kind of information in question;

appartenant aux milieux qui s'occupent normalement du genre de renseignements en question ou ne leur sont pas aisément accessibles;

(b) the information has actual or potential commercial value because it is secret; and

b) les renseignements ont une valeur commerciale, réelle ou potentielle, du fait qu'ils sont secrets; et

(c) the person lawfully in control of the information has taken reasonable steps under the circumstances to keep it secret.

c) la personne licitement en possession de ces renseignements a pris des dispositions raisonnables, compte tenu des circonstances, en vue de les garder secrets.

2. A Party may require that to qualify for protection a trade secret must be evidenced in documents, electronic or magnetic means, optical discs, microfilms, films or other similar instruments.

2. Une Partie pourra exiger que, pour faire l'objet d'une protection, un secret commercial soit établi par des documents, des médias électroniques ou magnétiques, des disques optiques, des microfilms, des films ou autres supports analogues.

3. No Party may limit the duration of protection for trade secrets, so long as the conditions in paragraph 1 exist.

3. Aucune des Parties ne pourra restreindre la durée de protection des secrets commerciaux tant que subsistent les conditions énoncées au paragraphe 1.

4. No Party may discourage or impede the voluntary licensing of trade secrets by imposing excessive or discriminatory conditions on such licenses or conditions that dilute the value of the trade secrets.

4. Aucune des Parties ne pourra entraver ou empêcher l'octroi de licences volontaires à l'égard de secrets commerciaux en imposant des conditions excessives ou discriminatoires à l'octroi de ces licences ou des conditions qui réduisent la valeur des secrets commerciaux.

5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed tests or other data necessary to determine whether the use of such products is safe and effective, the Party

5. Lorsqu'une Partie subordonne l'approbation de la commercialisation de produits pharmaceutiques ou de produits chimiques pour l'agriculture qui comportent des éléments chimiques nouveaux, à la communication de données non divulguées résultant d'essais ou d'autres données non

shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

divulguées nécessaires pour déterminer si l'utilisation de ces produits est sans danger et efficace, cette Partie protégera ces données contre toute divulgation, lorsque l'établissement de ces données demande un effort considérable, sauf si la divulgation est nécessaire pour protéger le public, ou à moins que des mesures ne soient prises pour s'assurer que les données sont protégées contre toute exploitation déloyale dans le commerce.

6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

6. Chacune des Parties prévoira, en ce qui concerne les données visées au paragraphe 5 qui lui sont communiquées après la date d'entrée en vigueur du présent accord, que seule la personne qui les a communiquées peut, sans autorisation de cette dernière à autrui, utiliser ces données à l'appui d'une demande d'approbation de produit au cours d'une période de temps raisonnable suivant la date de leur communication. On entend généralement par période de temps raisonnable, une période d'au moins cinq années à compter de la date à laquelle la Partie en cause a donné son autorisation à la personne ayant produit les données destinées à faire approuver la commercialisation de son produit, compte tenu de la nature des données, ainsi que des efforts et des frais consentis par cette personne pour les produire. Sous réserve de cette disposition, rien n'empêchera une Partie d'adopter à l'égard de ces produits des procédures d'homologation abrégées fondées sur des études de bioéquivalence et de biodisponibilité.

7. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with

7. Lorsqu'une Partie se fie à une approbation de commercialisation accordée par une autre Partie, la période raisonnable d'utilisation

obtaining the approval relied on shall begin with the date of the first marketing approval relied on.	exclusive des données présentées en vue d'obtenir l'approbation en question commencera à la date de la première approbation de commercialisation.
[Emphasis added]	[Non souligné dans l'original]

[73] Paragraph 3 of Article 39 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* provides as follows:

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.	3. Lorsqu'ils subordonnent l'approbation de la commercialisation de produits pharmaceutiques ou de produits chimiques pour l'agriculture qui comportent des entités chimiques nouvelles à la communication de données non divulguées résultant d'essais ou d'autres données non divulguées, dont l'établissement demande un effort considérable, les Membres protégeront ces données contre l'exploitation déloyale dans le commerce. En outre, les Membres protégeront ces donné es contre la divulgation, sauf si cela est nécessaire pour protéger le public, ou à moins que des mesures ne soient prises pour s'assurer que les données sont protégées contre l'exploitation déloyale dans le commerce.

