Federal Court  Cour fédérale

Date: 20111209

Docket: T-2044-10

Citation: 2011 FC 1444

Ottawa, Ontario, December 9, 2011

PRESENT: The Honourable Mr. Justice Near

BETWEEN:

TAKEDA CANADA INC.

Applicant

and

THE MINISTER OF HEALTH
ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] This is an application for judicial review of a decision of the Minister of Health (the Minister) through the Office of the Patented Medicines and Liaison (OPML) dated November 8, 2010. The Minister refused to list the Applicant's drug, DEXILANT, on the Register of Innovative Drugs (Register) and provide data protection in accordance with section C.08.004.1 of the *Food and Drug Regulations*, CRC c 870, as amended by the *Regulations Amending the Food and Drug Regulations (Data Protection)*, SOR/2006-2411 (the Regulations).

[2] For the following reasons, this application is dismissed.

I. Background

[3] The Applicant, Takeda Canada Inc., filed a New Drug Submission (NDS) for DEXILANT on August 11, 2009. This was based on extensive clinical trial data generated to establish the safety and efficacy of the drug for marketing approval. A Notice of Compliance (NOC) to market the drug was issued by the Minister on July 22, 2010.

[4] DEXILANT contains the medicinal ingredient dexlansoprazole. Dexlansoprazole is an enantiomer, or mirror image, of lansoprazole. Currently marketed as the drug PREVACID, lansaprazole is a racemic mixture of the two enantiomers.

[5] DEXILANT is intended for use in the treatment of gastroesophageal reflux disease (GERD).

[6] On July 16, 2009, the Applicant requested data protection from the Minister under the Regulations for these DEXILANT studies.

II. Decision Under Review

[7] The OPML provided a preliminary assessment on behalf of the Minister in a letter dated July 22, 2010. DEXILANT was not eligible for data protection because it did not meet the

definition of an “innovative drug” as required under the Regulations. The medicinal ingredient dexlansoprazole was an enantiomer of a previously-approved medicinal ingredient lansoprazole, currently marketed as PREVACID.

[8] In response, the Applicant submitted written representations taking issue with the OPML’s interpretation of the Regulations. Given the nature of the data filed to support regulatory approval, the Applicant asserted that dexlansoprazole should be considered an “innovative drug” as opposed to a variation. In addition, the Applicant called attention to the broader interpretation used in granting protection to three other drugs (PRECEDEX, AVAMYS and TORISEL) in comparable circumstances.

[9] A final decision was issued by the OPML, on behalf of the Minister, in a letter dated November 8, 2010. It maintained that dexlansoprazole was a variation within the meaning of the Regulations as an enantiomer of the previously-approved medicinal ingredient lansoprazole. The OPML did not agree with the interpretation suggested by the Applicant and insisted that the nature and extent of data submitted in the regulatory approval process was not relevant to the decision to grant data protection. Accordingly, dexlansoprazole was not eligible for listing on the Register.

[10] The OPML also addressed the three drugs raised in the Applicant’s written submissions, noting that a determination on data protection is case-specific. The circumstances surrounding the provision of data protection for those drugs could be distinguished from dexlansoprazole.

III. Data Protection Provisions

[11] The Regulations provide protection for data submitted as part of the drug marketing approval process leading to the issuance of a NOC. This protection can, however, only be extended to an "innovative drug" defined in subsection C.08.004.1(1) as 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."

[12] Once deemed eligible for listing on the Register, an "innovative drug" receives data protection consisting of two formal restrictions. Firstly, a generic drug manufacturer cannot file a submission based on a comparison to an "innovative drug" within the first six years of the eight-year period after the drug has received a NOC (subsection C.08.004.01(3)(a)). Secondly, the Minister may not issue a NOC to the generic drug manufacturer before the end of the eight-year period (subsection C.08.004.01 (3)(b)).

[13] As stated in subsection C.08.004.1(2), the data protection provisions apply to the implementation of Article 1711 of the *North American Free Trade Agreement*, 1992, 32 ILM 296 (NAFTA) and paragraph 3 of Article 39 in the *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1869 UNTS 299 (TRIPS). Where a person submits undisclosed data for approval of a pharmaceutical product, and the product utilizes a "new chemical entity", signatory states commit to preventing other persons from making "unfair commercial use" of that data and (for a reasonable time) from relying on that data in their own applications for approval.

