

Federal Court
of Appeal



Cour d'appel
fédérale

Date: 20120229

Docket: A-211-11

Citation: 2012 FCA 68

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

BETWEEN:

APOTEX INC.

Appellant

and

**ASTRAZENECA CANADA INC. AND
AKTIEBOLAGET HÄSSLE**

Respondents

Heard at Toronto, Ontario, on February 28, 2012.

Judgment delivered at Toronto, Ontario, on February 29, 2012.

REASONS FOR JUDGMENT BY:

STRATAS J.A.

CONCURRED IN BY:

**DAWSON J.A.
TRUDEL J.A.**

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REASONS FOR JUDGMENT

STRATAS J.A.

[1] Apotex Inc. appeals from the judgment dated May 20, 2011 of the Federal Court (*per* Justice Mosley) (2011 FC 598) which dismissed an appeal from an order dated April 8, 2011 of Prothonotary Lafrenière.

[2] In the relevant portions of his order, the Prothonotary granted leave to the respondents to amend their pleading by adding five paragraphs. He refused leave to add two other paragraphs. That aspect of his order has not been appealed.

[3] Broadly speaking, the five paragraphs allege that Apotex is estopped from litigating certain findings of fact made in a decision of the United States District Court, Southern District of New York. They read as follows:

43. Apotex's Omeprazole capsules are the same formulation in Canada and the United States.
44. The proceeding in the United States District Court, Southern District of New York (*In re Omeprazole Patent Litigation*, M-21-81, MDL Docket No. 1291) ("the U.S. Proceeding"):
 - (a) involved the same parties (or their privies) that are before the Court in the present action;
 - (b) determined that Apotex's Omeprazole capsules infringe U.S. Patent No. 4,786,505 ("505"), the United States equivalent of the '693 patent;
 - (c) determined that Apotex failed to show that any claims of the '505 patent are invalid;
 - (d) resulted in a final decision (*In re Omeprazole Patent Litigation*, 490 F. Supp. 2d 381 (S.D.N.Y. 2007), affirmed by 281 Fed. App. 974 (Fed. Cir. 2008) and 536 F. 3d 1361 (Fed. Cir. 2008), petition for writ of certiorari denied by 129 S. Ct. 1593).
45. Matters of fact were fully litigated and finally decided in the U.S. Proceeding and by reason of issue estoppel and abuse of process are binding in respect of the present action. The findings of fact that are binding in the present proceeding include the following:

- (a) Apotex's Omeprazole capsules all use identical pellets;
 - (b) Apotex's Omeprazole capsule pellet cores contain omeprazole, povidone ("PVP"), magnesium hydroxide, and mannitol;
 - (c) Apotex applies an enteric coating to its Omeprazole capsule pellet cores;
 - (d) Apotex's Omeprazole capsule pellets are dried until the moisture content is not more than 1.5% by weight;
 - (e) Apotex's Omeprazole capsule pellets contain an enteric coating layer that includes copolymerized methacrylic acid ("MACP") and triethyl citrate;
 - (f) Apotex's Omeprazole capsules are oral pharmaceutical preparations;
 - (g) Apotex's Omeprazole capsule pellets contain a therapeutically effective amount of omeprazole;
 - (h) Apotex's Omeprazole capsule pellets have cores with a microenvironmental pH between 7 and 12;
 - (i) Apotex's Omeprazole capsule pellets have a core region containing omeprazole, a sublayer around the core region, and an enteric coating;
 - (j) The sublayer in Apotex's Omeprazole capsule pellets is 2 to 6 microns thick;
 - (k) Apotex's Omeprazole capsule pellets have a continuous, inert sublayer that hugs the surface of the core and separates the core from the enteric coating; and
 - (l) Apotex's Omeprazole capsule pellets contain an *in situ* formed sublayer that is inert, continuous and rapidly disintegrating in water.
46. Further, by reason of issue estoppel and abuse of process, excluding matters regarding claim construction, Apotex is precluded from contesting or making any allegations inconsistent with the findings of fact that were fully litigated and finally decided in the U.S. Proceeding as they are binding in respect of the present action.