[74] These two international obligations "provide protection to innovators in respect of 'undisclosed tests or other data' that they must provide to government entities in order to obtain approval for their new drugs" by requiring that "a scheme [be provided] for protecting against the unfair commercial use of undisclosed data, the origination of which involved considerable effort": *Apotex*, *supra* at paragraph 110; *Epicept Corporation v. Canada (Minister of Health)*, 2010 FC 956 at paragraph 21.

[75] Here again, the Regulatory Impact Analysis Statement for the data protection regulations is useful. The RIAS confirms that TRIPS and NAFTA "require the granting of protection for undisclosed data, the origination of which involved a considerable effort": *Canada Gazette*, Part II, vol. 140, no. 21, page 1496. The RIAS also confirms that the data protection regulations and the provisions of TRIPS and NAFTA they implement are aimed at "[providing] an adequate incentive for innovators to invest in research, and to develop and market their products in Canada": *ibid*.

[76] Based on the foregoing considerations, in *Apotex*, *supra* at paragraph 114, this Court described the purpose of the data protection regulations as follows:

> The true purpose of the [data protection regulations] is not to balance the commercial interests of innovators and generic drug manufacturers, but rather to ensure that Canadians have reasonable access, at reasonable prices, to new, safe and effective drugs. In other words, the Regulations as a whole encourage the research and development of new medicines that save lives, prevent diseases, heal and cure and improve the health of Canadians, who can only benefit from the discovery and development of new medicines after the information and data generated in extensive pre-clinical and clinical trials demonstrate the "innovative drug's" safety and efficacy to the satisfaction of the Minister. The [data protection regulations play] an important part in this regulatory scheme.

[77] Some further words concerning the purpose behind the provisions of TRIPS and NAFTA – and, thus, the purpose behind the data protection regulations discussed in *Apotex* – are apposite.

[78] Today, ready for our use, are many new, safe, and efficacious drugs. But behind them, invisible to us, are years of financial investment, effort, research and testing, all undertaken with no assurance of success. Indeed, the entire process is pregnant with risk – economic, scientific, and regulatory. For example, a test can demonstrate that a new drug concept is faulty; then, suddenly, unexpectedly, all that investment, effort, research and testing ends up for naught.

[79] When deciding what to do in a particular case, drug innovators, as profit maximizers, engage in risk-reward assessments. The greater the risks and the smaller the potential rewards, the less likely investment, effort, research and testing will happen.

[80] One area of risk concerns the valuable data generated by innovators during testing. Innovators submit the data in support of their applications for marketing approval. But if competitors can use submitted data immediately in order to obtain their own marketing approval, what is the incentive for the innovator to innovate, submit data, and bring new drugs to market?

[81] TRIPS and NAFTA address this by providing innovators with data protection in certain circumstances. For a certain time, the innovator is the only one who can use the data for marketing authorization. This protection alters the risk-reward equation for the innovator, creating greater incentives to research, discover and develop new drugs. This is especially important where the market for a particular new drug is relatively small, *i.e.*, the reward is relatively small. Minimizing risks in that area assumes greater importance.

[82] Two particular aspects of TRIPS and NAFTA, however, ensure that innovators get data protection only where the public will benefit: the innovator must have engaged in "considerable effort" in generating the data, and a "new chemical entity" (the concept of difference/newness I mentioned above) must be present.

[83] Neither TRIPS nor NAFTA define these terms. However, the concept behind them can be seen from the foregoing analysis. Trivial efforts, such as perfunctory and simple testing, do not warrant protection. Similarly, engaging in considerable efforts to test enantiomers which differ little from a racemic mixture or each other in safety or efficacy – in every relevant sense, old chemical entities – does not warrant protection. In both cases, an innovator would receive the large reward of protection in circumstances where it incurred little risk. That is not what the TRIPS and NAFTA provisions are aimed at. Instead, they are aimed at altering the risk-reward equation for innovators, giving them an incentive to undertake considerable effort in circumstances where the safety and efficacy of a candidate drug are uncertain.

[84] "Considerable effort" within the drug approval process, consistent with the purposes of the relevant provisions of TRIPS and NAFTA, must mean new and significant evidence bearing upon the safety and efficacy of the drug. "New chemical entity" must mean that the medicinal ingredient in the drug is "new" in the sense that it has qualities of safety and efficacy materially different from a previously approved medicinal ingredient. Both these meanings implement the purposes of the relevant provisions of TRIPS and NAFTA: they alter the risk-reward equation for innovators, create appropriate incentives, and ensure that data protection is afforded only where the risk undertaken merits it.

