Federal Court  Cour fédérale

**Date: 20200724**

**Docket: T-1353-19**

**Citation: 2020 FC 788**

**Ottawa, Ontario, July 24, 2020**

**PRESENT: Mr. Justice McHaffie**

**BETWEEN:**

**NATCO PHARMA (CANADA) INC.**

**Applicant**

**and**

**MINISTER OF HEALTH AND ATTORNEY GENERAL OF CANADA AND GILEAD SCIENCES CANADA INC.**

**Respondents**

# JUDGMENT AND REASONS

## I. Overview

[1] Health Canada refused to accept Natco Pharma (Canada) Inc's abbreviated new drug submission (ANDS) for a drug that contains two medicinal ingredients, tenofovir alafenamide hemifumarate (TAF) and emtricitabine. Health Canada concluded that Natco's ANDS was prohibited by the data protection provisions of the *Food and Drug Regulations*, CRC, c 870.

Under those provisions, a manufacturer may not file an ANDS for a new drug "on the basis of a direct or indirect comparison between the new drug and an innovative drug" for a defined period.

[2] TAF and emtricitabine are antiretroviral agents used in the treatment of HIV/AIDS. Both TAF and emtricitabine are found in two products marketed by Gilead Sciences Canada Inc: DESCOVY, which contains just those two medicinal ingredients; and GENVOYA, which also contains two other antiretroviral agents. Health Canada considers GENVOYA an "innovative drug" under the data protection provisions because TAF had not been previously approved in a drug when GENVOYA was approved. DESCOVY, approved subsequently, is not an innovative drug. Natco's ANDS compared its drug to DESCOVY. It therefore argues it did not make a comparison to an innovative drug, and the data protection provisions do not prevent it from filing its ANDS.

[3] Health Canada's reasons for refusing Natco's ANDS under the data protection provisions considered their intent, which is to implement certain trade agreements. Health Canada found that those agreements required the protection of TAF during the data protection term, such that DESCOVY is "protected" under the GENVOYA period of data protection because it also contains TAF. Health Canada also noted that Gilead's submission for DESCOVY relied on comparative bioavailability studies for DESCOVY compared to GENVOYA. Health Canada found this reliance "further support[ed] the position" that DESCOVY is protected under the same data protection term as GENVOYA.

[4] I conclude that Health Canada's decision was reasonable. I agree with the Attorney General of Canada that Health Canada effectively concluded that Natco's ANDS indirectly compared its drug to the innovative drug GENVOYA by comparing its drug to DESCOVY. Although it could have been expressed more clearly, a review of Health Canada's decision as a whole makes clear that this is the nature of its conclusion. In my view, this conclusion is a reasonable, and indeed inevitable, one in the circumstances.

[5] I agree with Natco that some of Health Canada's reasoning unduly privileges the intent of the *Food and Drug Regulations* and the underlying trade agreements over the language of the provisions. Nevertheless, when reviewed as a whole and in its administrative context, I am satisfied that Health Canada's decision establishes a line of analysis that reasonably justifies the refusal to accept the application, namely that Natco's ANDS indirectly compares its drug to an innovative drug.

[6] The application for judicial review is therefore dismissed without costs.

## II. Issue and Standard of Review

[7] The issue raised on this application for judicial review is whether Health Canada's conclusion that Natco's submission could not be accepted for filing until the expiry of the data protection term for GENVOYA was reasonable.

[8] As this formulation of the issue suggests, the applicable standard for reviewing the decision is that of reasonableness. The parties agree this standard is dictated by the Supreme

Court of Canada's recent decision in *Canada (Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at paras 16–17, 23–25. No party suggested that any legislative indicator of intent or any rule of law requirement rebutted the general presumption of reasonableness established by *Vavilov*.

## III. Analysis

### A. *The Regulatory Framework of the Data Protection Provisions*

[9] I begin with the relevant provisions in the *Food and Drug Regulations* and the treaty provisions underlying them. I do this before turning to Health Canada's decision, both because the regulatory framework is necessary to understand the decision, and because the governing statutory scheme, the treaty obligations they implement, and the cases interpreting them act as "constraints" on Health Canada's decision making: *Vavilov* at paras 108–114.

#### (1) Section C.08.004.1 of the *Food and Drug Regulations*

[10] At issue in this application is section C.08.004.1 of the *Food and Drug Regulations*, known as the "data protection" provisions. The relevant parts of this section are set out in full in Appendix A. The operational heart of the section is subsection C.08.004.1(3), which sets out two main time periods:

- a "no file" period of six years, during which a manufacturer may not file an ANDS or other submission for a notice of compliance (paragraph C.08.004.1(3)(*a*)); and

- a “data protection” or “market exclusivity” period of eight years, during which the Minister may not approve a submission or issue a notice of compliance (paragraph C.08.004.1(3)(*b*)), which is lengthened to eight years and six months if certain conditions are met regarding clinical trials involving pediatric populations (subsection C.08.004.1(4)).

[11] Each of these periods is triggered in the following circumstances:

| | |
|---|---|
| **(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 : |
| [Emphasis added.] | [Je souligne.] |

[12] As this language sets out the trigger for the “no file” and “market exclusivity” periods, the central question in deciding whether the provisions apply is whether the manufacturer sought “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.” In the present case, there is no issue Natco sought a notice of compliance for a new drug. I therefore agree with the Attorney General that the key question for Health Canada was whether Natco did so “on the basis of a direct or indirect comparison” between its new drug and an “innovative drug.”

[13] The term “new drug” is used throughout Part C of the *Food and Drug Regulations*. The term “innovative drug,” however, is particular to the data protection provisions and is defined in subsection C.08.004.1(1):

| | |
|---|---|
| ***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*** 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. |
| [Emphasis added.] | [Je souligne.] |

[14] In this case, the "medicinal ingredient" at issue is TAF. GENVOYA is the first drug approved by the Minister that contains TAF. Health Canada recognizes GENVOYA as an innovative drug. While Natco does not agree, it does not contest this issue on this application.

[15] The definition of "innovative drug" has been the subject of prior judicial consideration in a number of cases raised by the parties. In particular:

- in *Epicept*, Justice Near, then of this Court, held that the second reference to "drug" in the definition includes not just new drugs, but drugs issued by a Drug Identification Number (DIN) or a natural health product: *Epicept Corporation v Canada (Health)*, 2010 FC 956 at paras 62, 65, 78, appeal dismissed as moot, 2011 FCA 209;

- in *Teva*, Justice Stratas concluded that "previously approved" meant prior market approval and did not include approval under a Special Access Programme: *Teva Canada Limited v Canada (Health)*, 2012 FCA 106 at para 42;

- in *Celgene*, Justice Gauthier found that "previously approved" included prior market approval that had subsequently been withdrawn: *Celgene v Canada*, 2013 FCA 43 at paras 41–46; and

- in *Takeda*, Justice Dawson, for the majority of the Court of Appeal, held that an enantiomer of a previously approved medicinal ingredient was a "variation," even if it took considerable effort to create data showing its safety and effectiveness: *Takeda Canada Inc v Canada (Health)*, 2013 FCA 13 at paras 122–131.

[16] While these cases determined different issues than that raised on this application, they each include discussion relevant to the questions raised here, and they are referenced further below. Also valuable is the decision of the Court of Appeal in *Apotex*, in which Justice Nadon concluded the data protection provisions were within the regulation-making authority of the Governor in Council under the *Food and Drugs Act* and within federal legislative competence: *Apotex v Canada (Health)*, 2010 FCA 334 at paras 55, 94, 118, 132.

[17] The data protection provisions contain an express purpose clause in subsection C.08.004.1(2). It states that the purpose of section C.08.004.1 is to implement provisions in two trade agreements: the North American Free Trade Agreement (NAFTA) and the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS). In particular, the section implements paragraphs 5 to 7 of Article 1711 of NAFTA and paragraph 3 of Article 39 of TRIPS, so as to encourage the development of new drugs: *Apotex* at paras 71–72, 76, 85, 117; *Teva* at para 35. Consideration of the context of the data protection provisions therefore requires consideration of these provisions of NAFTA and TRIPS, which are set out in full in Appendix B.

