Date: 20080123

Docket: A-283-07

Citation: 2008 FCA 25

CORAM: **DÉCARY J.A.**
NADON J.A.
TRUDEL J.A.

BETWEEN:

BAYER HEALTHCARE AG and
BAYER INC.

Appellants

and

SANDOZ CANADA INCORPORATED and
THE MINISTER OF HEALTH

Respondents

Heard at Toronto, Ontario, on January 21, 2008.

Judgment delivered at Toronto, Ontario, on January 23, 2008.

REASONS FOR JUDGMENT BY: TRUDEL J.A.

CONCURRED IN BY: DÉCARY J.A.
NADON J.A.

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REASONS FOR JUDGMENT

TRUDEL J.A.

[1] On April 18, 2006, the Minister of Health (the Minister) issued a Notice of Compliance (NOC) in favour of Sandoz Canada Incorporated (Sandoz) allowing it to market an intravenous drug called ciprofloxacin (Sandoz's Vials).

[2] Bayer's application for judicial review of the Minister's decision was dismissed by O'Reilly J. of the Federal Court [2007 FC 590]. Hence, the present appeal.

Relevant Facts

[3] Bayer has NOCs for two different ciprofloxacin I.V. drug products: one called CIPRO® I.V. (first approved in October 7, 1991), referred to as Bayer's Vials, and the other called CIPRO® I.V. Minibags (first approved on March 13, 1998), referred to as Bayer's Minibags (Patent '006 which expires on March 26, 2008).

[4] At the time Sandoz's contested NOC was issued, patents against the Bayer's Vials were no longer listed on the Patent Register as Bayer had since withdrawn its Vials from the Canadian market.

[5] The procedures leading to the issuance of the contested NOC were started by Sabex taken over since by Sandoz. This corporate change being irrelevant, I refer to Sandoz when reviewing the submission's process.

[6] Sandoz obtained a NOC for its Vials in September 2004. About 3 weeks later, that NOC was rescinded by Health Canada when the Minister's officials realized that Bayer's Minibags was the Canadian reference product used by Sandoz in its Abbreviated New Drug Submission (ANDS) for bioequivalence purposes, not the Bayer's Vials.

[7] Patent '006 being listed on the Patent Register, Sandoz could not receive a NOC without first addressing that patent as required by the *Patented Medicines (Notice of Compliance) Regulations* (PM (NOC), SOR/ 93-133).

[8] Therefore, a Notice of Non-Compliance was issued to Sandoz and it was advised of the possibility of establishing pharmaceutical equivalence of its product "with the 10 mg/mL strength of the innovator product marketed in an equivalent jurisdiction" (Notice of Non-Compliance, AB VII, Tab 37, 7/151).

[9] Sandoz did, providing physiocochemical studies comparing its Vials to the American manufactured equivalent of Bayer's Vials. However, the ANDS continued to include a reference to Bayer's Minibags in that Sandoz submitted that an impurity contained in its product was tolerable given that the same impurity existed in Bayer's Minibags.

[10] These facts brought to life the issue at bar in front of the first Judge: Did the Minister err in deciding that the Regulations do not apply in the circumstances and, as a consequence, in granting Sandoz a NOC for its product?

Judgment of the Federal Court

[11] The Judge, on a standard of correctness, upheld the Minister's decision and dismissed the application for judicial review with costs.

Standard of review

[12] The appropriate standard of review to be applied by the Federal Court in an application for judicial review of a determination by the Minister that a generic drug manufacturer is not required to address a particular patent under the *NOC Regulations* is correctness for questions of law, and

patent unreasonableness for questions of fact. (*Ferring Inc. v. Canada (Minister of Health)*, 2007 FCA 276).

[13] Our Court will not interfere with the first Judge's decision unless there is a palpable and overriding error (*Housen* v. *Nikolaisen*, 2002 CSC 33).

Analysis

[14] To answer the question at bar, the Judge referred to subsections 5(1) and 5(1.1) of the *PM(NOC) Regulations* as they existed prior to October 2006. Subsection 5(1) has been amended since while subsection 5(1.1) has been revoked (SOR/ 2006-242).

[15] For the essential, I agree with the first Judge and I propose to dismiss this appeal for the reasons that follow.

[16] The Judge correctly concluded that obligations under subsection 5(1) would arise only in circumstances where the generic manufacturer makes a comparison to a patented drug for demonstrating bioequivalence. He found that "Sandoz did not compare its product with, or refer to, Bayer's mini-bag for purposes of showing bioequivalence with it" [see paragraph 19]. There was evidence upon which he could rely to reach that conclusion.

[17] The record shows that the Minister found that reference to Bayer's Minibags in the ANDS concerned only the establishment of a safe limit for a certain impurity. It formed no part of any

comparison for establishing bioequivalence, [Ms. Bowes Supplemental Affidavit, AB VII, Tab 35, at paragraph 5; and cross-examination, AB VII, Tab 36, p. 6/313]. Therefore, I see no reason to disturb the Judge's finding, as he made no palpable or overriding error. Since Sandoz was not relying on Bayer's Minibags for bioequivalence, it did not have to address the '006 patent, pursuant to subsection 5(1).

[18] The Judge also found that subsection 5(1.1) did not apply in this case. I agree. Subsection 5(1) of the *PM(NOC) Regulations* applied to Sandoz's ANDS, and the relevant patents had expired. Since subsection 5(1) applied, subsection 5(1.1) did not. There was also evidence on record from the Minister to the effect that Bayer's patented drug contains a different strength of ciprofloxacin than the Sandoz drug, allowing the Judge to conclude as he did.

[19] It becomes unnecessary to discuss any other arguments to dispose of this appeal, which I propose to dismiss with costs.

[20] The parties are at liberty to submit a motion for directions regarding the assessment of costs pursuant to Rule 403.

"Johanne Trudel"

J.A.

"I agree
Robert Décary"

"I agree
M. Nadon"

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-283-07

(AN APPEAL ON BEHALF OF THE APPELLANTS, FROM THE JUDGMENT OF O'REILLY J., OF THE FEDERAL COURT, DATED JUNE 6, 2007, REGARDING AN APPLICATION FOR JUDICIAL REVIEW; TRIAL FILE No. T-775-06)

STYLE OF CAUSE: BAYER HEALTHCARE AG and BAYER INC.

Appellant

and

SANDOZ CANADA INCORPORATED
and THE MINISTER OF HEALTH

Respondents

PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	JANUARY 21, 2008
REASONS FOR JUDGMENT BY:	TRUDEL, J.A.
CONCURRED IN BY:	DÉCARY J.A. NADON J.A.
DATED:	JANUARY 23, 2008

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