[85] Various foreign jurisdictions with legal traditions similar to our own have implemented the relevant provisions of TRIPS into their domestic law based on their assessment of TRIPS' purpose and what it requires them to do. Under the domestic law of these jurisdictions, data protection from drugs is not withheld merely because their medicinal ingredients are enantiomers: see, *e.g.*, *The*

Drug Price Competition and Patent Term Restoration Act, Pub. L. 98-417, 98 Stat. 1585 (1984), section 505, as amended by Pub. L. No. 110-85, 121 Stat. 823 (2007), section 505(u) (U.S.A.); Regulation 726/2004, article 3.2 (E.U.); *Therapeutic Goods Act, 1989*, No. 21 (1990), section 25A (Australia); *Medicines Act, 1981*, No. 118, sections 23A, 23B, and 23C (New Zealand). Each jurisdiction defines requirements for data protection in its own way. In some cases, the requirements include the presence of some new, significant clinical benefit and significant studies offered in support. In all cases, the requirements reflect the twin concepts of "new chemical entity" and "considerable effort".

– VI –

[86] The purpose of the relevant provisions of TRIPS and NAFTA, as I have construed them, must shape the interpretation of Canada's data protection regulations.

[87] It is a well-known, common law principle of interpretation that legislative provisions implementing international obligations are to be interpreted in accordance with the purposes underlying those obligations: *National Corn Growers Association v. Canada (Canadian Import Tribunal)*, [1990] 2 S.C.R. 1324 at page 1371; *Daniels v. White*, [1968] S.C.R. 517 at page 541; Ruth Sullivan, *Sullivan on the Construction of Statutes*, 5th ed. (Markham: LexisNexis, 2008) at pages 538-539.

[88] But in this case, more than the common law is involved. In this case, two legislative provisions tell us to have regard to the relevant provisions of TRIPS and NAFTA.

[89] The first provision, subsection C.08.004.1(2), tells us expressly that the purpose of the data protection regulations in section C.08.004.1 is to implement the international obligations:

C.08.004.1. (2) This section applies to the implementation of Article 1711 of the North American Free Trade Agreement, as defined in the definition "Agreement" in subsection 2(1) of the *North American Free Trade Agreement Implementation Act*, and of paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the World Trade Organization Agreement, as defined in the definition "Agreement" in subsection 2(1) of the *World Trade Organization Agreement Implementation Act*.	**C.08.004.1.** (2) Le présent article s'applique à la mise en œuvre de l'article 1711 de l'Accord de libre-échange nord-américain, au sens du terme « Accord » au paragraphe 2(1) de la *Loi de mise en œuvre de l'Accord de libre-échange nord-américain*, et du paragraphe 3 de l'article 39 de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce figurant à l'annexe 1C de l'Accord sur l'Organisation mondiale du commerce, au sens du terme « Accord » au paragraphe 2(1) de la *Loi de mise en œuvre de l'Accord sur l'Organisation mondiale du commerce*.

[90] The second provision, subsection 30(3) of the *Food and Drugs Act*, R.S.C. 1985, c. F-27, s. 30(3), added by S.C. 1994, c. 47, s. 117, tells us that the very *raison d'être* of the data protection regulations is to implement the international obligations:

30. (3) Without limiting or restricting the authority conferred by any other provisions of this Act or any Part thereof for carrying into effect the purposes and provisions of this Act or any Part thereof, the Governor in Council may make such regulations as the Governor in Council deems necessary for the purpose of implementing, in	**30.** (3) Sans que soit limité le pouvoir conféré par toute autre disposition de la présente loi de prendre des règlements d'application de la présente loi ou d'une partie de celle-ci, le gouverneur en conseil peut prendre, concernant les drogues, les règlements qu'il estime nécessaires pour la mise en oeuvre

relation to drugs, Article 1711 of the North American Free Trade Agreement or paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the WTO Agreement.	de l'article 1711 de l'Accord de libre-échange nord-américain ou du paragraphe 3 de l'article 39 de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce figurant à l'annexe 1C de l'Accord sur l'OMC.