IV. Issues

[14] This application raises the following issues:

(a) Did the Minister err in interpreting the definition of an "innovative drug" to exclude DEXILANT as a variation within the meaning of subsection C.08.004.1 (1) of the Regulations?

(b) Did the Minister breach a duty of fairness owed to the Applicant in refusing to consider the data submitted?

V. Standard of Review

[15] The parties disagree as to the appropriate standard of review to be applied in the present case. The Applicant insists that statutory interpretation is a question of law requiring a standard of correctness. By contrast, the Respondent contends that the issue raised is whether dexlansoprazole is a variation within the meaning of the subsection C.08.004.1 (1), a matter of mixed fact and law reviewed based on reasonableness. If the matter is considered a purely legal question, however, the Respondent suggests that it may still be addressed by the reasonableness standard.

[16] Since the primary issue I am concerned with in this application is the assessment of conflicting approaches to statutory interpretation, the appropriate standard of review is correctness. I must determine whether the Minister misinterpreted the definition of "innovative drug" to exclude an enantiomer, such as dexlansoprazole, as a variation.

[17] The factors I identified in making a similar determination regarding a review of the interpretation accorded to an "innovative drug" in *Epicept Corporation v Canada (Minister of Health)*, 2010 FC 956, [2010] FCJ No 1188 at para 39 remain relevant. These include that:

> i. There is no privative clause in the *Regulations or the Food and Drugs Act*, R.S.C. 1985, c. F-27 (*"Act"*)
>
> ii. The statutory interpretation of the definition of "innovative drug" is a pure question of law.
>
> iii. Under the *Act* and *Regulations*, the Minister has jurisdiction with respect to the approval of drugs. However, the Minister has no expertise in deciding pure questions of law, as explained below.
>
> iv. The Court is as well placed as the Minister to determine the proper statutory interpretation of the *Regulations*.

[18] The correctness standard I applied in *Epicept*, above, to interpret the "innovative drug" definition was followed in *Teva Canada Ltd v Canada (Minister of Health)*, 2011 FC 507, 2011 CarswellNat 1450 at para 35.

[19] Although *Celgene Corp v Canada (Attorney General)*, 2011 SCC 1, 89 CPR (4th) 1 at para 34 recently questioned in *obiter* whether the correctness standard was appropriately applied to a decision of a specialized tribunal, the Patented Medicines Prices Review Board, in interpreting its enabling legislation; that decision is not applicable to the present case. The Minister and the OPML are not acting as specialized tribunals in the interpretation of an enabling statute. In addition, *Celgene*, above, did not reach any definitive conclusion on this matter.

[20] Similarly, the Respondent relies on *Scott Paper Ltd v Canada (Attorney General)*, 2008 FCA 129, [2008] FCJ No 539 at para 11 to assert that legal questions may be accorded deference and reviewed on a standard of reasonableness when they are squarely within a decision-makers' expertise and the question is not of central importance to the legal system, even when there is no privative clause. This decision is, however, of limited assistance. Deference may occasionally be warranted for questions of law, but this is not always the case.

[21] A more pertinent approach was arrived at in *Bristol-Myers Squibb Co v Canada (Attorney General)*, 2005 SCC 26, 39 CPR (4th) 449 at para 36 where it was found that on a question of conflicting interpretations given to the regulations, the Minister's opinion is not entitled to deference and a standard of correctness is required. As Justice Bastarache elaborated at paragraph 88 in his dissent, the Minister's expertise relates to the evaluation of scientific evidence in interpreting the safety and efficacy of drugs and "such expertise is not engaged when simply interpreting the *NOC Regulations*, divorced from their relationship to the science."

[22] The same reasoning applies in this case. The Minister's expertise is confined to scientific assessments as opposed to legal interpretation. The legal question is also one of general application to the drug listing determination process. A standard of correctness must therefore be applied by this Court in reviewing the interpretation of the "innovative drug" definition and exclusion of variations.

[23] It is well established that questions of procedural fairness are also reviewed based on the correctness standard (see *Canada (Minister of Citizenship and Immigration) v Khosa*, 2009 SCC 12, 2009 CarswellNat 434 at para 43).