(2) Data protection obligations in NAFTA and TRIPS

[18] Paragraph 5 of Article 1711 of NAFTA and paragraph 3 of Article 39 of TRIPS contain similar language. Each says that if the state, as a condition of approving the marketing of pharmaceutical products that "utilize new chemical entities," requires the submission of "undisclosed test or other data" that is the product of "considerable effort," then the state shall protect such data against disclosure or unfair commercial use.

[19] It is important to distinguish between three concepts referred to in the trade agreements: the *new chemical entity*; the *pharmaceutical product* that utilizes the new chemical entity; and the *data* filed to obtain approval of the pharmaceutical product. The concept of a "new chemical entity" in the agreements is reflected in section C.08.004.1 in the phrase "medicinal ingredient not previously approved in a drug" in the definition of "innovative drug", as well as in the related language regarding "variations" in that definition: *Celgene* at paras 48–49; *Takeda* at paras 129–131. The term "pharmaceutical product" used in the trade agreements is replaced by "drug" in the regulation, in keeping with the terminology defined in the *Food and Drugs Act*, RSC 1985, c F-27 and used in the *Food and Drug Regulations*. As Justice Gauthier noted in *Celgene*, "[i]t is quite usual for the words of a treaty to be harmonized with the language used in one's own regulatory scheme": *Celgene* at para 48.

[20] The term "data" is not used in section C.08.004.1. Rather, the submission of data is recognized as implicit in the approval of a new drug, and reliance on that data is implicit in a generic manufacturer's comparison to that drug: *Apotex* at paras 77, 91; *Teva* at paras 18–20.

This raises another important distinction, namely the difference between the obligations set out in the trade agreements and the manner in which the Governor in Council chose to meet those obligations in the regulations. The obligation in the trade agreements is to protect certain data from disclosure or unfair commercial use. The Governor in Council chose to meet that obligation by conferring market exclusivity based on the trigger set out in subsection C.08.004.1(3): *Apotex* at paras 76, 85–88. In the words of the Attorney General, the approved innovative drug is the "vehicle" through which the regulations protect the data filed to support the marketing approval of a pharmaceutical product containing a new chemical entity. As a result, the test under the regulations "is not reliance on an innovator's data, either by the Minister or by the generic manufacturer, but rather whether there has been a comparison, direct or indirect, between the generic manufacturer's new drug and an innovative drug" [emphasis in original]: *Apotex* at para 88.

[21] At the same time, since the regulations are the means chosen to implement the obligations in the trade agreements, the context of the trade agreements' obligation to protect data remains relevant to, though not determinative of, the interpretation of the data protection provisions: *Teva* at paras 35–39; *Apotex* at paras 75–77, 90–91; *Takeda* at paras 129–131.

(3) Regulatory Impact Analysis Statement

[22] Health Canada in its decision, and each party in their submissions, referred to the Regulatory Impact Analysis Statement (RIAS) that accompanied the current data protection provisions when they were promulgated in 2006 as an amendment to the prior provisions: RIAS, SOR/2006-241, *Canada Gazette Part II*, Vol 140, No 21 at p 1495 (*Regulations Amending the*

*Food and Drug Regulations (Data Protection)*) [RIAS (2006-241)]. While not part of the regulations, the RIAS has been recognized as a useful tool to understand how regulations work, and as "useful contextual information" relevant to interpretation: *Mounted Police Association of Ontario v Canada (Attorney General)*, 2015 SCC 1 at para 113; *Bristol-Myers Squibb Co v Canada (Attorney General)*, 2005 SCC 26 [*Biolyse*] at paras 156–157 (*per* Bastarache J (dissenting, but not on this point)); *Takeda* at para 124; *Apotex* at paras 22, 86–91; *Celgene* at paras 38, 49.

[23] The RIAS confirms that the amendments to section C.08.004.1 were intended to "clarify and effectively implement Canada's [NAFTA] and [TRIPS] obligations with respect to the protection of undisclosed test or other data necessary to determine the safety and effectiveness of a pharmaceutical or agricultural product which utilizes a new chemical entity": RIAS (2006-241) at p 1495. The RIAS notes that the definition of "innovative drug" specifically prohibits innovators from "obtaining additional terms of data protection for variations of medicinal ingredients": RIAS (2006-241) at p 1496. With respect to the triggering mechanism, the RIAS states the provisions are "intended to capture generic and second entrant manufacturers that are seeking to rely on direct or indirect comparison between their drug and the innovative drug": RIAS (2006-241) at p 1497.

[24] The RIAS also refers to combination products that include previously approved medicinal ingredients, stating they "are not eligible for an additional data protection period": RIAS (2006-241) at p 1496. It gives a specific example of a combination of an innovative drug and another medicinal ingredient not covered by data protection, indicating that a generic

manufacturer would not be able to file or obtain approval in respect of the combination "until expiry of the original data protection period of the innovative drug": RIAS (2006-241) at pp 1496–1497. Drug products that contain the same medicinal ingredient as an innovative drug, but vary in certain respects (such as additional medicinal ingredients or different formulations), are sometimes referred to as "product line extensions."

[25] It is in the context of this regulatory framework that Natco sought to file its ANDS and Health Canada made its decision refusing to accept it for filing.

B. *Health Canada's Decision*

(1) Natco's abbreviated new drug submission and its submissions to Health Canada

[26] Natco filed an ANDS seeking a notice of compliance for its NAT-EMTRICITABINE-TENOFOVIR tablets. This product would be a generic version of DESCOVY, containing TAF and emtricitabine. Natco's ANDS identified DESCOVY as the Canadian reference product (CRP), as defined in section C.08.001.1 of the *Food and Drug Regulations*, and sought approval in accordance with section C.08.002.1.

[27] Health Canada sent an initial letter to Natco indicating that, subject to any further representations from Natco, the ANDS could not be accepted because TAF was listed on the Register of Innovative Drugs in respect of the innovative drug GENVOYA. The Register of Innovative Drugs contains information relating to innovative drugs and data protection periods and is maintained by the Minister pursuant to subsection C.08.004.1(9). Health Canada stated

that "[c]onsistent with the intent of section C.08.004.1 to protect new chemical entities, drugs containing [TAF], such as DESCOVY, benefit from the same period of data protection" [emphasis added].

[28] Natco responded with submissions to Health Canada that GENVOYA was not an "innovative drug." It argued that TAF was not a "medicinal ingredient not previously approved in a drug," since it was a "variation" of a form of tenofovir contained in previously approved drugs. In accordance with Health Canada's guideline on the provisions, "Guidance Document: Data Protection under C.08.004.1 of the *Food and Drug Regulations*" [the Guideline], a challenge to the status of an innovative drug is sent to the manufacturer of the innovative drug. Health Canada did so, and subsequently wrote to both Natco and Gilead, indicating it remained of the preliminary view that GENVOYA was properly granted data protection in respect of TAF, and invited further submissions before making a final decision.

[29] On June 3, 2019, Natco filed a further submission. That submission briefly disagreed that GENVOYA was properly granted data protection. However, Natco primarily set out a new argument, namely that even if GENVOYA was an "innovative drug," DESCOVY was not. Natco argued its ANDS sought an NOC "on the basis of a direct comparison to DESCOVY," and made "no comparison to GENVOYA as a reference product," so it was not precluded by the data protection provisions. Natco noted the product monograph for DESCOVY indicated there were no independent safety studies in respect of DESCOVY. Rather, Gilead sought to reduce the study requirements for DESCOVY "by relying on similarity to the previously approved drug GENVOYA."

(2) Health Canada's final decision

[30] In its decision issued July 26, 2019, Health Canada confirmed its view that GENVOYA was an "innovative drug" that was properly granted data protection for the medicinal ingredient TAF. It also repeated its view that "consistent with the intent of section C.08.004.1 to protect new chemical entities, other drugs containing [TAF], such as DESCOVY, also benefit from the same period of data protection."