[91] As a regulation-making provision, subsection 30(3) of the *Food and Drugs Act* is especially important. The data protection regulations must implement the relevant provisions of TRIPS and NAFTA. The data protection regulations cannot be interpreted to do anything short of that or different from that. If they do, they will be invalid. See generally *Bristol-Myers Squibb Co.*, *supra*, at paragraph 38. Therefore, in this case, to the extent possible, the data protection regulations must be given an interpretation that implements the relevant provisions of TRIPS and NAFTA.

[92] As mentioned above and as was mentioned in *Apotex*, *supra* at paragraph 110, the international obligations "provide protection to innovators in respect of 'undisclosed tests or other data' that they must provide to government entities in order to obtain approval for their new drugs" by requiring that "a scheme [be provided] for protecting against the unfair commercial use of undisclosed data, the origination of which involved considerable effort." The data protection regulations, and in particular the meaning of "variation" in subsection C.08.004.1(1) must give effect to that. The interpretation I have reached in paragraphs 37 and 38, above, does just that.

[93] In order to implement the relevant provisions of TRIPS and NAFTA, subsection C.08.004.1(1) must embody the twin concepts of "new chemical entity" and "considerable effort." The interpretation I have reached in subsections 37 and 38, above, does just that: it grants data

protection where the medicinal ingredient in the drug is "new" in the sense that it has qualities of safety and efficacy materially different from a previously approved medicinal ingredient and where the evidence offered in support of that is new and significant.

[94] Also key to the interpretation of the subsection is that the NAFTA and TRIPS protections are designed to protect trade secrets: see NAFTA, Article 1711, sections 1-4 and TRIPS, Article 39, sections 1-2. Thus, the data sought to be protected under the subsection must be confidential data. Again, the interpretation I have reached in paragraphs 37 and 38, above, incorporates the necessary element of confidentiality.

[95] Given this analysis of C.08.004.1(1) and the international obligations contained in TRIPS and NAFTA, the words "variation…such as a salt, ester, enantiomer, solvate or polymorph" in the subsection are indeed open-ended and flexible. The listing of the five categories of substance – salts, esters, enantiomers, solvates and polymorphs – is directory in its import, not mandatory. The five categories are substances where, owing to their physical similarity to a substance in a previously approved drug, special scrutiny is warranted. But the five categories do not categorically foreclose data protection.

– VII –

[96] In my view, the Minister's interpretation of the subsection – making the five categories of substance mandatory and absolute examples of "variations" – will lead to results which are contrary to Canada's NAFTA and TRIPS obligations, rendering the subsection *ultra vires* the regulation-

making power in the Act. In many cases, it would deny protection against the unfair commercial use of confidential data, generated with considerable effort, for drugs that are in every sense new in terms of their safety and efficacy. Under the Minister's interpretation, data protection to a drug – even one that is demonstrably safe and effective in saving or improving many lives – will be denied despite years of necessary effort, millions of dollars invested in its development and the assumption of much risk. This happens for only one reason: its medicinal ingredient happens to be an enantiomer.

[97] Given the purpose of the international obligations that Canada is implementing in its data protection regulations and given the absence of definitive text in the data protection regulations to the contrary, why shouldn't data protection be given in such a circumstance? Research and development into such drugs should be encouraged not discouraged. That is the primary aim of the international obligations Canada is supposed to be implementing in its data protection regulations.

[98] Needless to say, the Minister's interpretation would create incentives against the development of beneficial new drugs. For example, if enantiomers are automatically excluded, then the innovators of the arguably new, safe and efficacious thalidomide drug (discussed at paragraph 66, above) and the innovators of other drugs whose medical ingredients are enantiomers that give rise to greater safety and efficacy (discussed at paragraph 65, above), would not receive data protection.

[99] As I have noted in paragraph 85, above, the Minister's interpretation would also put Canada at odds with other significant jurisdictions such as Europe, the United States, Australia and New

Zealand. These jurisdictions have not automatically withheld data protection from drugs merely because their medicinal ingredients are enantiomers. To the extent it is possible and acceptable, uniform interpretations of international treaties should be adopted: *Febles v. Canada*, 2012 FCA 324 at paragraph 24.