VI. Analysis

Issue A: *Did the Minister Err in Interpreting the Definition of an "Innovative Drug" to Exclude DEXILANT as a Variation Within the Meaning of Subsection C.08.004.1(1) of the Regulations?*

[24] The Applicant submits that the Minister's interpretation of the definition of an "innovative drug" in the Regulations is overly restrictive. In particular, the Applicant insists that the phrase "not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph" should not be used to automatically exclude enantiomers, such as dexlansoprazole. The Minister should consider the nature and extent of data submitted. According to the Applicant, the interpretation adopted does not respect legislative intent, leads to an absurd result and puts Canada in breach of its international obligations. In addition, the interpretation is inconsistent with the approach used in providing data protection to other drugs.

[25] The Respondent contends that the wording of the Regulations clearly denies protection to drugs that are mere variations, such as the enantiomer dexlansoprazole. Data protection is intended to apply to new chemical entities. A review of the nature and extent of data collected is only relevant to an assessment of whether products constitute variations not already listed. In addition, the treatment of other drugs is not pertinent to a determination of whether the Minister erred in its application of the Regulations in the present case.

[26] To assess these claims, I begin with a brief summary of the relevant principles of statutory interpretation. This is followed by a consideration of how subsection C.08.004.1(1) should be interpreted, specifically the phrase related to potential variations. Based on this interpretation, I will determine whether the Minister erred in excluding DEXILANT from data protection as one of these variations.

(i) Principles of Statutory Interpretation

[27] The predominant approach to statutory interpretation was articulated by the Supreme Court in *Canada Trustco Mortgage Co v Canada*, 2005 SCC 54, [2005] 2 SCR 601 at para 10:

> [10] It has been long established as a matter of statutory interpretation that "the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament": see *65302 British Columbia Ltd. v. Canada*, 1999 CanLII 639 (SCC), [1999] 3 S.C.R. 804, at para. 50. The interpretation of a statutory provision must be made according to a textual, contextual and purposive analysis to find a meaning that is harmonious with the Act as a whole. When the words of a provision are precise and unequivocal, the ordinary meaning of the words play a dominant role in the interpretive process. On the other hand, where the words can support more than one reasonable meaning, the ordinary meaning of the words plays a lesser role. The relative effects of ordinary meaning, context and purpose on the interpretive process may vary, but in all cases the court must seek to read the provisions of an Act as a harmonious whole.

[28] Consistent with these principles, particular attention should be paid in the interpretation of regulations to the whole context of the authorising statute (*Bristol Myers-Squibb*, above, at para 39). In addition, there is a presumption against an interpretation that would lead to absurd consequences

(Ruth Sullivan, *Sullivan on Construction of Statutes*, 5th ed (Markham: LexisNexis, 2008) at 223, 300-301).

[29] Where possible, statutes should be interpreted in a way that makes their provisions consistent with Canada's international treaty obligations and principles of international law (*Németh v Canada (Justice)*, 2010 SCC 56, [2010] 3 SCR 281 at para 34). Those treaty obligations should be interpreted "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose" (*Vienna Convention on the Law of Treaties*, 23 May 1969, 1155 UNTS 331, art 31).

[30] Mindful of these principles, I will examine the definition of an "innovative drug" and the term "variation" within the meaning of subsection C.08.004.1(1) of the Regulations.

(ii) Interpretation of "Innovative Drug"

[31] A reading of the "innovative drug" definition in its grammatical and ordinary sense is relatively clear. There are two conditions under which a drug will not be considered "innovative" and entitled to data protection. This includes when a drug contains a previously approved medicinal ingredient or is considered a variation of a previously approved medicinal ingredient.

[32] While the term "variation" is not explicitly defined, subsection C.08.004.1(1) does provide a non-exhaustive list of examples, including "salt, ester, enantiomer, solvate or polymorph." These concrete examples represent the types of chemical compounds presumed to fall under the term

"variation" of a previously approved medicinal ingredient for the purposes of the "innovative drug" definition and data protection.

[33] Additional guidance as to what constitutes a "variation" not formally listed may come from the dictionary definition of "a change or slight difference in condition, amount or level" (*Oxford English Dictionary* 11th ed (New York: Oxford University Press, 2004) at 1599). As the subsection is worded, however, it is implied that the examples provided would by their very nature represent a "change" or "slight difference in condition." This is certainly true of an enantiomer which is defined as "a molecule that is the mirror image of another" (*Concise Canadian Oxford Dictionary* (Toronto: Oxford University Press, 2005) at 431). Given the terminology used in the definition and its ordinary meaning, it is conceivable that an enantiomer, along with the other examples, will always constitute a "variation" within the meaning of subsection C.08.004.1(1).