[31] Health Canada's reasons begin with a review of the applicable regulatory framework, setting out the definition of "innovative drug" from subsection C.08.004.1(1) of the *Food and Drug Regulations*, and paraphrasing the prohibitions set out in subsections C.08.004.1(3) and (4).

[32] Health Canada then described the nature of GENVOYA and DESCOVY and the conclusion that GENVOYA was eligible for data protection. It reproduced the entry for GENVOYA on the Register of Innovative Drugs, which lists TAF as the medicinal ingredient and includes DESCOVY among other drugs that contain that ingredient. Health Canada noted both TAF and emtricitabine had been approved in a drug at the time DESCOVY was approved, so it was not eligible for a separate term of data protection. However, "DESCOVY was protected under the data protection term for GENVOYA with respect to [TAF] because DESCOVY also contains this medicinal ingredient."

[33] Health Canada addressed Natco's submission that its ANDS was filed based on a direct comparison to DESCOVY and made no comparison to GENVOYA in three sections of its decision. The first, entitled "Intent of Section C.08.004.1 of the *Regulations*" referred to the intent to implement the treaty obligations and cited the NAFTA and TRIPS provisions, which it then discussed in the following language:

> The presence of a new chemical entity in a drug is central to the obligations under the above-noted treaty provisions. The concept of the new chemical entity is incorporated into the definition of "innovative drug" […] as 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. The obligations to protect the new chemical entity exist for the entire duration of the data protection term granted by section C.08.004.1.
>
> [Emphasis added.]

[34] In a second section, entitled "Drugs Containing the Same Medicinal Ingredient," Health Canada considered product line extensions. Health Canada concluded the treaty obligations to protect data "necessarily extend to these additional products also containing the same new chemical entity during the data protection term for the original innovative drug."

[35] After referring to portions of the RIAS discussing combination products, as well as the discussion of product line extensions in its Guideline, Health Canada reached the following conclusion:

> Therefore, a combination drug containing a medicinal ingredient that was the basis for a previous "innovative" drug designation, i.e. a new chemical entity, will also benefit from any term of the data protection for the innovative drug that is still in effect. This position is consistent with the regulatory intent in view of Canada's treaty obligations for pharmaceutical products containing new chemical entities. If the protection was not maintained, a

> subsequent manufacturer would be able to obtain approval for a product containing the new chemical entity by comparing to another drug containing that new chemical entity, despite the data protection in place in respect of the new chemical entity in the original innovative drug. Such an outcome would circumvent Canada's obligations under NAFTA, TRIPS, and CETA [the Comprehensive and Economic Trade Agreement] to protect the undisclosed test or other data regarding the new chemical entity from unfair commercial use, where the origination of the test or other data involved a considerable effort.
>
> [Emphasis added.]

[36] In a third section, entitled "Natco's Submissions on DESCOVY," Health Canada addressed Natco's argument that Gilead had sought to reduce study requirements by relying on similarity to GENVOYA. Health Canada confirmed that its Regulatory Decision Summary for DESCOVY acknowledged that the data to support DESCOVY were based on comparative bioavailability studies for DESCOVY compared to GENVOYA. After reproducing a portion of that Regulatory Decision Summary, Health Canada stated the following:

> In the view of the OSIP, however, the reliance on the data for GENVOYA in the approval of DESCOVY further supports the position that DESCOVY is properly protected under the same data protection term.
>
> [Emphasis added.]

[37] Finally, Health Canada addressed Natco's argument distinguishing its situation from examples given in the Guideline, again relying on the intent of section C.08.004.1 and the definition of "innovative drug".

[38] On these grounds, Health Canada concluded that "DESCOVY was properly protected under the data protection term for GENVOYA on the basis that it also contains [TAF]." Its reasons end with the following summary:

> In accordance with paragraph C.08.004.1(3)(a) of the *Regulations*, a subsequent manufacturer that seeks an NOC for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug may not file a submission 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. Natco's ANDS […] makes comparisons to DESCOVY, which benefits from the data protection term for GENVOYA, an innovative drug. As such, Natco's ANDS […] cannot be accepted for filing until after the expiration of the six-year "No File" period on November 27, 2021.

C. *Health Canada's Decision is Reasonable*

[39] As set out above, Health Canada's conclusion that the data protection provisions barred Natco's ANDS was based on (i) its assessment of the intent of the *Food and Drug Regulations* and the obligations set out in NAFTA and TRIPS, as described in paragraphs [32] to [35] above, and (ii) its assessment that the fact that the DESCOVY approval relied on data for GENVOYA "further supports" the position, as described in paragraph [36] above.

[40] I will address these two aspects of Health Canada's analysis, and Natco's arguments with respect to them, in turn.

(1) Health Canada's interpretation of the data protection provisions

[41] The applicable principles of statutory interpretation are not in dispute. The Supreme Court in *Vavilov* confirmed that the "modern principle" of interpretation applies to statutory

interpretation by an administrative tribunal, and that a reasonable statutory interpretation is one that is consistent with the text, context and purpose of the provision: *Vavilov* at paras 117–120, citing *Rizzo & Rizzo Shoes Ltd (Re)*, [1998] 1 SCR 27 at para 21. Reasonable reasons should demonstrate that the decision maker was "alive" to these elements: *Vavilov* at para 120.

[42] Also not in dispute is that the innovative drug at issue is GENVOYA, and that DESCOVY is not an innovative drug. Health Canada nonetheless found the data protection provisions were triggered by Natco's comparison to DESCOVY.

[43] The initial part of Health Canada's analysis considered the intent of the regulations and the obligations under the trade agreements. This is entirely reasonable. The Federal Court of Appeal has confirmed that the obligations of NAFTA and TRIPS, and the stated intent to implement those obligations, are an appropriate guide to interpretation of section C.08.004.1: *Teva* at paras 34–42; *Takeda* at paras 129–131. The "modern principle" requires such a contextual consideration: *Takeda* at paras 40, 43–44, 109; *Vavilov* at paras 114, 117–120.

[44] Health Canada noted the obligation under the trade agreements to protect data filed to obtain approval of a pharmaceutical product that utilizes a new chemical entity. It underscored the importance of the new chemical entity and the incorporation of that concept into the definition of "innovative drug" in subsection C.08.004.1(1).

[45] Natco argues that in doing so, Health Canada effectively broadened the definition of "innovative drug" to include other drugs with the same medicinal ingredient. I agree with Gilead

and the Attorney General that Health Canada's decision to extend data protection to DESCOVY does not in itself mean Health Canada concluded DESCOVY is an innovative drug or treated it as one. To the contrary, Health Canada agreed DESCOVY was "not eligible for its own separate term of data protection," which it would have been if it were an innovative drug. Health Canada instead concluded that DESCOVY was "protected under" or "benefited from" the term of data protection granted to GENVOYA as an innovative drug.

[46] While the mechanism used in the data protection provisions is that of "market exclusivity" and is based on the existence of an "innovative drug," I cannot agree with Natco that the only product that can trigger the market exclusivity protection is a generic version of the innovative drug. If this were the Governor in Council's intent, the regulations could and no doubt would express this.

[47] Relevant in this regard is the RIAS for the data protection provisions, which expressly recognizes a generic manufacturer may be prevented from filing a submission, or obtaining a notice of compliance, for a generic version of a drug other than the innovative drug during the "no file" and "market exclusivity" periods, respectively. As Health Canada noted, the RIAS discusses the following scenario at pages 1496–1497:

> Combinations of previously approved medicinal ingredients are not eligible for an additional data protection period. Where a combination consists of an innovative drug and another medicinal ingredient not covered by data protection, a generic manufacturer will not be allowed to file or receive a notice of compliance, as the case may be, in respect of the combination until expiry of the original data protection period of the innovative drug.
>
> [Emphasis added.]