[100] In interpreting subsection C.08.004.1(1) of the Regulations, the Federal Court (at paragraphs 40 and 41) placed considerable emphasis on the fact that the two international obligations, mentioned above, afford data protection to "new chemical entities," not new drugs. In its view, the five listed categories of substances are "variations" that are not "new chemical entities." The Minister also urges this point upon us.

[101] This interpretation does not fully take into account the purpose of the treaties and the data protection regulations that implement them: to encourage research and development in new medicines by protecting data created with considerable effort. As I have explained above, "new chemical entities" serves no purpose other than to ensure that an innovator does not take essentially the same substance, engage in perfunctory and simple testing, and get the reward of data protection without incurring any risk.

[102] The data protection regulations, as I have interpreted them in paragraphs 37 and 38 above, extend data protection , among other things, to medicinal ingredients – *i.e.*, chemical entities – that have not been previously approved by the Minister and that have safety and efficacy characteristics materially different from a previously approved medicinal ingredient – *i.e.*, chemical entities that are new in that sense. Further, on the interpretation I have adopted, a chemical entity in a medicinal

ingredient that has not been previously approved by the Minister and that is proven to be safe by necessary testing requiring considerable effort is, in a meaningful, purposive sense, a "new chemical entity." As I have explained, this is consistent with the evidence in the record that shows that enantiomers can be new in this sense and can give rise to new, safe and efficacious drugs (see paragraphs 65 and 66, above). The interpretation proposed by the Minister and adopted by the Federal Court cuts down the protection promised by TRIPS and NAFTA, leaves many innovators without data protection, and, thus, potentially inhibits the research, discovery and development of new, safe and efficacious drugs.

(3) Conclusion on the interpretation issue

[103] In light of the foregoing analysis, both the Minister and the Federal Court interpreted the definition of "innovative drug" in subsection C.08.004.1(1) incorrectly. The correct interpretation is that set out in paragraphs 37 and 38, above.

G. Remedy

[104] It follows that I would quash the Minister's decision that DEXILANT is not an "innovative drug."

[105] Whether DEXILANT is an "innovative drug" under subsection C.08.004.1(1) of the Regulations must be redetermined in light of the interpretation set out in paragraphs 37 and 38 of these reasons.

[106] Takeda urges us not to remit the matter to the Minister for redetermination. In paragraph 70 of its memorandum of fact and law, Takeda submits that this Court is "in at least as good a position as the Minister or the Court below" to determine the matter.

[107] I disagree. The question whether DEXILANT is an "innovative drug" – *i.e.*, whether it satisfies the definition set out in paragraphs 37 and 38, above – draws upon, among other things, factual, scientific and regulatory appreciation. Accordingly, this is a question for the Minister to consider, not us.

H. Proposed disposition

[108] Therefore I would allow the appeal, set aside the judgment of the Federal Court, quash the Minister's decision, and remit the matter to the Minister for redetermination in accordance with these reasons, with costs to Takeda throughout.

"David Stratas"

J.A.

DAWSON J.A.

[109] I have had the benefit of reading my colleague's reasons. I agree with his statement of the facts and with his articulation of the relevant principles of statutory interpretation, as set out at paragraphs 40, 43 and 44 of his reasons. I do not, however, agree with the application of those principles to the definition of "innovative drug." In my view, both the Minister and the Federal Court correctly interpreted the definition of "innovative drug." The Governor in Council, in the exercise of its discretion, has determined that salts, esters, enantiomers, solvates and polymorphs of previously approved medicinal ingredients are variations of those ingredients and so do not fall within the definition of "innovative drug".

[110] Before addressing the issue of statutory interpretation, I address the applicable standard of review.

Standard of Review

[111] I agree that the standard of review to be applied to the Minister's interpretation of the data protection provisions of the *Food and Drug Regulations* is correctness. I also agree that this conclusion is reached on the basis of an analysis of the four relevant factors identified in *Dunsmuir*, and with the analysis of those factors as set out at paragraph 29 of my colleagues' reasons.

