Federal Court of Appeal | Cour d'appel fédérale

Date: 20240410

Docket: A-21-23

Citation: 2024 FCA 66

CORAM: **STRATAS J.A.**
MONAGHAN J.A.
BIRINGER J.A.

BETWEEN:

JANSSEN INC.

Appellant

and

ATTORNEY GENERAL OF CANADA and THE MINISTER OF HEALTH

Respondents

Heard at Toronto, Ontario, on April 10, 2024.

Judgment delivered from the Bench at Toronto, Ontario, on April 10, 2024.

REASONS FOR JUDGMENT OF THE COURT BY: STRATAS J.A.

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(Delivered from the Bench at Toronto, Ontario, on April 10, 2024).

STRATAS J.A.

[1] Janssen Inc. appeals from the judgment of the Federal Court (*per* Manson J.): 2023 FC 7. The Federal Court dismissed Janssen's application for judicial review of a decision of the Minister of Health. The Minister found that Janssen's nasal spray, SPRAVATO, was not an

"innovative drug" under subsection C.08.004.1(1) of the *Food and Drug Regulations*, C.R.C., c. 870, and, thus, was not entitled to data protection.

[2] The appeal must be dismissed. We agree with the Federal Court's dismissal of the application, substantially for the reasons it gave on the reasonableness of the Minister's interpretation and application of subsection C.08.004.1(1).

[3] In particular, we agree with the Federal Court's conclusion that the *Canada-United States-Mexico Agreement*, effective in July 2020, does not displace this Court's previous interpretation of subsection C.08.004.1(1): *Takeda Canada Inc. v. Canada (Health)*, 2013 FCA 13, [2014] 3 F.C.R. 70 and *Janssen Inc. v. Canada (Attorney General)*, 2021 FCA 137. Since the *Agreement*, the wording of the definition of "innovative drug" in subsection C.08.004.1(1) has not changed. Thus, our two previous cases bind us: *R. v. Sullivan*, 2022 SCC 19, 472 D.L.R. (4th) 521; *Miller v. Canada (Attorney General)*, 2002 FCA 370, 220 D.L.R. (4th) 149. Accordingly, the interpretation of subsection C.08.004.1(1) adopted by the Minister in this case with substantial reasons offered in support remains reasonable.

[4] It is trite that while international treaties can form part of the context relevant to the adoption of legislation, they do not amend legislation: *Society of Composers, Authors and Music Publishers of Canada. v. Entertainment Software Association*, 2022 SCC 30, 471 D.L.R. (4th) 391. For good measure, section 3 of the *Canada-United States-Mexico Agreement Implementation Act*, S.C. 2020, c. 1 provides that the *Agreement* is to be used to interpret legislation, not amend it. And subsection 30(3) of the *Food and Drugs Act*, R.S.C. 1985, c. F-27 empowers the Governor in Council to make regulations bringing the *Agreement* into effect, but as far as subsection C.08.004.1(1) is concerned, it has not made any change. While subsection

C.08.004.1(2) provides that the purpose of section C.08.004.1 is to implement articles 20.48 and 20.49 of the *Canada-United States-Mexico Agreement*, it continues to provide that the section is to implement article 39 of the *Agreement on Trade Related Aspects of Intellectual Property Rights*, 1869 U.N.T.S. 299, which supports the previous interpretation of subsection C.08.004.1(1).

[5] If the unchanged, specific wording of subsection C.08.004.1(1), as interpreted by this Court, does not conform with the *Agreement*, other legal and political recourses may be available. In this regard, we underscore our agreement with paragraph 54 of the Federal Court's reasons. We add that any *vires* challenge cannot be inserted into this proceeding at this late time, as the notice of appeal purports to do. Rather, it must be brought in a new proceeding with an evidentiary record developed for that purpose.

[6] As for Janssen's submission that the Minister unreasonably refused to reassess the data protection eligibility of the nasal spray, SPRAVATO, given our resolution of the interpretation issue, this issue is moot. Any reassessment would not have resulted in relief.

[7] Therefore, we will dismiss the appeal with costs fixed at the agreed upon amount of $4,000.

"David Stratas"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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DELIVERED FROM THE BENCH BY:	STRATAS J.A.

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