[48] Natco points out that the combination drug scenario described in the RIAS is not the same as the current situation. DESCOVY does not contain all of the medicinal ingredients in GENVOYA plus others; it contains a subset of the medicinal ingredients in GENVOYA. However, this does not change the fact that the passage expressly refers to a generic version of a drug other than the innovative drug being precluded by the data protection provisions.

[49] The language used by Health Canada in its decision (and in its Guideline) may confuse the issue to some degree. Even if comparison to DESCOVY triggers the data protection provisions, it is not DESCOVY itself that is being protected or receiving benefit, although it may appear that way or have that effect. Rather, it remains GENVOYA, and in particular the data underlying the approval of GENVOYA, that is being protected. It may be, as the Attorney General argued, Health Canada's reference to DESCOVY as "protected under the data protection term for GENVOYA" was intended as a shorthand way of saying the protection of the data filed in support of GENVOYA is triggered by a comparison to DESCOVY. Regardless of terminology, though, the question remains the same: whether an ANDS that compares a new drug to DESCOVY triggers the data protection for GENVOYA.

[50] In my view, Health Canada's assessment of the obligation in the trade agreements that section C.08.004.1 is intended to implement was reasonable, as far as it went.

[51] However, Health Canada's analysis then jumped directly from its assessment of intent and the obligations under the trade agreements to the conclusion that drugs containing the same medicinal ingredient must benefit from the same period of data protection. It did so without first

assessing whether the circumstances it described involved a direct or indirect comparison to an innovative drug. In Natco's words, it "skips a step," namely the step of considering not only the regulatory intent and other contextual factors, but also the actual text of the triggering mechanism in subsection C.08.004.1(3).

[52] I agree with Natco that interpreting and applying the *Food and Drug Regulations* requires interpreting and applying the text of the regulations and not simply carrying out their intent: *Takeda* at paras 43–44, 117–123; *Teva* at paras 36–39; *Vavilov* at paras 120–121. In other words, while the intent of the regulations and the context of the trade agreements are relevant and important, the manner in which the Governor in Council has chosen to implement that intent, and the words used to do so, are critical. As Natco points out, the Federal Court of Appeal has emphasized that an international treaty cannot be used to override the clear words of a statutory provision: *Baker Petrolite Corp v Canwell Enviro-Industries Ltd*, 2002 FCA 158 at para 25; *Fraser v Janes Family Foods Ltd*, 2012 FCA 99 at para 19. For the same reasons, treaty obligations cannot be considered independently of the words of the regulatory provision that implements them.

[53] As set out by the Court of Appeal, the test under the regulations "is not reliance on an innovator's data, either by the Minister or by the generic manufacturer, but rather whether there has been a comparison, direct or indirect, between the generic manufacturer's new drug and an innovative drug" [emphasis in original]: *Apotex* at para 88. Health Canada set out the language of the triggering mechanism in its paraphrase of subsection C.08.004.1(3) at the outset of its reasons and again in its conclusion. However, it did not address this triggering question at all in

these two sections of its analysis before reaching a conclusion that the data protection provisions applied.

[54] I recognize that administrative statutory analyses may not engage in a formalistic interpretation exercise and may in some cases even omit pertinent aspects of the analysis without being unreasonable: *Vavilov* at paras 119, 122. However, I do not believe the administrative context can justify an analysis that assesses an outcome on the basis of whether it achieves a regulatory intent without consideration of how that regulatory intent is reflected in the statutory language. The statutory language is not "a minor aspect of the interpretive context": *Vavilov* at para 122.

[55] I am also sensible of the reminder in *Vavilov* that the expertise of an administrative decision maker may explain why a given issue is "treated in less detail": *Vavilov* at paras 93, 119. It may be that, in the application of its significant expertise in the area, Health Canada considers the question of comparison to be implicit in the existence of a product line extension. A company developing a product line extension or other product containing the same medicinal ingredient will presumably undertake comparative studies, reference data files, or otherwise make comparison to the innovative drug. In this manner, a comparison to the product line extension or other product may indirectly reference the innovative drug. While this may well be the case in a large majority of cases, it is not clear that it would invariably be so. In any event, I do not believe that reliance on Health Canada's expertise can go so far as to allow for the sole triggering mechanism in the regulations to be treated implicitly.

[56] The jump from intent to outcome causes Health Canada to make general conclusions that are not dependent on the trigger mechanism through which the trade agreements are implemented. This is seen most clearly in the following statement in the decision:

> Following the approval of an innovative drug, a company may develop product line extensions and other drugs containing the same medicinal ingredient that was the basis for the "innovative drug" designation, i.e. containing the new chemical entity. The obligations under NAFTA, TRIPS and CETA to protect the undisclosed test or other data of a pharmaceutical product that utilizes a new chemical entity necessarily extend to these additional products also containing the new chemical entity during the data protection term for the original innovative drug.
>
> [Emphasis added.]

[57] The only trigger for the "no-file" prohibition is a direct or indirect comparison to the innovative drug. To conclude that a product line extension or other drug containing the same new medicinal ingredient "necessarily" invokes data protection, regardless of whether it entails such a comparison, divorces the analysis from the regulatory scheme as promulgated. While Gilead argues that an indirect comparison is automatically triggered by the presence of the new chemical entity, the language of the data protection provisions does not support this position. The mere presence of the chemical entity does not mean there has been a "direct or indirect comparison" to the innovative drug that contains it. Health Canada's own Guideline recognizes that a new drug submission may contain the new chemical entity and not trigger the data protection provisions where the new drug is based on independent clinical trials.

[58] In this regard, the Guideline is consistent with the description of the triggering mechanism contained in the RIAS for the data protection provisions (at page 1497):

> Triggering mechanism
>
> The triggering mechanism is intended to capture generic and second entrant manufacturers that are seeking to rely on direct or indirect comparison between their drug and the innovative drug. As was observed by the Supreme Court of Canada in [*Biolyse*], such direct or indirect comparisons would exclude submissions in which the submission sponsor does not rely on another manufacturer's safety and efficacy data in seeking approval under the *Food and Drug Regulations*. This is consistent with Article 1711 of NAFTA and paragraph 3, Article 39 of TRIPS, since there would be no unfair commercial use of data or the reliance on such data for the approval of the product. The mechanism is intended to capture both submissions that fall under the abbreviated new drug submission provisions and submissions that are filed under the new drug submission provisions, so long as there is a direct or indirect comparison with the innovative drug.
>
> [Emphasis added.]

[59] DESCOVY, too, could theoretically have been approved based on independently filed studies and not comparison to, or reliance on, the data that underlay the GENVOYA approval. In such a case, comparison to DESCOVY would not entail any comparison at all to GENVOYA, despite the presence of the new chemical entity. An approach that assumes data protection applies based on the presence of the new chemical entity alone does not reflect the regulatory scheme.

[60] Had Health Canada stopped there and based its conclusion that comparison to DESCOVY triggered the data protection provisions solely on the fact that DESCOVY contained TAF, without assessing whether Natco's submission directly or indirectly compared its drug to the innovative drug GENVOYA, the decision would have been unreasonable. However, Health Canada went on to address a matter that it considered to "further support" the position, but that I consider determinative: reliance on the data for GENVOYA in the approval of DESCOVY.

[61] Before turning to that question, I will address one further argument regarding Health Canada's analysis of the trade agreements and the regulatory intent. Natco takes issue with Health Canada's description of the obligations in NAFTA and TRIPS, and the intent of section C.08.004.1, as being "to protect the new chemical entity." Natco argues this description shows Health Canada improperly conflated the term "innovative drug" with "new chemical entity." Gilead, on the other hand, submitted the purpose of the trade agreements was to protect new chemical entities.

[62] I agree it is a mischaracterization to describe the obligations in the trade agreements, or the intent of section C.08.004.1, as being to "protect the new chemical entity." The trade agreements provide for an obligation to protect the *data* filed to obtain approval of a drug that contains a new chemical entity, rather than for the protection of the new chemical entity itself: NAFTA, art 1711(5)–(7); TRIPS, art 39(3); *Apotex* at paras 72, 83–84, 110.