[34] This reading is also supported by the Regulatory Impact Analysis Statement (RIAS) (see *Canada Gazette Part II*, vol 140, No 21, 2006-10-18). The RIAS has been used in the past for the purpose of assessing legislative intent (see for example *Bristol-Myers Squibb*, above, and *Bayer Inc v Canada (Attorney General et al)* (1999), 87 CPR (3d) 293, 243 NR 170 (FCA). A passage at page 1496 addresses the definition of "innovative drug" and variations:

The definition of "innovative drug" specifically prohibits innovators from obtaining additional terms of data protection for variations of medicinal ingredients. The list of variations is not exhaustive, but rather meant to give examples of the types of variations not considered for	La définition de « drogue innovante » interdit spécifiquement aux innovateurs d'obtenir une période supplémentaire de protection des données du fait qu'ils ont varié les ingrédients médicinaux. La liste des variations n'est pas exhaustive, mais se veut plutôt une liste

protection. The exclusion of variations of a previously approved medicinal ingredient from the scope of protection was introduced to avoid the granting of an additional eight years of protection where an innovator seeks approval for a minor change to a drug. For other arguable variations not included in the list, such as metabolites, an assessment will be made as to whether or not approval is being sought primarily on the basis of previously submitted clinical data (i.e. without the support of new and significant clinical data) or not. This position is consistent with both NAFTA and TRIPS which only require the granting of protection for undisclosed data, the origination of which involved a considerable effort	d'exemples des types de variations qui n'avaient pas été prises en compte en matière de protection. L'exclusion de variations d'un ingrédient médicinal préalablement approuvé de la portée de la protection a été adoptée afin d'éviter l'octroi d'une période de protection supplémentaire de huit années quand un innovateur tente de faire approuver une modification mineure à un médicament. Pour d'autres variations douteuses qui ne sont pas incluses sur la liste, comme les métabolites, une évaluation sera effectuée dans le but de déterminer si oui ou non l'approbation demandée est principalement fondée sur des données cliniques préalablement soumises (c.-à-d. sans l'appui de données cliniques nouvelles et significatives). Cette position est conforme à l'ALÉNA et aux dispositions des ADPIC qui n'exigent l'octroi d'une protection que pour les données non divulguées, dont la création nécessite un effort considérable.

[35] The RIAS provides insight into the anticipated approach to interpretation. It highlights the importance placed on excluding variations from data protection where there is a "minor change to a drug." Although the Minister will consider variations other than those listed, the examples provided are reflective of the minor changes contemplated by the provision.

[36] Of particular significance is the reference to a further inquiry required "[f]or arguable variations not included in the list." This involves an assessment of new and significant clinical data that involved "considerable effort." However, the RIAS only envisions this type of inquiry for "arguable variations" to determine if they should also be excluded from the definition of an "innovative drug" – it is not required for the examples provided that are presumed to constitute variations outside the scope of data protection.

[37] Moreover, this interpretation does not lead to an absurd result. Where there is some dispute as to whether a medicinal ingredient constitutes a variation, the nature and extent of the data is a factor relevant to the assessment of its status as an "innovative drug." By contrast, the medicinal ingredients listed are excluded from the outset because they are widely recognized chemical variations. Even if the extent of the data were considered in these instances, this would not in itself be sufficient to ensure data protection. The Minister would still be entitled to dismiss these types of medicinal ingredients that, by their very nature, represent variations based on the overall intent of the provision. It is therefore appropriate to deny data protection without a more extensive inquiry.