[112] Where we part company is that I would not apply the presumption of reasonableness, articulated by the Supreme Court of Canada in *Alberta (Information and Privacy Commissioner) v. Alberta Teachers' Association* to the Minister's interpretation of the applicable regulation. While the Supreme Court has not recently considered the standard of review applicable to a Minister's

interpretation of legislation, the issue was squarely addressed by this Court in *Georgia Strait Alliance v. Canada (Minister of Fisheries and Oceans)*, 2012 FCA 40, 427 N.R. 110. There, Justice Mainville wrote for the Court as follows (underlining added):

> *The standard of review*
>
> *The Minister's position*
>
> 65 At its core, the principal question before this Court concerns the meaning of the words "legally protected by provisions in, or measures under, this or any other Act of Parliament" found in subsection 58(5) of the SARA. That is a question of statutory interpretation, and that is not disputed by the Minister.
>
> 66 However, the Minister submits that Parliament has entrusted him with the responsibility to manage the regulatory schemes under the [*Species At Risk Act*] SARA and the *Fisheries Act*, and that consequently, his interpretation of section 58 of the SARA - and of the provisions of the *Fisheries Act* and of its regulations as they relate to that section - should be given deference.
>
> 67 The Minister relies for this proposition on *Dunsmuir* and recent decisions of the Supreme Court of Canada which have all clearly emphasized the deference which courts must show to an administrative tribunal when it interprets a provision of its enabling (or "home") statute or statutes closely connected to its functions. The Minister notably relies on *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1, [2011] 1 S.C.R. 3 ("*Celgene*") at paragraphs 33-34, *Canada (Human Rights Commission) v. Canada (Attorney General)*, 2011 SCC 53 ("*Mowat*") at paragraphs 15 to 27 and *Smith v. Alliance Pipeline Ltd.*, 2011 SCC 7 , [2011] 1 S.C.R. 160 ("*Smith*") at paragraph 26. In this regard, I note that the standard which applies when the interpretation of a statute by a government official is raised in a judicial review proceeding has been questioned by this Court following *Dunsmuir*: see *Global Wireless Management v. Public Mobile Inc.*, 2011 FCA 194, [2011] 3 F.C.R. 344 at para. 35 and *Toussaint v. Canada (Attorney General)*, 2011 FCA 213, 420 N.R. 364 at para. 19.
>
> 68 The Minister also finds support for his position in *Adam v. Canada (Environment)*, 2011 FC 962; *sub nom. Athabasca Chipewyan First Nation v. Canada (Minister of the Environment)*, [2011] 4 C.N.L.R. 17 ("*Adam*"), a recent decision of the Federal Court. The applicants in *Adam* were asking the Court to order the Minister of the Environment to (a) finalize a recovery strategy under the SARA for the boreal caribou located in North-eastern Alberta and (b) recommend the adoption of an emergency protection order

> for these caribou under subsection 80(2) of the SARA. Without proceeding with a standard of review analysis, the Court in *Adam* concluded - based on its understanding of *Dunsmuir* and *Smith* - that the Minister of the Environment's interpretation of subsection 80(2) of the SARA was subject to review under a reasonableness standard. Since that minister was interpreting his "home" statute (the SARA), and since no constitutional question, no question of law of central importance to the legal system as a whole, and no jurisdictional question was raised by the proceedings, the Minister of the Environment's interpretation of subsection 80(2) of the SARA was reviewed on a standard of reasonableness: *Adam* at para. 40.
>
> 69 The Minister submits that as the "competent minister" with respect to aquatic species, he is entitled to the same deference as to his interpretation of the pertinent provisions of the SARA. Likewise, as the minister responsible for the *Fisheries Act*, deference should also be extended to his interpretation of that statute and of its regulations. In short, the Minister submits that pursuant to the most recent Supreme Court of Canada jurisprudence, a presumption of deference has been extended to administrative decision makers - such as himself - when they interpret their enabling (or "home") statutes.
>
> 70 I disagree with the Minister. For the reasons which follow, I have concluded that no deference is owed by this Court to the Minister as to the interpretation of the relevant provisions of the SARA or of the *Fisheries Act* and its regulations.

[113] Application of the presumption of deference to the Minister's interpretation of the data protection regulations is inconsistent with the prior decision of this Court in *Georgia Strait*.

[114] In my view, any departure from such a recent decision creates unacceptable uncertainty. This is particularly so where, in the present case, the issue was not raised. The parties were in agreement that the applicable standard of review is correctness, no one argued that the presumption of reasonableness applied and no one argued that *Georgia Strait* was improperly decided.

[115] Furthermore, the Supreme Court has in the past applied the correctness standard to such decisions. For example, in *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560, the Court wrote at paragraph 25:

> The outcome of this appeal turns on conflicting interpretations of the *NOC Regulations*. On a question of legal interpretation, the Minister's opinion is not entitled to deference. The Federal Court of Appeal properly found that the standard of review on the point in issue is correctness.