[63] It appears that the "protect new chemical entities" language may come from the decision of Justice Near in *Epicept*. At paragraph 63 of that decision, he stated:

> The Applicant's position is based on the argument that the data protection regulations are to protect the extensive clinical data performed to gain approval for a "new drug". However, as set out in the relevant NAFTA and TRIPS provisions, the *Regulations* are to protect "new chemical entities". Not all "new drugs" are "new chemical entities".

[64] This statement must be considered in context. Justice Near was responding to Epicept's argument that its drug was still an "innovative drug," even though previously approved drugs contained the medicinal ingredient, since the approved drugs were not "new drugs" but natural

health products or drugs approved under a DIN. His point was that the trade agreements protect data specifically associated with "new chemical entities" and not data associated with any new pharmaceutical product: *Epicept* at paras 62–66, 72. Elsewhere, Justice Near confirmed the intent of section C.08.004.1 was to "implement NAFTA and TRIPS for the protection of undisclosed test or other data necessary to determine the safety and effectiveness of a pharmaceutical or agricultural product which utilizes a new chemical entity" [emphasis added]: *Epicept* at para 48(ii).

[65] I therefore do not consider Justice Near to have been suggesting in paragraph 63 that the intent of section C.08.004.1 was to "protect new chemical entities," in the sense of ensuring that those chemical entities are protected independently of either the drug that contains that chemical entity, or the data filed to support the approval to market that drug. I similarly do not take Justice Dawson's statement that NAFTA and TRIPS require parties "to protect pharmaceutical products that utilize 'new chemical entities'" to have changed the Court of Appeal's assessment of the trade agreements, which expressly require the protection of data rather than either drug products, or chemical entities: *Takeda* at para 130; *Apotex* at paras 76, 85, 110.

[66] I do not view this as a merely semantic matter. Considering the trade agreements to oblige states to "protect new chemical entities" gives a different context and focus to the interpretation and application of the regulations than if they oblige states to "protect data"—particularly when the regulations expressly implement the trade agreements.

[67] However, I do not believe using this language renders Health Canada's decision unreasonable. Health Canada elsewhere in its decision, including in the passage reproduced at paragraph [56], appropriately refers to the obligations under the treaties as being "to protect undisclosed test or other data of a pharmaceutical product that utilizes a new chemical entity." On an overall review of the decision, I do not understand Health Canada to have misunderstood the nature of the treaty obligations or the intent of the regulations.

(2) Health Canada's conclusion that Natco indirectly compared to GENVOYA

[68] In its Regulatory Decision Summary for DESCOVY, Health Canada stated, "[t]he data to support Descovy was based on comparative bioavailability studies for Descovy as compared to Genvoya." Natco itself submitted that Gilead sought to reduce study requirements for DESCOVY by relying on similarity to the previously approved drug GENVOYA.

[69] As set out above, Health Canada in its decision noted these facts, saying the Regulatory Decision Summary for DESCOVY "specifically acknowledges that the data to support DESCOVY <u>were based on comparative bioavailability studies for DESCOVY compared to GENVOYA</u>" [emphasis added]. After quoting the summary, Health Canada briefly stated its view that "the reliance on the data for GENVOYA in the approval of DESCOVY <u>further supports</u> the position that DESCOVY is properly protected under the same data protection term" [emphasis added]

[70] The Attorney General argues this statement represents Health Canada's finding that a comparison to DESCOVY constitutes an indirect comparison to GENVOYA, which is

prohibited by subsection C.08.004.1(3). In other words, in the Attorney General's submission, supported by Gilead, Health Canada in this passage assesses the key question: is Natco's ANDS based on a direct or indirect comparison to an innovative drug, GENVOYA?

[71] Natco argues this passage cannot be read as Health Canada making a determination of indirect comparison, that the Minister and the Attorney General should not be able to raise such an argument on this application, and that in any case, such a determination would be unreasonable.

[72] I agree that Health Canada's statement is not clear. Certainly, given that the "key question" (in the Attorney General's language) or the "test" (in the Federal Court of Appeal's language) is whether there has been a direct or indirect comparison to GENVOYA, one might expect to see that regulatory language used in assessing the question. Health Canada did not state clearly, as it might have, that it concluded from the fact that DESCOVY made comparisons to GENVOYA that Natco's comparison to DESCOVY constituted an indirect comparison to GENVOYA. Indeed, even the Attorney General conceded that in an "ideal world," Health Canada would have made a more express finding with respect to the existence of a direct or indirect comparison.

[73] Nonetheless, I am satisfied this passage is fairly read as Health Canada making the determination that Natco's ANDS indirectly compared its drug to GENVOYA. I say this for three reasons.

[74] First, the only basis on which "reliance on the data for GENVOYA in the approval of DESCOVY" might possibly be taken to support the position that the data protection provisions apply is because it shows an indirect comparison between Natco's ANDS and GENVOYA. I can see no other basis for Health Canada's statement except to make the link between the comparison to DESCOVY in Natco's ANDS and the comparison to GENVOYA as an innovative drug.

[75] Second, as the Supreme Court has recently reiterated, reasonableness review involves examining reasons with respectful attention and "seeking to understand the reasoning process": *Vavilov* at para 84. The reasons are to be read with sensitivity to the administrative context in which they are given, recognizing that an administrative decision may not always look like a legal or judicial decision: *Vavilov* at paras 91–92. Applying these principles, I do not believe I should disregard a portion of Health Canada's reasons that appear to speak to the central question just because they do not use the regulatory language that a lawyer or Court might expect to see. I say this notwithstanding the fact that other portions of Health Canada's reasons include discussion of regulatory intent and treaty provisions that might be seen in a more formal legal analysis.

[76] Finally, the reasons are also to be read "holistically and contextually" to understand the basis for the decision in the relevant context, including the evidence and submissions before the decision maker: *Vavilov* at paras 94, 97. The absence of specific discussion of the "direct or indirect comparison" language in the decision may be due in part to the fact that neither Natco, nor Gilead addressed this question in their submissions. Natco focused its final submission on

DESCOVY not being an innovative drug, and to the specific examples of product line extensions in the Guideline, while Gilead focused on the appropriateness of GENVOYA being recognized as an innovative drug based on TAF being a new medicinal ingredient. This is not to say that Health Canada did not need to address the central question before it—whether Natco's ANDS made a comparison to an innovative drug—but this provides context for the absence of specific language in the discussion of the comparison that was made.

[77] While Health Canada described this conclusion simply as being "further support" for its conclusion that the data protection provisions apply, in my view it was essential to it. As noted above, had Health Canada not made this determination, it would not have answered the central question of whether Natco's ANDS made a direct or indirect comparison to an innovative drug. The fact that Health Canada does not describe it as the central basis for its reasoning does not affect its reasonableness. *Vavilov* recognizes there may be multiple lines of analysis within reasons, one of which may support a reasonable outcome. A reviewing court must be satisfied "there is [a] line of analysis within the given reasons that could reasonably lead the tribunal from the evidence before it to the conclusion at which it arrived" [emphasis added]: *Vavilov* at para 102 [emphasis added; modification in original]. This reference to "a line of analysis" adopts the Supreme Court's earlier statement that a decision "will be unreasonable only if there is no line of analysis within the given reasons that could reasonably lead the tribunal from the evidence before it to the conclusion at which it arrived" [emphasis added]: *Law Society of New Brunswick v Ryan*, 2003 SCC 20 at para 55; *Vavilov* at para 102.