[38] Relevant to the broader context and purpose of data protection is the analysis of the Federal Court of Appeal in *Canadian Generic Pharmaceutical Assn v Canada (Minister of Health)*, 2010 FCA 334, [2010] FCJ No 1582 at paras 113-114:

> [113] In my view, what the entire context reveals is that the DPR is a mechanism deemed necessary to balance the effects of the regulatory scheme set forth in the Regulations, the purpose of which is to protect public health and safety. In particular, the DPR plays an important role with regard to the ANDS process by counteracting, or reducing, the negative aspects thereof. More particularly, by granting innovators a period of market protection for eight years, the DPR puts in place a regime which provides incentives for innovators to

> continue their search for "innovative drugs". Ultimately, the DPR exists to encourage the development of new drugs which, there cannot be much dispute, constitutes a valid public health and safety purpose.
>
> [114] Although it is true, as the Judge found at paragraph 79 of his Reasons, that the DPR seeks to balance "commercial considerations between the protection of an innovator drug manufacturer's investments... and the eventual NOC approval of a generic drug manufacturer's ANDS", the Judge erred, in my respectful view, in failing to consider the entire context in which the DPR finds itself. The true purpose of the DPR is not to balance the commercial interests of innovators and generic drug manufacturers, but rather to ensure that Canadians have reasonable access, at reasonable prices, to new, safe and effective drugs. In other words, the Regulations as a whole encourage the research and development of new medicines that save lives, prevent diseases, heal and cure and improve the health of Canadians, who can only benefit from the discovery and development of new medicines after the information and data generated in extensive pre-clinical and clinical trials demonstrate the "innovative drug's" safety and efficacy to the satisfaction of the Minister. The DPR plays an important part in this regulatory scheme.

[39] Data protection is considered central to the overall regulatory scheme in protecting public health and safety. It is intended to encourage research and development of drugs to improve the health of Canadians. At all times, however, data protection is to be extended to “innovators”, providing an incentive to develop “innovative drugs.” It does not imply that such protection will always be in the interest of public health where it applies to less significant changes in medicinal ingredients. It is open to question whether the information related to the research and development of these mere variations should not be widely available.

[40] This interpretation is also consistent with Canada’s international treaty obligations under NAFTA and TRIPS. As I alluded to in paragraph 63 of *Epicept*, above, data protection is only intended to protect “new chemical entities” as opposed to “new drugs.” As a consequence, not all

"new drugs" will be entitled to data protection. This is why the related Canadian Regulations set out clear variations to a medicinal ingredient that will not be considered an "innovative drug", even if they qualify as an NDS. To put it another way, the specified variations cannot be considered "new chemical entities."

(iii) DEXILANT as Variation

[41] Given this interpretation, it was correct for the Minister to exclude DEXILANT from data protection. Dexlansoprazole, the medicinal ingredient in DEXILANT, is a recognized enantiomer of lansoprazole. It therefore falls under one of the recognized variations within the meaning of subsection C.08.004.1(1), irrespective of the extent of the data collected by the Applicant as part of the NDS. Data protection is only intended to apply to "new chemical entities" falling under the definition of an "innovative drug" and that do not constitute variations.

[42] The Applicant's submissions with respect to other drugs that have received data protection and were not automatically excluded as being one of the recognized variations do not alter my interpretation. I cannot evaluate what factors were taken into account in the decision to grant data protection in those instances. The Minister's interpretation of the "innovative drug" definition to automatically exclude DEXILANT as a variation corresponds to the ordinary meaning, legislative intent and is consistent with international obligations.

Issue B: *Did the Minister Breach a Duty of Fairness Owed to the Applicant in Refusing to Consider the Data Submitted?*

[43] Given the conclusion reached on Issue A, it is unnecessary for me to deal extensively with the Applicant's argument that fairness was denied by not considering the nature of the data submitted. In my view, how the Minister has dealt with the comparator drugs mentioned (PRECEDEX, AVAMYS and TORISEL) that may be similar is largely irrelevant. Those drugs were dealt with based on their particular facts situation.

[44] Irrespective of the Applicant's dissatisfaction with the outcome, the process afforded to them was fair as it provided an opportunity to present written submissions and reasons were given.

VII. Conclusion

[45] The Minister adopted the correct interpretation in determining that, as an enantiomer, the dexlansoprazole in DEXILANT could not obtain data protection as a variation within the meaning of the innovative drug definition in subsection C.08.004.1(1). It could not be listed on the Register for Innovative Drugs. In addition, I do not find that there was any breach of the duty of fairness owed to the Applicants.

[46] Accordingly, this application for judicial review is dismissed. No costs are awarded.

JUDGMENT

THIS COURT'S JUDGMENT is that this application for judicial review is dismissed.

No costs are awarded.

" D. G. Near "
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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