[116] As well, the Supreme Court has, albeit without discussion of the standard of review, applied a correctness review to the Minister of Citizenship and Immigration's interpretation of a provision of the *Immigration and Refugee Protection Act*, S.C. 2001, c. 27, (*Medovarski v. Canada (Minister of Citizenship and Immigration*); *Esteban v. Canada (Minister of Citizenship and Immigration)*, 2005 SCC 51, [2005] 2 S.C.R. 539). In *Hilewitz v. Canada (Minister of Citizenship and Immigration)*; *De Jong v. Canada (Minister of Citizenship and Immigration)*, 2005 SCC 57, [2005] 2 S.C.R. 706, at paragraph 71, the Supreme Court accepted the joint submission of the parties that correctness should be applied to a visa officer's interpretation of the *Immigration Act*, R.S.C. 1985, c. I-2. Under the *Immigration Act*, a visa officer was an "immigration officer stationed outside Canada and authorized by order of the Minister [of Citizenship and Immigration] to issue visas" (subsection 2(1) of the *Immigration Act*). A visa officer was, therefore, a delegate of the Minister.

The Interpretation of "Innovative Drug"

[117] Turning to the issue of the correct interpretation of the definition of "innovative drug," as my colleague notes, attention must be paid to the text, context and purpose surrounding the provision at issue.

[118] For ease of reference, I repeat the definition of "innovative drug" contained in subsection C.08.004.1(1) (emphasis added):

C.08.004.1 (1) The following definitions apply in this section.	C.08.004.1 (1) Les définitions qui suivent s'appliquent au présent article.
[…]	. . .
"innovative drug" means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. (*drogue innovante*)	« drogue innovante » S'entend de toute drogue qui contient un ingrédient médicinal non déjà approuvé dans une drogue par le ministre et qui ne constitue pas une variante d'un ingrédient médicinal déjà approuvé tel un changement de sel, d'ester, d'énantiomère, de solvate ou de polymorphe. (*innovative drug*)

The text

[119] Words of a provision are to be read in their ordinary, grammatical sense. Where the words of a provision are precise and unequivocal, the ordinary meaning is to play a dominant part in the interpretive process.

[120] The New Shorter Oxford English Dictionary (1993 edition) defines the phrase "such as" to mean "for example." This is consistent with the common usage of the phrase. To illustrate, "I like dogs that do not shed, such as Kerry Blue and Soft Coated Wheaten terriers." Kerry Blue and Soft Coated Wheaten terriers are examples of non-shedding dogs.

[121] Reading the definition in its ordinary, grammatical sense, an "innovative drug" is one that:

i. Contains a medicinal ingredient not previously approved in a drug by the Minister; and

ii. Is not a variation of a previously approved medicinal ingredient.

[122] To aid in the interpretation of what constitutes a "variation" five examples are cited in the definition of "innovative drug". Salts, esters, enantiomers, solvates and polymorphs are listed as examples of molecular structures that are variations of a previously approved medicinal ingredient. The Governor in Council would have created an incoherent scheme if the enumerated examples of variations are, in some unarticulated circumstances, not variations. The interpretation that all of the listed examples are variations avoids such incoherence.

[123] In my view, the definition is sufficiently precise that its ordinary meaning should play the dominant role in its interpretation. However, notwithstanding my view as to the clarity of the language used, it is necessary to consider the context and purpose of the definition.

The context

[124] I agree that the Regulatory Impact Analysis Statement (RIAS) which accompanied the data protection regulations provides useful contextual information. Under the heading "Innovative Drug", the RIAS advises (emphasis added):

> Innovative Drug
>
> The definition of "innovative drug" specifically prohibits innovators from obtaining additional terms of data protection for variations of medicinal ingredients. <u>The list of variations is not exhaustive, but rather meant to give examples of the types of variations not considered for protection</u>. The exclusion of variations of a previously approved medicinal ingredient from the scope of protection was introduced to avoid the granting of an additional eight years of protection where an innovator seeks approval for a minor change to a drug.

