#### Date: 20071016

**Docket: A-51-06** 

Citation: 2007 FCA 327

# CORAM: SEXTON J.A. SHARLOW J.A. TRUDEL J.A.

**BETWEEN:** 

# ASTRAZENECA AB and ASTRAZENECA CANADA INC.

Appellants

and

# **APOTEX INC. and THE MINISTER OF HEALTH**

Respondents

Heard at Ottawa, Ontario, on October 16, 2007.

Judgment delivered from the Bench at Ottawa, Ontario, on October 16, 2007.

REASONS FOR JUDGMENT OF THE COURT BY:

SHARLOW J.A.

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## **REASONS FOR JUDGMENT OF THE COURT** (Delivered from the Bench at Ottawa, Ontario, on October 16, 2007)

#### SHARLOW J.A.

[1] This is an appeal from the judgment of Justice Layden-Stevenson (2006 FC 7) dismissing the application of the appellant for an order prohibiting the Minister of Health from issuing a notice of compliance to the respondent Apotex Inc. for its 10 and 20 mg magnesium omeprazole tablets until after the expiration of Canadian Patent No. 2,186,037.

[2] The only claim in issue is claim 1. It reads as follows:

1. An oral pharmaceutical dosage form comprising:

(a) a core material that contains a proton pump inhibitor and an alkaline reacting compound;

(b) an enteric coating layer comprising an enteric coating polymer; and

(c) a water soluble separating layer that is formed in situ as a water soluble salt between the core material and the enteric coating layer by a reaction between the enteric coating polymer and the alkaline reacting compound.

[3] Justice Layden-Stevenson construed element (a) as requiring the proton pump inhibitor and the alkaline reacting compound to be two different substances. The appellant argues that this construction is incorrect, and that the material described in element (a) could be a single substance that is both a proton pump inhibitor and an alkaline reacting compound.

[4] The main argument for the appellant is that Justice Layden-Stevenson, having recognized that the language of element (a) could include a single substance that functions as both a proton pump inhibitor and an alkaline reacting compound, was not entitled to consider any other interpretation. We do not accept that argument. Justice Layden-Stevenson was faced with a situation where the claim language was capable of bearing more than one meaning. To resolve the ambiguity, she considered the language of the patent claim and the disclosure, informed by a detailed analysis of conflicting expert evidence. We can find no error in her analysis or her conclusion.

[5] It is undisputed that the Apotex product will have a core that does not contain an alkaline reacting compound that is separate from the proton pump inhibitor. It follows that Justice Layden-Stevenson was correct to find that the non-infringement allegation is justified, and to dismiss the prohibition application.

[6] The appeal will be dismissed with costs.

"K. Sharlow" J.A.

## FEDERAL COURT OF APPEAL

## NAMES OF COUNSEL AND SOLICITORS OF RECORD

**DOCKET:** 

A-51-06

(APPEAL FROM AN ORDER OF LAYDEN-STEVENSON J. DATED JANUARY 4, 2006, DOCKET NO. T-766-03)

**STYLE OF CAUSE:** 

ASTRAZENECA AB and ASTRAZENECA CANADA INC. and APOTEX INC. and THE MINISTER OF HEALTH

**PLACE OF HEARING:** 

**DATE OF HEARING:** 

**REASONS FOR JUDGMENT OF THE COURT BY:** 

**DELIVERED FROM THE BENCH BY:** 

## **APPEARANCES**:

Y. Kang S.A. Beeser

A. R. Brodkin Mr. Rick Tuzi

No one appearing

## **SOLICITORS OF RECORD**:

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OCTOBER 16, 2007

**URT BY:** SEXTON, SHARLOW, TRUDEL JJ.A.

SHARLOW J.A.

FOR THE APPELLANTS

FOR THE RESPONDENT APOTEX INC.

FOR THE RESPONDENT THE MINISTER OF HEALTH

FOR THE APPELLANTS

FOR THE RESPONDENTS APOTEX INC.

FOR THE RESPONDENTS THE MINISTER OF HEALTH