

Federal Court of Appeal



Cour d'appel fédérale

Date: 20140314

**Dockets: A-462-11
A-27-12**

Citation: 2014 FCA 66

**CORAM: SHARLOW J.A.
PELLETIER J.A.
MAINVILLE J.A.**

Docket: A-462-11

BETWEEN:

**SANOFI-AVENTIS, SANOFI-AVENTIS
DEUTSCHLAND GmbH
and SANOFI-AVENTIS CANADA INC.**

Appellants

and

APOTEX INC.

Respondent

Docket: A-27-12

AND BETWEEN:

**SANOFI-AVENTIS, SANOFI-AVENTIS
DEUTSCHLAND GmbH
and SANOFI-AVENTIS CANADA INC.**

Appellants

and

APOTEX INC.

Respondent

Heard at Toronto, Ontario, on October 30, 2013.
Judgment delivered at Ottawa, Ontario, on March 14, 2014.

REASONS FOR JUDGMENTS BY:

MAINVILLE J.A.

CONCURRED IN BY:

**SHARLOW J.A.
PELLETIER J.A.**

Federal Court of Appeal



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REASONS FOR JUDGMENTS

MAINVILLE J.A.

[1] These reasons concern two appeals brought by Sanofi-Aventis, Sanofi-Aventis Deutschland GmbH and Sanofi-Aventis Canada Inc. (collectively referred to herein as “Sanofi”) in dockets A-462-11 and A-27-12. These appeals were heard with appeals in dockets A-191-12, A-193-12, A-397-12 and A-474-12 concerning an action commenced by Apotex Inc. (“Apotex”) on August 14, 2009 seeking compensation from Sanofi pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (“*NOC Regulations*”) with respect to its generic version of the drug ramipril.

[2] This Court has concurrently issued judgments for the appeals in dockets A-191-12, A-193-12, A-397-12 and A-474-12 for reasons cited as 2014 FCA 68. These reasons should be read in conjunction with the reasons issued in the other related appeals.

[3] The appeal in docket A-462-11 is from an order of Snider J. of the Federal Court (“Trial Judge”) dated November 25, 2011 which dismissed Sanofi’s appeal from an order of Prothonotary Aalto dated October 12, 2011 denying its motion seeking amendments to its statement of defence to include allegations respecting the two following issues.

[4] The first amendment sought to assert that in the hypothetical market which had to be established to determine the level of compensation owed to Apotex under section 8 of the *NOC Regulations*, Pharmascience Inc. (“Pharmascience”) would have been the first generic drug manufacturer to enter the generic ramipril market.

[5] The second amendment sought to add to the statement of defence that the HOPE indications (Heart Outcomes Prevention Evaluation *i.e.* use of ramipril in the prevention of cardiovascular events and of stroke, diabetes and congestive heart failure) for Apotex's generic version of ramipril was a significant unapproved indication, and that section 8 of the *NOC Regulations* does not contemplate recovery of damages in respect of lost sales of a generic drug product for such an unapproved indication.

[6] The appeal in docket A-27-12 is from another order of the Trial Judge dated January 11, 2012 which granted in part a motion brought by Apotex seeking to strike certain portions of Sanofi's expert reports. As a result of that order, passages from the report of Dr. Carbone that quantified the impacts of the HOPE indications on Apotex's market share were struck out, as well as passages from the report of Mr. Hamilton that sets out his estimate of Apotex's lost profits in the scenario where Pharmascience was regarded as the first generic drug manufacturer entering the generic ramipril market.

[7] At the time it submitted its motion for amendments to its defence in the Apotex litigation, Sanofi was also involved in additional litigation involving ramipril and section 8 of the *NOC Regulations* with other generic drug manufacturers, notably Laboratoire Riva Inc. and Teva. Sanofi sought similar amendments in all three proceedings, and all these motions were heard and decided together by Prothonotary Aalto.

[8] Prothonotary Aalto noted that Sanofi had sought these amendments to its pleadings (with a related motion to examine a representative of Pharmascience) some three months prior to the trials

in both the Teva and Apotex proceedings. The prothonotary also noted that Sanofi had cast the two amendments in dispute as mere “clarifications” or house keeping amendments.

[9] After a careful review of the parties’ submissions, Prothonotary Aalto took the view that, contrary to Sanofi’s representations, both suggested amendments added new, substantial and largely speculative allegations. The prothonotary further took into account the late timing of the amendments relative to the then-looming trial dates, and concluded that Apotex would be prejudiced by the real risk of having the trial adjourned as a result of the need to alter expert reports which had already been exchanged between the litigants.

[10] Reviewing the prothonotary’s decision *de novo*, the Trial Judge dismissed Sanofi’s appeal for essentially the same reasons as those given by the prothonotary. The Trial Judge concluded, in light of all the circumstances, that the interests of justice would not be served by allowing the amendments.

[11] In her subsequent order striking out passages from the reports of Dr. Carbone and Mr. Hamilton, the Trial Judge found that these passages were directly related to the struck pleadings and therefore could not be admitted into evidence.

[12] The litigants rightfully acknowledge that the result of the appeal on the amendments governs the result in the other appeal.

[13] The facts that are relevant to Sanofi's appeal on the amendments, and the applicable principles, are substantially the same as those in docket A-460-11 (*Sanofi v. Teva Canada Limited*), and the outcome must be the same. Judgment dismissing the appeal in docket A-460-11 was rendered concurrently with this one, for reasons cited as 2014 FCA 65. Sanofi's appeal on the amendments in this case will be dismissed for same reasons. It necessarily follows that Sanofi's appeal of the order striking passages from the reports of Dr. Carbone and Mr. Hamilton must also be dismissed.

[14] I would therefore dismiss both appeals, with costs in favour of Apotex.

"Robert M. Mainville"

J.A.

"I agree.
Karen Sharlow J.A."

"I agree.
J.D. Denis Pelletier J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-462-11

**(APPEAL FROM AN ORDER OF THE HONOURABLE JUSTICE SNIDER OF THE
FEDERAL COURT DATED NOVEMBER 25, 2011, IN COURT FILE NO. T-1357-09.)**

STYLE OF CAUSE: SANOFI-AVENTIS, SANOFI-
AVENTIS DEUTSCHLAND GmbH
and SANOFI-AVENTIS CANADA
INC. v. APOTEX INC.

PLACE OF HEARING: TORONTO, ONTARIO

DATE OF HEARING: OCTOBER 30 AND 31, 2013

REASONS FOR JUDGMENT BY:

MAINVILLE J.A.

CONCURRED IN BY:

SHARLOW J.A.
PELLETIER J.A.

DATED: MARCH 14, 2014

APPEARANCES:

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David Tait
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FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKETS: A-27-12

**(APPEAL FROM AN ORDER OF THE HONOURABLE JUSTICE SNIDER OF THE
FEDERAL COURT DATED JANUARY 11, 2011, IN COURT FILE NO. T-1357-09.)**

STYLE OF CAUSE: SANOFI-AVENTIS, SANOFI-
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and SANOFI-AVENTIS CANADA
INC. v. APOTEX INC.

PLACE OF HEARING: TORONTO, ONTARIO

DATE OF HEARING: OCTOBER 30 AND 31, 2013

REASONS FOR JUDGMENT BY: MAINVILLE J.A.

CONCURRED IN BY: SHARLOW J.A.
PELLETIER J.A.

DATED: MARCH 14, 2014

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