Federal Court  Cour fédérale

Date: 20200918

Docket: T-827-19

Citation: 2020 FC 904

Ottawa, Ontario, September 18, 2020

PRESENT: The Honourable Mr. Justice Zinn

BETWEEN:

JANSSEN INC.

Applicant

and

ATTORNEY GENERAL OF CANADA AND THE MINISTER OF HEALTH

Respondents

JUDGMENT AND REASONS

[1] The Applicant attempts to persuade this Court that the decision under review, interpreting regulations, is unreasonable even though it accords with a decision of the Federal Court of Appeal. For the reasons set out below, I am not persuaded.

[2] The Applicant developed what it describes as "a lifesaving innovative drug" named SPRAVATO that is used to treat major depressive disorder [MDD]. MDD is a psychological

disorder that causes depressed mood, loss of interest or pleasure in regular activities, decreased energy, and poor concentration. The disease is difficult to treat and sufferers experience high rates of suicide and limited treatment options.

[3] The medicinal ingredient in SPRAVATO is esketamine hydrochloride, an enantiomer of ketamine hydrochloride.

[4] The Applicant applied for data protection for SPRAVATO under the *Food and Drugs Regulations*, CRC c 870 [the Regulations]. Drugs that receive data protection are entitled to enhanced protection. They receive an eight-year period of market exclusivity, including a six-year no-filing period, from the time the drug is approved for sale in Canada.

[5] Canada's data protection regime arises out of its obligation under four treaties: North American Free Trade Agreement [NAFTA], Agreement on Trade-related Aspects of Intellectual Property rights [TRIPS], Comprehensive Economic and Trade Agreement [CETA] and the Canada-United States-Mexico Agreement [CUSMA]. As the Applicant notes, "These treaties require signatories to protect the data of innovative drug manufacturers that is required in order to establish the safety and efficacy of a drug containing a new chemical entity where the origination of the data required considerable effort." No definition is provided for the phrase "new chemical entity".

[6] Article C.08.004.1 (1) of the Regulations provides that the purpose of that section is to implement the relevant treaty provisions. Data protection is afforded to "innovative drugs" defined in Article C.08.004.1 (1) of the Regulations as follows:

> **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)

[7] The Applicant concedes that its product contains an enantiomer of the previously approved medicinal drug found in KETALAR, but argue the product should be granted data protection. It submitted that the Minister should "look beyond the fact that esketamine is an enantiomer of ketamine when assessing whether it is eligible for data protection." This "looking beyond" would require that the Minister not follow and apply the decision of the Federal Court of Appeal in *Takeda Canada Inc v Canada (Minister of Heath)*, 2013 FCA 13, [*Takeda*].

[8] At paras 122-123 of *Takeda*, the Federal Court of Appeal, applying a correctness standard of review held that the meaning of 'innovative drug' in Article C.08.004.1 (1) of the Regulations, means that <u>all</u> enantiomers are necessarily variations, and thus not entitled to data protection:

> 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.
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> 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.

[9] Notwithstanding *Takeda*, the Applicant urged the Minister "to apply a flexible, contextual and case specific approach to its interpretation of the data protection provisions under section C.08.004.1 of the Regulations." The Applicant made the following submissions:

> Janssen submits that although SPRAVATO contains the medicinal ingredient esketamine hydrochloride, which is an enantiomer of the previously approved medicinal ingredient ketamine hydrochloride, SPRAVATO is eligible for data protection because it provides a novel therapeutic mechanism of action for treating Major Depressive Disorder, a new indication, a new route of administration, a new dosage form, and a new strength, as compared to the previously approved drugs containing the medicinal ingredient ketamine hydrochloride. Further, Janssen submits that granting data protection to its drug SPRAVATO aligns with Health Canada's decision to grant its new drug submission ("NDS") for SPRAVATO "Priority Review" status. Finally, Janssen submits that it is seeking approval for its NDS for SPRAVATO on the basis of considerable effort, specifically its own clinical data without reference to any data Health Canada may have on file in respect to ketamine hydrochloride or any other drug.

[10] In its decision, the Minister held that SPAVATO would not be granted data protection or added to the Register of Innovative Drugs for the following reasons.

[11] It found that the product fails the data protection eligibility test. Specifically, the product is not a new chemical entity or an innovative drug based on jurisprudence. The Minister outlines that to assess data protection eligibility two questions are asked. The first is whether the medicinal ingredient in the drug under consideration is a new chemical entity. The second is

whether the generation of the data that supports the approval of the medicinal ingredient in the drug required considerable effort.

[12] It notes Justice Near's guidance in *Epicept Corporation v Canada (Minister of Health)*, 2010 FC 956, outlining the definition of a new chemical entity, based a two-step approach: (1) whether the medicinal ingredient was previously approved in a drug by the Minister, and (2) whether the medicinal ingredient is a variation of a previously approved medicinal ingredient.

[13] It was found, and it is not disputed, that SPRAVATO meets the first step of that test.

[14] As to the second step, the Minister sets out that if the chemical structure of one medicinal ingredient is an enantiomer of the chemical structure of another previously approved medicinal ingredient, then the drug is not innovative.

[15] The Minister restates this justification in a later portion of the decision by writing that once it is established that the medicinal ingredient has been previously approved in a drug or is a variation of a previously approved medicinal ingredient then the data protection eligibility assessment concludes since the medicinal ingredient is not a "new chemical entity" and the drug is not deserving of data protection.

[16] Despite SPAVATO's new methods of treating MDD and the additional distinctions that contrast it to previously approved drugs with the medicinal ingredient of ketamine, the Minister notes the decision in *Takeda*. Moreover, the decision also notes that the scope of data protection

should not be expanded to include product variations that have different efficacy profiles because of a 2006 Governor-in-Council decision which focused on this specific issue and concluded that no expansion should be given.

