Federal Court of Appeal | Cour d'appel fédérale

Date: 20100421

Docket: A-33-10

Citation: 2010 FCA 111

CORAM: **NOËL J.A.**
DAWSON J.A.
STRATAS J.A.

BETWEEN:

ASTRAZENECA CANADA INC. and ASTRAZENECA AKTIEBOLAG

and

ASTRAZENECA CANADA INC. and ASTRAZENECA AB

Appellants

and

APOTEX INC. and THE MINISTER OF HEALTH

Respondents

Heard at Ottawa, Ontario, on April 21, 2010.

Judgment delivered from the Bench at Ottawa, Ontario, on April 21, 2010.

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

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REASONS FOR JUDGMENT OF THE COURT
(Delivered from the Bench at Ottawa, Ontario, on April 21, 2010.)

NOËL J.A.

[1] This is an appeal from a decision of Hughes J. (the Federal Court Judge) upholding the interlocutory order of Prothonotary Aalto (the Prothonotary) refusing to strike the affidavit of John Hems (Hems affidavit) from the record. The proceedings arise in the course of two applications by

AstraZeneca Canada Inc. and AstraZeneca AB (the appellants) under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the Regulations) to prevent Apotex Inc. (Apotex) from selling its version of esomeprazole magnesium tablets.

[2] The Hems affidavit indicates that Apotex will only use one of two suppliers identified in a portion of the Abbreviated New Drug Submissions (ANDS) disclosed to the appellants in support of the Notices of Allegations (NOAs). The appellants maintain, as they did before the Prothonotary and the Federal Court Judge, that in withdrawing one of the two suppliers from its ANDS, Apotex is, in effect, making an impermissible change to the factual basis for its NOAs and depriving them of their right under the Regulations to make an informed decision about initiating a prohibition proceeding and assuming potential liability pursuant to section 8 of the Regulations.

[3] According to the appellants, Apotex removed the name of the supplier in question after becoming aware that the drug substance produced by that supplier was an infringing product. They maintain that the NOAs as originally framed are doomed to fail and that Apotex cannot alter them. To the extent that Apotex intends to rely solely on the other supplier, it should withdraw the existing NOAs and initiate fresh ones.

[4] Against this background, the appellants contend that the Federal Court Judge came to a conclusion that was "plainly wrong" in refusing to strike the Hems affidavit (*Z.I. Pompey Industrie v. ECU-Line N.V.*, 2003 SCC 27, (2003), 224 D.L.R. (4th) 577 at paragraph 18. See also *Merck & Co. v. Apotex Inc.*, 2003 FCA 488, [2004] 2 F.C.R. 459 at paragraphs 19 and 20).

[5] Assuming, without deciding, that the supplier in question was removed for the reason alleged by the appellants, the only basis on which Apotex's NOAs can be said to have been bound to fail is if the two suppliers identified in the ANDS were joint rather than alternative suppliers. The Federal Court Judge read the disclosure as indicating that Apotex would use one supplier or the other but not both. That is the basis on which he found that, by removing the supplier in question, Apotex was not materially altering the NOAs but merely narrowing them. This is a reading that was open to him when regard is had to the disclosed portions of the ANDS.

[6] The Federal Court Judge's further conclusion that the appellants were not prejudiced by the change is also supported by the record. In particular, the appellants were not aware of Apotex's source of supply when they launched their prohibition proceedings since this fact had yet to be disclosed. It follows that the disclosure could not have influenced the appellants' decision to initiate the proceedings and expose themselves to section 8 damages. Furthermore, the fact that the prohibition proceedings are being pursued despite the withdrawal of the supplier suggests that the appellants would have initiated their proceedings and assumed the potential section 8 liability whether or not the supplier in question had been named.

[7] Finally, the decision of the Federal Court in *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1381 (at paragraph 9) is of no assistance to the appellants. In that case, Simpson J. was concerned that the second person, by incorporating a revised product monograph in its NOA, was raising a novel ground of non-infringement. No such issue arises here.

[8] The appeal will be dismissed with costs.

"Marc Noël"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-33-10
(APPEAL FROM AN ORDER OF THE HONOURABLE JUSTICE HUGHES OF THE FEDERAL COURT OF CANADA DATED NOVEMER 24, 2009, NO. T-371-08 AND T-372-08.)	
STYLE OF CAUSE:	AstraZeneca Canada Inc. and AstraZeneca Aktiebolag and AstraZeneca Canada Inc. and AstraZeneca AB – and – Apotex Inc. and the Minister of Health
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	April 21, 2010
REASONS FOR JUDGMENT OF THE COURT BY:	Noël, Dawson, Stratas JJ.A.
DELIVERED FROM THE BENCH BY:	Noël J.A.

APPEARANCES:

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Andrew R. Brodkin	FOR THE RESPONDENT (Apotex Inc.)

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