[78] Natco also argues that the Minister and the Attorney General, who were jointly represented on this application, should not be permitted to effectively supplement the reasons by characterizing this passage as a finding that there was an indirect comparison to GENVOYA. As this characterization was raised for the first time on this application, Natco submits it should be viewed "with deep suspicion": see *Stemijon Investments Ltd v Canada (Attorney General)*, 2011 FCA 299 at para 41. I agree a decision maker should not be permitted to "bootstrap" by adding arguments on judicial review that are not contained in its decision: *Ontario (Energy Board) v Ontario Power Generation Inc*, 2015 SCC 44 at paras 63–69. For this reason among others, decision makers are not typically party to applications for judicial review in this Court: *Federal Courts Rules*, SOR/98-106, Rule 303(1)(*a*). However, in my view, the Attorney General's argument is one of characterization of the existing words of an administrative decision, rather than an attempt to bootstrap reasons by adding arguments that are not there: see *Ontario (Energy Board)* at para 68. While the distinction may admittedly be fine at times, I am satisfied Health Canada's reasons are fairly characterized as the Attorney General proposed.

[79] I therefore conclude that Health Canada found on the facts of the case before it that the new drug submission for DESCOVY made comparison to the new drug submission for GENVOYA, and that Natco's submission comparing its drug to DESCOVY thereby made a "direct or indirect comparison" to GENVOYA, an innovative drug. This conclusion was reasonable in light of the record, the history and context of the proceeding, and the relevant factual and legal constraints on the decision: *Vavilov* at paras 91–101. While Health Canada's reasoning may not contain "all the arguments, statutory provisions, jurisprudence or other details

the reviewing judge would have preferred," this is not the standard on which the Court must assess the decision, nor is this a basis for setting the decision aside: *Vavilov* at para 91.

[80] I also note that Health Canada's factual finding, that "the data to support DESCOVY were based on comparative bioavailability studies for DESCOVY compared to GENVOYA," which Natco does not challenge, was amply supported by the record. This included the Regulatory Decision Summary for DESCOVY, referred to by Health Canada, and the Preliminary Data Protection Eligibility Assessment for DESCOVY, which refers to the various clinical studies relating to the four-ingredient product now named GENVOYA. Given this factual finding, the conclusion that comparison to DESCOVY involves a "direct or indirect comparison" to GENVOYA flows from the test set out in subsection C.08.004.1(3), read in light of its context.

[81] In this case, the underlying data in question was apparently submitted in both the DESCOVY and GENVOYA files, and there was at some point a question whether GENVOYA or DESCOVY would be approved first and become the "innovative drug." Natco concedes, and I agree, that this does not affect the outcome. An interpretation of subsection C.08.004.1(3) that depended on the particular form of comparison or reliance—whether by way of cross-reference or by way of filing additional copies of the same data—is not sustainable. Keeping in mind the relationship between the obligation under the trade agreements to protect data, the intent of section C.08.004.1 to implement those agreements, and the mechanism by which that implementation was done (market exclusivity triggered by direct or indirect comparison),

reliance on the same TAF studies is sufficient to mean that comparison to DESCOVY constitutes direct or indirect comparison to GENVOYA.

(3) Natco's additional arguments on interpretation

[82] Natco argues that even if Health Canada did conclude that its comparison to DESCOVY was an indirect comparison to GENVOYA, it was unreasonable for it to do so. It argues the term "direct or indirect comparison" to an innovative drug does not capture comparison to a line extension drug, even if that line extension drug was approved based on a comparison to the innovative drug.

[83] As the Attorney General and Gilead argue, and Natco concedes, these arguments were not raised before Health Canada. Indeed, many of them were not raised until oral argument, as Natco's written submissions focused on whether Health Canada conferred protection on a non-innovative drug, DESCOVY, and had overly relied on the treaty obligations and regulatory intent. Generally speaking, parties are not entitled to raise arguments before this Court that were not raised before the administrative decision maker: *Alberta (Information and Privacy Commissioner) v Alberta Teachers' Association*, 2011 SCC 61 at paras 22–26.

[84] Natco argues it raises these issues now because Health Canada's preliminary decisions never stated Natco's submission made an "indirect comparison" to GENVOYA. While this is true, this was likely because Natco's submissions to that point were directed to GENVOYA not being an innovative drug. It was not until its final submission that Natco argued that even if GENVOYA was an innovative drug, DESCOVY was not, and so comparison to DESCOVY was

not comparison to an innovative drug. Regardless, given that the only trigger for data protection under section C.08.004.1 is a "direct or indirect comparison" to an innovative drug, I believe the question whether there was "indirect" comparison to GENVOYA was in play, even if not expressly raised by Health Canada, and even if Natco argued it made no direct comparison to GENVOYA.

[85] Nonetheless, I believe it is appropriate to consider and address Natco's arguments on this issue, even though Health Canada did not have the opportunity to do so. I say this in part because I agree with Natco that Health Canada's expression of its conclusions regarding indirect comparison to GENVOYA are not entirely clear, even in its final decision, and its consideration of the text of the regulations and how the regulatory context affects the interpretation of that text is at best implicit. I also say this because the data protection provisions and the issues raised have potential impact beyond these parties, and it is more efficient to address these arguments now that they have been raised with the Court and responded to by the Attorney General and Gilead.

[86] Natco's strongest argument on this issue is that the same language of "direct or indirect comparison" appears in contemporaneous amendments to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*PM(NOC) Regulations*]. The Governor in Council introduced amendments to the *PM(NOC) Regulations* at the same time as the amendments to the *Food and Drug Regulations* that amended the data protection provisions, and indeed, as the regulation immediately following: *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2006-242. These 2006 amendments introduced the following language into subsection 5(1) of the *PM(NOC) Regulations*:

| | |
|---|---|
| **5.** (1) If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the submission, with respect to each patent on the register in respect of the other drug, […] | **5.** (1) Dans le cas où la seconde personne dépose une présentation pour un avis de conformité à l'égard d'une drogue, laquelle présentation, directement ou indirectement, compare celle-ci à une autre drogue commercialisée sur le marché canadien aux termes d'un avis de conformité délivré à la première personne et à l'égard de laquelle une liste de brevets a été présentée — ou y fait renvoi —, cette seconde personne doit, à l'égard de chaque brevet ajouté au registre pour cette autre drogue, inclure dans sa présentation : […] |
| [Emphasis added.] | [Je souligne.] |

[87] The *PM(NOC) Regulations* have been subsequently amended, but the "directly or indirectly compares" language remains in the current version. Under the *PM(NOC) Regulations*, a manufacturer (the "second person") that seeks to make a generic version of a drug (the "other drug") must address the patents listed on the Patent Register in respect of the other drug in the manner specified in the regulations.

[88] The RIAS for the data protection amendments refers to the 2006 amendments to the *PM(NOC) Regulations*, and vice versa: RIAS (2006-241) at 1498–1499; RIAS, SOR/2006-242, *Canada Gazette Part II*, Vol 140, No 21, p 1510 [RIAS (2006-242)] at pp 1519, 1521. It is clear the two amending regulations were part of a program of amendments promulgated to address issues that had arisen in the operation of the two regulatory schemes, each of which operate in the context of the approval of generic drugs. The two are also meant to work together. For

example, the two-year difference between the “no file” period and the “market exclusivity” period was designed to reflect the time required for the generic manufacturer to meet its requirements under the *PM(NOC) Regulations*: RIAS (2006-241) at p 1496.

[89] Natco argues the similar language in the two coordinated regulations must be given the same interpretation. Since the phrase “directly or indirectly compares” in the *PM(NOC) Regulations* covers comparison only to the drug of which the generic version is being sought, the phrase “direct or indirect comparison” in the data protection provisions ought to similarly cover only that same drug. Conversely, Natco argues, if a manufacturer making a generic version of a product line extension makes a “direct or indirectly comparison” to the underlying innovative drug for purposes of the data protection provisions, applying the same interpretation to the *PM(NOC) Regulations* would lead to impractical results. That is, a company making a generic version of a line extension drug would have to address not only the patents listed on the Patent Register for the line extension drug, but also those listed in respect of the underlying innovative drug, and any other drugs to which the submission for the line extension made reference.

[90] While there is attraction to Natco’s arguments based on the presumption of consistent expression, in my view, the presumption is rebutted in this case, and the phrase “direct or indirect comparison” in section C.08.004.1 of the *Food and Drug Regulations* must be read differently than the phrase “directly or indirectly compares” in the *PM(NOC) Regulations*.