[17] The Minister also notes that the granting of priority review status to the Applicant's new drug submission is not a relevant consideration for granting data protection. The purpose of priority review is simply to engage in an accelerated review period of 180 calendar days for the submission. Most importantly, a drug submission does not have to have or relate to a "new chemical entity" for it to be available for priority review status, which is available for any new drug submission, or supplemental new drug submission, that aims to treat a serious or life-threatening disease.

[18] As noted above, the Minister concluded that because the Applicant's product contained an enantiomer of a previously approved medicinal ingredient it is not necessary to examine the additional consideration of whether the Applicant's data is new and significant, or whether it involved a considerable effort.

[19] In the review of the decision before this Court, the Applicant submits that the point in issue is "whether the Minister's decision that SPAVATO is not an innovative drug and not eligible for data protection, solely on the basis that esketamine is an enantiomer of ketamine, was reasonable." The Minister submits that the decision under review was not made "solely" on that basis. I need not explore that assertion for if it is found that the Minister's interpretation that all

enantiomers of a previously approved medicinal ingredient are excluded from data protection is reasonable, then the application must fail.

[20] The Applicant submits that *Takeda* is not binding on this Court, or on the Minister. Relying on *Carter v Canada (Attorney General)*, 2015 SCC 5, at paragraph 44, it says that this Court may reconsider the Federal Court of Appeal's interpretation of "innovative drug" in the Regulations where a new legal issue is raised or there is a change in the circumstances or evidence that fundamentally shifts the parameters of the debate.

> The doctrine that lower courts must follow the decisions of higher courts is fundamental to our legal system. It provides certainty while permitting the orderly development of the law in incremental steps. However, *stare decisis* is not a straitjacket that condemns the law to stasis. Trial courts may reconsider settled rulings of higher courts in two situations: (1) where a new legal issue is raised; and (2) where there is a change in the circumstances or evidence that "fundamentally shifts the parameters of the debate" (*Canada (Attorney General) v. Bedford*, 2013 SCC 72, [2013] 3 S.C.R. 1101, at para. 42).

[21] The Applicant submits that both of these situations arise in the matter before this Court. *Takeda* was decided prior to the decision in *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 [*Vavilov*] which established a new framework for reviewing administrative decisions that emphasizes interpreting legislation consistently with international obligations, applying the purposive approach when interpreting legislation, and ensuring decisions are reasonable and made based on all relevant factors. It is submitted that the "emphasis in *Vavilov* on ensuring that legislation is interpreted in the proper statutory scheme and consistently with international obligations raises a new legal issue."

[22] I agree with the Minister's submission that there is nothing new in ensuring that legislation is interpreted consistent with international obligations. In *Baker v Canada (Minister of Citizenship and Immigration)* at paragraph 70, the Supreme Court of Canada observed:

> [T]he values reflected in international human rights law may help inform the contextual approach to statutory interpretation and judicial review. As stated in R. Sullivan, *Driedger on the Construction of Statutes* (3rd ed. 1994), at p. 330:
>
> > [T]he legislature is presumed to respect the values and principles enshrined in international law, both customary and conventional. These constitute a part of the legal context in which legislation is enacted and read. In so far as possible, therefore, interpretations that reflect these values and principles are preferred. [emphasis added.]

[23] Moreover, it cannot be said that the majority in *Takeda* were unaware of Canada's international obligations that underpinned the provisions of the Regulations at issue, as is evident in paragraphs 129-131 of the reasons:

> 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.
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> 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.
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> 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.

[24] Lastly, while *Vavilov* does establish that administrative decisions, with very limited exceptions, are to be reviewed on the reasonableness test, the Applicant overlooks that the Federal Court of Appeal in *Takeda* applied the stricter and more challenging standard of correctness. Having held that the correct interpretation of the Regulations is that no enantiomer of a previously approved medicinal ingredient is entitled to data protection, it runs contrary to common sense and legal analysis that a reasonable interpretation to the opposite effect is to be preferred.

[25] The Applicant submits that the evidence here differs significantly from that in *Takeda*. In *Takeda*, the same company developed both drugs, which were both used in the same manner for the same indication. None of those facts exists in this matter. The Applicant submits that the facts in *Takeda* were the kind of "mere variation" that the exception to innovative drug was designed to catch and that the situation here is markedly dissimilar.

[26] I agree that those factual differences exist; however, there is nothing in *Takeda* to suggest that the interpretation was based on or influenced by those facts. In my view, the factual differences are not such that this Court can refuse to follow *Takeda*.

[27] The Applicant further submits that this Court has evidence that was not before the court in *Takeda*; namely, that the interpretation given to the definition of "innovative drug" in the Regulations "puts Canada at odds with other countries and would render it *ultra vires*."

[28] As noted earlier, the treaties give no interpretation of the phrase "new chemical entities" and thus each country was to implement legislation based on its specific interpretation. It is hardly surprising that the variations now noted by the Applicant exist. However, if Canada is now of the view that its interpretation of its treaty obligations is inconsistent with that of others and ought to be changed, that is a matter for the Governor in Council – not this Court.

[29] Lastly, I agree with the Minister that the interpretation given the Regulations was such that data protection could not have been granted to the Applicant despite its submission about the "considerable effort" put into developing SPRAVATO. The text of the Regulations, Canada's treaty obligations, jurisprudence, and the RIAS support its determination that a "considerable efforts" examination was not needed in this matter once it failed the eligibility test.

[30] For these reasons, this application must be dismissed. The parties advised the Court that they had reached agreement on costs.

JUDGMENT IN T-827-19

THIS COURT'S JUDGMENT is that this application is dismissed, with costs payable according to the agreement of the parties.

"Russel W. Zinn"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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