

Federal Court of Appeal



Cour d'appel fédérale

Date: 20231121

Docket: A-192-23

Citation: 2023 FCA 229

**CORAM: WEBB J.A.
LASKIN J.A.
LOCKE J.A.**

BETWEEN:

JANSSEN INC.

Appellant

and

**THE MINISTER OF HEALTH and
ATTORNEY GENERAL OF CANADA**

Respondents

Heard at Ottawa, Ontario, on November 21, 2023.
Judgment delivered from the Bench at Ottawa, Ontario, on November 21, 2023.

REASONS FOR JUDGMENT OF THE COURT BY:

LOCKE J.A.

Federal Court of Appeal



Cour d'appel fédérale

Date: 20231121

Docket: A-192-23

Citation: 2023 FCA 229

CORAM: WEBB J.A.
LASKIN J.A.
LOCKE J.A.

BETWEEN:

JANSSEN INC.

Appellant

and

THE MINISTER OF HEALTH and
ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR JUDGMENT OF THE COURT
(Delivered from the Bench at Ottawa, Ontario, on November 21, 2023).

LOCKE J.A.

[1] Janssen Inc. (Janssen) obtained notices of compliance in respect of supplemental new drug submissions (SNDSs) numbered 224739 and 244670 on January 23, 2020 and September 9, 2021, respectively. Canadian Patent No. 3,113,837 (the 837 Patent) issued on July 12, 2022, and on July 25, 2022, Janssen submitted a patent list (pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (the *Regulations*)) in respect of SNDS 244670

identifying the 837 Patent. SNDS 224739 was not mentioned in this July 25, 2022 submission. It was only on September 14, 2022 that Janssen sought to include SNDS 224739 in the patent list.

[2] Health Canada's Office of Submissions and Intellectual Property (OSIP), on behalf of the Minister of Health, refused to accept the patent list in respect of SNDS 224739 citing several reasons. Janssen sought judicial review of OSIP's decision before the Federal Court, but this was dismissed (2023 FC 870, *per* Justice Mandy Ayles). For the purposes of the present appeal, it is sufficient to address only one of the reasons cited by OSIP: that the patent list submitted on July 25, 2022 did not relate to SNDS 224739, and the submission on September 14, 2022 that did mention SNDS 224739 was outside the 30-day period from the date of issuance of the 837 Patent, as contemplated in subsection 4(6) of the *Regulations*. Because of our conclusion on this issue, it is not necessary to address other questions raised in this appeal, such as (i) whether the September 14, 2022 submission satisfied the other requirements for a patent list, and (ii) whether part of subsection 4(6) of the *Regulations* (unrelated to the 30-day period referred to above) is *ultra vires*.

[3] The parties agree on the standard of review, and we concur. As discussed in *Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 S.C.R. 559 at para. 45, the question for this Court to decide is whether the Federal Court identified the appropriate standard of review and applied it correctly. We are to step into the shoes of the Federal Court and focus on OSIP's decision. The parties also agree, as do we, that the Federal Court identified the appropriate standard of review: reasonableness. The issue therefore is whether the Federal Court correctly applied the reasonableness standard of review.

[4] In respect of the one issue that we must address in this appeal, OSIP noted that subsection 4(4) of the *Regulations* enumerates requirements for a patent list, including paragraph 4(4)(a) concerning identification of the SNDS (or new drug submission) to which the list relates. OSIP noted correctly that the patent list submitted on July 25, 2022 did not identify SNDS 224739, and hence this requirement was not met. OSIP rejected Janssen's arguments that (i) the later September 14, 2022 submission could change the nature of the July 25, 2022 patent list, and (ii) OSIP's preliminary response to the July 25, 2022 patent list acknowledged that it also concerned SNDS 224739. OSIP also noted that the 30-day deadline contemplated in subsection 4(6) of the *Regulations* expired on August 11, 2022. Therefore, the September 14, 2022 submission was too late, even assuming (contrary to OSIP's view) that it met the requirements for a patent list.

[5] We are not convinced that there was anything unreasonable in OSIP's analysis in this regard. We also do not agree with Janssen's argument that subsection 4(7) of the *Regulations* should be read to permit it to update the patent list by adding reference to an additional SNDS. Subsection 4(7) provides that a first person "must keep the information on the list up to date"; this subsection does not permit adding a patent to the list. We see nothing in the patent list in this case that would have engaged this provision. The information on the patent list was up to date. Janssen cannot, under the guide of keeping the information on the patent list up to date, add a different SNDS to an existing patent list.

[6] It follows from the foregoing that we find no reviewable error in the Federal Court's conclusion that OSIP's refusal to add the patent list against SNDS 224739 was reasonable.

[7] We will dismiss this appeal with costs.

"George R. Locke"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-192-23

STYLE OF CAUSE: JANSSEN INC. v. THE
MINISTER OF HEALTH and
ATTORNEY GENERAL OF
CANADA

PLACE OF HEARING: OTTAWA, ONTARIO

DATE OF HEARING: NOVEMBER 21, 2023

**REASONS FOR JUDGMENT OF THE COURT
BY:** WEBB J.A.
LASKIN J.A.
LOCKE J.A.

DELIVERED FROM THE BENCH BY: LOCKE J.A.

APPEARANCES:

Sana Halwani
Jordana Sanft

FOR THE APPELLANT
JANSSEN INC.

Elizabeth Koudys
James Schneider
Leah Bowes

FOR THE RESPONDENTS
THE MINISTER OF HEALTH
and ATTORNEY GENERAL OF
CANADA

SOLICITORS OF RECORD:

Lenczner Slaght LLP
Toronto, Ontario

FOR THE APPELLANT
JANSSEN INC.

Shalene Curtis-Micallef
Deputy Attorney General of Canada

FOR THE RESPONDENTS
THE MINISTER OF HEALTH
and ATTORNEY GENERAL OF
CANADA