[91] The presumption of consistent expression presumes the same language appearing in different places in a statute is intended to mean the same thing: *Merck & Co Inc v Apotex Inc*,

2010 FC 1265 at paras 147–150, aff'd 2011 FCA 363. However, while the presumption may apply across related statutes, different statutory or regulatory contexts may dictate that different meanings be given to the same language: *Canada (Information Commissioner) v Canada (Minister of National Defence)*, 2011 SCC 25 at paras 69–74, aff'g 2009 FCA 175 and 2009 FCA 181, aff'g in part and rev'g in part 2008 FC 766 at paras 47(3), 76.

[92] In the present case, while the data protection provisions and the *PM(NOC) Regulations* arise in similar contexts (the approval of generic medications), they have different purposes, different regulatory language, and different regulatory and jurisprudential contexts.

[93] The data protection regulations are promulgated under the *Food and Drugs Act* to implement Canada's treaty obligations to protect data associated with the approval of certain pharmaceutical products, so as to encourage the development of new drugs: *Apotex* at paras 71–72, 76, 85, 117. The *PM(NOC) Regulations*, on the other hand, are promulgated under section 55.2 of the *Patent Act*, as part of the balance between the early-working exception and the prevention of patent infringement: *Biolyse* at paras 50–54. This different purpose informs the interpretation of the language of the provisions in the two regulations.

[94] Significantly, the *PM(NOC) Regulations* refer to a submission that "directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada […] and in respect of which a patent list has been submitted" [emphasis added]: *PM(NOC) Regulations*, s 5(1). A patent list may be submitted in respect to each new drug: *PM(NOC) Regulations*, s 4. The *PM(NOC) Regulations* also require the second person to address the patents on the Patent

Register only with respect to the "other drug," that is, the drug of which a generic version is being made. This language originally appeared in the amendments to subsection 5(1) of the *PM(NOC) Regulations* promulgated in 2006; it now appears in subsection 5(2.1). Thus the structure of the *PM(NOC) Regulations* supports the interpretation that the direct or indirect comparison in question refers only to the "other drug," even if that other drug is a product line extension that obtained approval through reference to another drug submission.

[95] The data protection regulations, on the other hand, do not have these contextual indicators that suggest inherent limits on the word "indirectly." To the contrary, the context of section C.08.004.1 suggests the very use of "direct or indirect comparison" is designed to deal with any comparison to the "innovative drug," even if that comparison may be a step or more removed.

[96] In this regard, the obligations of the trade agreements and the intent of the regulations are instructive. If the phrase "direct or indirect comparison" was limited to the comparison with the CRP, as Natco suggests, the generic manufacturer would be able to take advantage of the data submitted to obtain approval of the innovative drug. This loophole would be contrary to the intent of the trade agreements. It is possible for the Governor in Council to promulgate regulations that do not in fact meet the obligations of the trade agreements, despite the stated intention to do so: *Takeda* at paras 129–131; *Nova Tube Inc/Nova Steel Inc v Conares Metal Supply Ltd.*, 2019 FCA 52 at paras 57-58. However, the presumption is that they have not done so: R Sullivan, *Sullivan on the Construction of Statutes*, 6th ed (Toronto: LexisNexis Canada, 2014) at §§18.4–18.6, 18.47–18.49; *Teva* at paras 37–41. As described above, this potential

loophole was one of the primary factors Health Canada considered in its decision, but it considered this factor as the basis for a particular outcome, rather than as a clue to interpreting the given regulatory language.

[97] The RIAS for the two different regulations are also relevant context. As set out in the passage reproduced at paragraph [47], the RIAS for the data protection provisions shows an intent that the phrase "direct or indirect comparison" in that legislation not be limited to the CRP for the generic drug: RIAS (2006-241) at pp 1496–1497. The RIAS for the 2006 amendments to the *PM(NOC) Regulations*, on the other hand, confirms a more limited reading of the phrase "directly or indirectly compares" when used in those regulations, covering only the patents listed on the register for the drug. At pages 1510 and 1519, the RIAS (2006-242) states the following:

> The PM(NOC) Regulations [ensure the early working exception is not abused] by linking Health Canada's ability to approve a generic drug to the patent status of the equivalent innovative product the generic seeks to copy. Under the current scheme, a generic drug company which compares its product directly or indirectly with a patented, innovative drug in order to establish the former's safety and efficacy and secure marketing approval from Health Canada (which comes in the form of a "notice of compliance" or "NOC") must make one of two choices. It can either agree to await patent expiry before obtaining its NOC or make an allegation justifying immediate market entry that is either accepted by the innovator or upheld by the court.
>
> […]
>
> Under the amendments to section 5, a generic manufacturer that files a submission or supplement for a NOC in respect of a generic version of an innovative drug is only required to address the patents on the register in respect of the innovative drug as of that filing date. Patents added to the register thereafter will not give rise to any such requirement.
>
> [Emphasis added.]

[98] These passages confirm what is clear from the regulatory structure of the *PM(NOC) Regulations*, namely "directly or indirectly compares" triggers only an obligation to address patents in respect of the "equivalent innovative product the generic seeks to copy." This different regulatory structure gives the words a different meaning than that found in the data protection provisions. It is also perhaps worth noting that the passages directly above even use the term "innovative drug" in a manner different from its definition in the data protection provisions.

[99] Finally, the jurisprudential background to the amendments to the data protection provisions and the *PM(NOC) Regulations* is relevant to the differences in meaning given to similar language in the two regulations. The amendments to the data protection provisions were promulgated subsequent to the Federal Court of Appeal's decision in *Bayer Inc v Canada (Attorney General)*, 1999 CanLII 8099, 87 CPR (3d) 293 (FCA). That case assessed an earlier version of section C.08.004.1, which was also designed to implement the same sections of the NAFTA. The trigger mechanism in that version required the Minister to "examine" information or material filed with the Minister and "rely on data" contained in the information or material. The Court of Appeal found that since the Minister did not actually "examine" and "rely on" data in the original submission when approving a generic product, the section was not triggered every time that a generic made a comparison to a CRP: *Bayer* at paras 6–8. Significantly, the Court of Appeal made the following statement at paragraph 9 of its reasons:

> As Evans, J. pointed out, the appellant's argument would require that the Court read into the regulation the word "indirectly" or some other modifier to capture the idea that whenever a generic manufacturer files an ANDS comparing its product to an innovator's product, that there is implicit examination and reliance on the confidential information previously submitted by the innovator in its NDS. The Court cannot read words into the regulation.

[100] The trigger mechanism in the amended data protection provisions no longer refers to examination or reliance on data. It refers to direct or indirect comparison to the innovative drug, comparison to the drug entailing implicit reliance on the data that was filed for its approval. The RIAS for the amendments to the data protection provisions make clear that they respond to this ruling: RIAS (2006-241) at pp 1495–1496. After referring to *Bayer*, the RIAS states the following:

> While the comparison necessary to demonstrate bioequivalence rarely involves an examination of the innovator's data, it does involve reliance on the innovator's product. Therefore, these amendments are being introduced to clarify that the aforementioned reliance will give rise to an exclusivity period.

This passage, particularly when read together with that reproduced in paragraph [47] regarding combination products, shows the Governor in Council's intent to promulgate regulations that protected the underlying data, even where the reliance on the innovative drug was an indirect one.

[101] The jurisprudential background to the amendments to the *PM(NOC) Regulations* was quite different. Efforts to avoid the obligation to address the patents on the register had included generic companies seeking to refer to approved generic drugs, rather than to the original product. A new subsection 5(1.1) had been introduced to deal with this issue, but ultimately the Federal Court of Appeal determined that section 5(1) captured the situation: *Merck & Co, Inc v Canada (Attorney General)*, 2000 CanLII 15094, 5 CPR (4th) 138 (FCA) at paras 30–37. Notably, the Court distinguished the analysis in *Bayer* based on the differences in the legislative scheme: *Merck* at paras 34, 36–37. Nonetheless, the amended subsection 5(1) included the "directly or indirectly" language, presumably to avoid doubt: RIAS (2006-242) at pp 1519–1520.

