Federal Court of Appeal  Cour d'appel fédérale

Date: 20190424

Docket: A-319-17

Citation: 2019 FCA 97

CORAM: **WEBB J.A.**
BOIVIN J.A.
RENNIE J.A.

BETWEEN:

APOTEX INC.

Appellant

and

MINISTER OF HEALTH AND
ATTORNEY GENERAL OF CANADA

Respondent

Heard at Toronto, Ontario, on April 9, 2019.

Judgment delivered at Toronto, Ontario, on April 24, 2019.

REASONS FOR JUDGMENT BY: RENNIE J.A.

CONCURRED IN BY: WEBB J.A.
BOIVIN J.A.

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REASONS FOR JUDGMENT

RENNIE J.A.

[1] Apotex Inc. (Apotex) appeals from a decision of the Federal Court (2017 FC 857), dismissing its judicial review of a decision of the Minister of Health. In that decision, the Minister decided to cancel a process for the reconsideration of the refusal to grant a Notice of Compliance in respect of Apo-Omeprazole (omeprazole magnesium) delayed release tablets and to treat Apotex's corresponding Abbreviated New Drug Submission (ANDS) as withdrawn.

[2] The statutory, regulatory and policy context which frame the decision under review are fully described in the decision of Justice Roy and are not in contention. It is sufficient for these purposes to say that, following a review of Apotex's ANDS in respect of Apo-Omeprazole, the Minister refused to issue a Notice of Compliance and issued a Notice of Non-Compliance – Withdrawal letter (NON-W). The Minister was not satisfied that Apo-Omeprazole was bioequivalent to the relevant Canadian reference product.

[3] Health Canada's policy on the "Reconsideration of Final Decisions Issued for Human Drug Submissions" provides, in broad terms, a mechanism for reconsideration of issues of genuine scientific dispute either by an internal scientific advisory committee or an external panel of experts. The policy is triggered by a request for reconsideration by the sponsor (in this instance, Apotex), and a determination by the Therapeutic Products Division of Health Canada that the question to be resolved is one which meets certain eligibility requirements. Apotex sought recourse under the policy and the eligibility requirements were met. The Minister decided that the reconsideration would be referred to an external panel.

[4] Apotex and Health Canada could not reach agreement on the precise question to be put to the external panel. The Minister issued an ultimatum to Apotex – either to agree to the question as framed by her or she would consider Apotex to have withdrawn from the reconsideration process. Agreement was not forthcoming, the process was cancelled and a final NON-W issued. The decision that is at the heart of the judicial review reads:

> You disagree with the question I have proposed for the reconsideration panel, and despite my comment that I am prepared to be somewhat flexible, you did not provide an alternative. The question that I have posed in the November 6, 2015 letter is not a fettering of my discretion as you claim, but is an approach in line

> with assessing whether the regulatory requirement C.08.002.1(2) of the *Food and Drug Regulations* has been met.
>
> You also continue to request that the scope of the panel be expanded to deal with your objections to the process itself, which I take to mean going back to revisit your company's previous submissions. This is not the purpose of a reconsideration. A reconsideration panel is put together to provide expert analysis and advice on a scientific question, and not to address information or issues that were not expressed in the negative decision letter.
>
> Since we remain at an impasse, and as I indicated in my letter of November 6, 2015, the reconsideration of this submission, control number 162270 is cancelled, and the Notice of Non-Compliance –Withdrawal issued on July 28, 2014 is now final.

[5] In its Notice of Application to the Federal Court, Apotex sought an order directing the Minister to continue the reconsideration process without fettering her discretion by insisting on a definition of bioequivalence prescribed by policies and guidelines, along with "[s]uch further and other relief as [the] Honourable Court may deem just." The Notice of Application explains in some considerable detail why the Minister's formulation of the question was unreasonable.

[6] After a thorough consideration of the merits of the competing questions, Justice Roy concluded that the question, as formulated by the Minister, was reasonable. The Minister did not, according to the judge, fetter her discretion by insisting that the question to be put to the panel include consideration of bioequivalence. Exclusion of bioequivalence in favour of safety and effectiveness alone "would be outside the scope of the Regulations" (at para. 108).

[7] On appeal, Apotex recast its position. While maintaining the question was unreasonable, Apotex now argues that the Minister had no authority to cancel the reconsideration process entirely. In its Notice of Appeal (see, for example, paragraph 11(h)-(j)), Apotex asserts that it

had a legitimate expectation that the reconsideration process would continue on the basis of the Minister's question, notwithstanding its continued disagreement with the question to be put to the expert panel.

[8] Apotex did not raise this as a ground in its Notice of Application. No relief was sought compelling the Minister to continue with the process, rather, the relief was to require the Minister to frame the question without regard to bioequivalence. The lawfulness of the decision to unilaterally cancel the reconsideration process was not an issue before Justice Roy. Apotex argues that the question was embedded, necessarily, in the challenge to the reasonableness of the scientific question.

[9] Notwithstanding counsel for Apotex's argument, the question whether Apotex had a legitimate expectation that the process would continue in the absence of Apotex's agreement with the question is not properly before us, and I am otherwise satisfied, based on the reasons given by the Federal Court, that the question as framed by the Minister was reasonable.

[10] I would therefore dismiss the appeal with costs in the amount of $5,000.

"Donald J. Rennie"

J.A.

"I agree
Wyman W. Webb J.A."

"I agree
Richard Boivin J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-319-17
STYLE OF CAUSE:	APOTEX INC. v. MINISTER OF HEALTH AND ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	APRIL 9, 2019
REASONS FOR JUDGMENT BY:	RENNIE J.A.
CONCURRED IN BY:	WEBB J.A. BOIVIN J.A.
DATED:	APRIL 24, 2019

APPEARANCES:

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