48. Further, in *Apotex Inc. v. AB Hassle, AstraZeneca AB and AstraZeneca Canada Inc.*, 2003 FCA 409 (“the Canadian Proceeding”), a final decision in a matter involving the same parties (or their privies) that are before the Court in the present action, the Court of Appeal determined that “claim 1 describes a pharmaceutical preparation which, in its finished product form, contains a subcoating or separating layer between the core and enteric coating, however the subcoating or separating layer is formed”. By reason of issue estoppel and abuse of process, this finding is binding in the present action.

[4] Before the Prothonotary, Apotex argued that the paragraphs sought to be added to the pleading are not sustainable in law and would raise significant new issues at a late stage of the proceedings, causing it irreparable prejudice. The Prothonotary rejected these arguments in the case of these five paragraphs. He concluded that the amendments would survive a motion to strike and would not cause irreparable prejudice to Apotex.

[5] Apotex advanced substantially the same arguments before the Federal Court judge. The Federal Court judge found that the Prothonotary’s decision to grant the amendments was not vital to the final outcome of the case. Accordingly, it was incumbent on Apotex to demonstrate that the Prothonotary based his decision on a wrong principle or upon a misapprehension of the facts. The Federal Court judge found that Apotex had not made this demonstration. Further, the Federal Court judge observed that even if he exercised his discretion *de novo*, he would have allowed the amendments.

[6] In its written submissions in this Court, Apotex advanced substantially the same arguments made before the Federal Court. However, at the hearing of this appeal, Apotex limited its submissions in two respects. First, it conceded that the Federal Court was right in applying a

deferential standard of review, *i.e.*, Apotex must demonstrate that the Prothonotary based his decision on a wrong principle or upon a misapprehension of the facts. Second, in light of a recent adjournment of the upcoming trial, Apotex no longer argued that the amendments would cause it irreparable prejudice.

[7] In my view, substantially for the reasons offered by the Federal Court, Apotex has not demonstrated that, in granting the amendments, the Prothonotary based his decision on a wrong principle or upon a misapprehension of the facts.

[8] In this Court, Apotex emphasized that the amendments could not succeed in law. It submitted that issue estoppel cannot arise from the foreign court's construction of the claims in the patent. It invoked authority to support this: *Johnson & Johnson Inc. v. Boston Scientific Ltd.*, 2008 FC 552. In its view, the facts alleged in the paragraphs sought to be added to the pleading are inextricably bound or related to the foreign court's construction of the claims.

[9] A review of the paragraphs sought to be added to the pleading shows that this argument cannot be accepted. On their face, the paragraphs allege facts, not the foreign court's construction of the claims in the patent, and allege a legal result, that issue estoppel arises from them. Indeed, paragraph 46, set out above, alleges that Apotex is barred from relitigating matters but it expressly excludes matters of claims construction. In my view, it is not plain and obvious at this time that the facts alleged are inextricably bound or related to the foreign court's construction of the claims and that these paragraphs cannot succeed in law.

[10] It will be for the trial judge to determine on the evidence whether the facts alleged in these paragraphs are proven and whether, in law, they give rise to issue estoppel.

[11] Therefore, for the foregoing reasons, I would dismiss the appeal with costs.

“David Stratas”

J.A.

“I agree
Eleanor R. Dawson J.A.”

“I agree
Johanne Trudel J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-211-11

APPEAL FROM AN ORDER OF THE HONOURABLE MR. JUSTICE MOSLEY OF THE FEDERAL COURT DATED MAY 20, 2011, DOCKET NO. T-1409-04.

STYLE OF CAUSE: APOTEX INC. v.
ASTRAZENECA CANADA
INC. AND AKTIEBOLAGET
HÄSSLE

PLACE OF HEARING: Toronto, Ontario

DATE OF HEARING: February 28, 2012

REASONS FOR JUDGMENT BY: STRATAS J.A.

CONCURRED IN BY: DAWSON J.A.
TRUDEL J.A.

DATED: February 29, 2012

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