[102] I therefore conclude that even though similar language appears in the data protection provisions and the *PM(NOC) Regulations*, different meaning must be given to them to reflect their respective regulatory contexts.

[103] Similarly, I agree with Gilead and the Attorney General that Natco's reference to the "comparison" described in subsection C.08.002.1(1) of the *Food and Drug Regulations* does not assist. Natco notes the comparison in that section is between a generic product and the CRP it seeks to copy and argues the same comparison must be intended in subsection C.08.004.1(3). However, subsection C.08.004.1(3) has both a different comparator (an "innovative drug" rather than a CRP) and the additional "direct or indirect" language not seen in subsection C.08.002.1(1). I cannot draw any conclusions on the scope of subsection C.08.004.1(3) from the use of the word "comparison" in the two provisions.

[104] Natco's other arguments suggesting a narrower reading of "direct or indirect comparison" in subsection C.08.004.1(3) are less persuasive.

[105] Natco argues that even if the triggering mechanism were to be limited to comparison to the innovative drug, the word "indirect" still has meaning. It points to the observation in *Apotex* that "generic manufacturers […] are in effect relying, at least indirectly, on the information and data provided by innovators" [emphasis added]: *Apotex* at para 108. However, there is an important distinction between indirect reliance on *data*, to which Justice Nadon was referring, and indirect comparison to an *innovative drug*. The Governor in Council chose the latter as the triggering mechanism for the amended data protection provisions: *Apotex* at paras 87–88.

Nothing in the statement in *Apotex* suggests a narrower reading of the provision. Natco also argues that "indirectly" would also retain meaning by referring to other contexts such as biologics or non-Canadian drugs. Be that as it may, the fact that an "indirect" comparison could refer to other sorts of comparisons does not mean it excludes comparisons to a line extension drug whose approval involved comparison to an innovator drug.

[106] Natco also relies on a passage in the RIAS for the data protection provisions that describes comments received during the public consultation period on the proposed regulations. At page 1501, the RIAS summarized submissions from the innovative drug industry:

> [The innovative drug industry] 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.
>
> [Emphasis added.]

[107] Natco argues the Governor in Council did not amend the draft regulations in response to these submissions, which indicates its intention not to provide protection to products incorporating the medicinal ingredient, such as line extension products. In *Takeda*, Justice Dawson adopted such an approach in respect of another passage in the same paragraph of the RIAS: *Takeda* at paras 127–128. Nevertheless, I cannot accept Natco's argument with respect to the underlined passage above. Unlike the passage at issue in *Takeda*, both the nature of the submission and the reason for not making amendments to the draft regulations in consequence are far from clear. It may be that the innovative industry advocated for protecting such line extension products by granting them a full term of protection—that is, giving them the same treatment as "innovative drugs." If so, that contention may have been rejected, as these

products are clearly treated differently in the regulations as promulgated. It may also be that the Governor in Council did not amend the draft regulations in response to those submissions because it did not agree the language "inadequately reflects the intent" described. I therefore do not believe the foregoing passage supports Natco's position on the meaning of "direct or indirect comparison" in section C.08.004.1 as promulgated.

[108] I conclude that none of Natco's additional arguments suggest the interpretation of subsection C.08.004.1(3) that Health Canada implicitly adopted is unreasonable. To the contrary, having considered both the contextual issues raised by Health Canada, and the additional arguments raised by Natco and the parties, it becomes clear to me that the "interplay of text, context and purpose leaves room for a single reasonable interpretation" of the regulation: *Vavilov* at para 124. That is, the "direct or indirect comparison" to an innovative drug that forms the trigger for data protection provisions may include a manufacturer's comparison to a drug product that in turn was compared to the innovator product for approval. Given Health Canada's finding that Natco compared its product to DESCOVY, and the approval of DESCOVY was based on comparison to GENVOYA and the very data supporting its innovative drug status, the outcome that Natco's ANDS could not be accepted for filing was inevitable.

## IV. Conclusion

[109] The application for judicial review is therefore dismissed.

[110] The parties have advised the Court that they have conferred and have agreed that no party is seeking costs, regardless of the outcome.

**JUDGMENT IN T-1353-19**

**THIS COURT'S JUDGMENT is that**

1. The application for judicial review is dismissed, without costs.

"Nicholas McHaffie"

Judge

## APPENDIX A – DATA PROTECTION PROVISIONS

| ***Food and Drug Regulations*, CRC c 870** | ***Règlement sur les aliments et drogues*, CRC ch 870** |
|---|---|
| **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*) |
| **(2)** The purpose of this section is to implement 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 paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the Agreement Establishing the World Trade Organization, as defined in the definition ***Agreement*** in subsection 2(1) of the *World Trade Organization Agreement Implementation Act.* | **(2)** L'objet du présent article est de mettre en œuvre 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 le 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 instituant 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 | ***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 |

which the first notice of compliance was issued to the innovator in respect of the innovative drug; and

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.

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

**(3)** 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.

**(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 there-by 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.

[…]

[…]

**(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).

## APPENDIX B – TREATY PROVISIONS

| NORTH AMERICAN FREE TRADE AGREEMENT | ACCORD DE LIBRE-ÉCHANGE NORD-AMÉRICAIN |
|---|---|
| **Part VI: Intellectual Property** | **Partie VI : Propriété intellectuelle** |
| **Chapter 17: Intellectual Property** | **Chapitre 17 : Propriété intellectuelle** |
| **Article 1711: Trade Secrets** | **Article 1711 : 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 test or other data necessary to determine whether the use of such products is safe and effective, the Party 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. | **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 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 | **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 |

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.

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 obtaining the approval relied on shall begin with the date of the first marketing approval relied on.

**7.** Lorsqu'une Partie se fie à une approbation de commerciali-sation accordée par une autre Partie, la période raisonnable d'utilisation exclusive des données présentées en vue d'obtenir l'approbation en question commencera à la date de la première approbation de commercialisation.

**AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS**

**Section 7: protection of undisclosed information**

***Article 39***

[…]

**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.

**ACCORD SUR LES ASPECTS DES DROITS DE PROPRIÉTÉ INTELLECTUELLE QUI TOUCHENT AU COMMERCE**

**Section 7: Protection des renseignements non divulgués**

***Article 39***

[…]

**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 données 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.

**FEDERAL COURT**

**SOLICITORS OF RECORD**

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|---|---|
| **DOCKET:** | T-1353-19 |
| **STYLE OF CAUSE:** | NATCO PHARMA (CANADA) INC v MINISTER OF HEALTH ET AL |

**HEARING HELD BY VIDEOCONFERENCE ON JUNE 22, 2020 FROM OTTAWA, ONTARIO AND TORONTO, ONTARIO**

| | |
|---|---|
| **JUDGMENT AND REASONS:** | MCHAFFIE J. |
| **DATED:** | JULY 24, 2020 |

**APPEARANCES:**

| | |
|---|---|
| Lesley Caswell<br>Bryan Norrie | FOR THE APPLICANT |
| J. Sanderson Graham<br>Charles Maher | FOR THE RESPONDENTS<br>MINISTER OF HEALTH AND ATTORNEY GENERAL OF CANADA |
| Kristin Wall<br>Jordana Sanft<br>William Chalmers | FOR THE RESPONDENT<br>GILEAD SCIENCES CANADA INC. |

**SOLICITORS OF RECORD:**

| | |
|---|---|
| Aitken Klee LLP<br>Barristers and Solicitors<br>Ottawa, Ontario | FOR THE APPLICANT |
| Attorney General of Canada<br>Ottawa, Ontario | FOR THE RESPONDENTS<br>MINISTER OF HEALTH AND ATTORNEY GENERAL OF CANADA |

Norton Rose Fulbright LLP
Toronto, Ontario

FOR THE RESPONDENT
GILEAD SCIENCES CANADA INC.