> For other arguable variations not included in the list, such as metabolites, an assessment will be made as to whether or not approval is being sought primarily on the basis of previously submitted clinical data (i.e. without the support of new and significant clinical data) or not. This position is consistent with both NAFTA and TRIPS which only require the granting of protection for undisclosed data, the origination of which involved a considerable effort.

[125] The second sentence of the RIAS is consistent with interpreting the enumerated substances in the definition all to be variations of a previously approved medical ingredient.

[126] Also consistent with this interpretation is the later sentence which commences: "[f]or other arguable variations not included in the list". It is only for substances other than salts, esters, enantiomers, solvates and polymorphs that it is necessary to consider the nature of the previously submitted clinical data.

[127] Also significant is the third paragraph in the RIAS under the heading "Consultation" which states (underlining added):

> *Consultation*
>
> […]
>
> Proponents for the innovative drug industry supported the eight-year term of data protection but urged the government to adopt a data protection period consistent with that of the European Union. The innovative drug industry requested that the scope of data protection be expanded to include product variations that have different safety and efficacy profiles from the original product, such as metabolites, enantiomers, salts and esters. In addition, they requested that the term of data protection be extended for new indications for previously approved compounds and on the switch of a product from prescription to non-prescription status. They also noted that the current language inadequately reflects the intent of providing protection to the original medicinal ingredient, and all products incorporating that medicinal ingredient, including combination products, different formulations and polymorphs.

[128] The significance of this passage is that prior to the amendment of the data protection regulations in 2006, the Governor in Council focused on the specific issue of whether data protection should be extended to enantiomers and the like, and concluded that it should not. The Governor in Council's decision must be respected.

Purpose

[129] The data protection regulations were intended to implement Canada's obligations under *The North American Free Trade Agreement* (NAFTA) and the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), both cited at paragraph 71 of my colleague's reasons. This is reflected in subsection C.08.004.1(2) of the data protection regulations.

[130] Under section 5 of Article 1711 of NAFTA (set out at paragraph 72 of my colleague's reasons), a party is required to protect pharmaceutical products that utilize "new chemical entities." Section 3 of Article 39 of TRIPS is of similar effect.

[131] These obligations required the Governor in Council to consider what constitutes "new chemical entities" when crafting the data protection regulations. It was open to the Governor in Council to decide, as a matter of policy, that salts, esters, enantiomers, solvates and polymorphs were not sufficiently different to be "new chemical entities." If, as the appellant argues, the data protection regulations are under inclusive, this is a matter for the Governor in Council to remedy. This Court ought not to thwart the decision of the Governor in Council as expressed in the definition of "innovative drug" and in its rejection of the request by the innovative drug industry that data protection be extended to salts, esters, enantiomers, solvates and polymorphs.

Takeda's Allegation of Procedural Unfairness

[132] As I would dismiss the appeal it is necessary to consider the appellant's alternate argument that the Minister breached the duty of fairness she owed to it by granting data protection to the enantiomer PRECEDEX and the esters AVAMYS and TORISEL.

[133] In my view this argument must fail for the following reasons.

[134] First, I see no error in the Federal Court's conclusion that the process afforded to Takeda was fair "as it provided an opportunity to present written submissions and reasons were given" (Federal Court Reasons at paragraph 44). On this appeal Takeda does not allege any procedural irregularity. Rather, it complains about the result of the process.

[135] Second, the essence of Takeda's argument is that it was inconsistent and unfair of the Minister to refuse data protection to DEXILANT when such protection was provided to the three drugs listed above. However, as my colleague notes at paragraph 59 of his reasons, the Minister's interpretation of the definition of innovative drug in other cases is not determinative of the accuracy of the interpretation. Under correctness review, courts are required to interpret for themselves the language used in legislation and regulations.

Conclusion

[136] For these reasons, I would dismiss the appeal with costs.

"Eleanor R. Dawson"

J.A.

"I agree
J.D. Denis Pelletier J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-9-12
APPEAL FROM A JUDGMENT OF THE HONOURABLE MR. JUSTICE NEAR DATED DECEMBER 9, 2011, NO. T-2044-10	
STYLE OF CAUSE:	Takeda Canada Inc. v. The Minister of Health and Attorney General of Canada
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	June 11, 2012
REASONS FOR JUDGMENT BY:	Dawson J.A.
CONCURRED IN BY:	Pelletier J.A.
DISSENTING REASONS BY:	Stratas J.A.
DATED:	January 18, 2013

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