

Date: 20000628

Docket: A-346-97

CORAM: LÉTOURNEAU, J.A.

EVANS, J.A.

SHARLOW, J.A.

BETWEEN:

MERCK & CO., INC., MERCK FROSST CANADA INC.,

ZENECA LIMITED and ZENECA PHARMA INC.

Appellants

(Plaintiffs)

- and -

APOTEX INC.

Respondent

(Defendant)

Heard at Toronto, Ontario, on Wednesday, June 28, 2000

Judgment delivered from the Bench at Toronto, Ontario, on Wednesday, June 28, 2000

REASONS FOR JUDGMENT OF THE COURT: EVANS J.A.

_. This is an appeal from an order of the Motions Judge, dated April 21, 1997, striking from the pleadings of the plaintiffs, the appellants in this proceeding, one paragraph and requiring an amendment to another, on the ground that, as worded, they did not disclose or advance a reasonable cause of action.

_. The motion arose from an action for patent infringement against the respondent ("Apotex") by the appellants, the patentee and licensees of the medicine lisinopril, which is the subject of Canadian Letters Patent No. 1,275,350 ("the "350 patent"). The patent is due to expire in 2007.

_. A Notice of Compliance ("NOC") was issued to Apotex in 1996 in respect of lisinopril, on the ground that it had imported its stock prior to the issuance of the "350 patent in 1990 and section 56 of the *Patent Act* R.S.C. 1985, c. P-4, as it was at that time, provided that the use of such inventory did not infringe the patent.

_. In *Zeneca Pharma Inc. v. Canada (Minister of National Health and Welfare)* (1996), 69 C.P.R. (3d) 451 (F.C.A.) this Court held that it was no impediment to the issuance of a NOC to Apotex for lisinopril that its pre-patent inventory might expire during the life of the "350 patent. The Court said (at p. 453):

It must be assumed that such party will observe the limits of its rights under s. 56 to sell only the pre-patent inventory.

_. The paragraphs, as worded, that the Motions Judge struck from the pleadings in the patent infringement action, instituted by the appellants shortly after the issuance of the NOC, are as follows:

19. Apotex has applied to have its APO-LISINOPRIL designated as a listed drug product under the *Ontario Drug Benefit Act*, R.S.C. C-O.10, 1990, as amended. In support of its application, as required by the applicable regulations, Apotex has submitted evidence that it is able to supply APO-LISINOPRIL in a quantity sufficient to meet the

anticipated demand for the product.

20. Apotex will continue to offer for sale and sell Lisinopril and APO-LISINOPRIL in Canada in response to the demand for same.

_. The Motions Judge struck paragraph 20 as worded, on the ground that it spoke "to the indefinite future" and that since a statement of claim for patent infringement may address past and present infringement "(and perhaps on a *quia timet* basis infringement in the immediate future"), it should not enable the plaintiffs on discovery to inquire about "possible infringement at an indefinite time in the future." He permitted an amendment of paragraph 20 so that it asserted that the defendant continues to offer for sale and sells the medicine in question. The Motions Judge found that paragraph 19 did not advance the *quia timet* aspect of the plaintiffs' action.

_. The appellants allege that the Motions Judge erred in that he failed to appreciate that this part of the pleadings supported their claim for an injunction *quia timet*, that is, an injunction to restrain an infringement that has not yet occurred but is about to occur. In order to obtain such an injunction a plaintiff must assert facts, which usually include an expressed intention on the part of the defendant to infringe, that show a high probability that, without the injunction, an infringement will occur imminently or in the near future: see Robert J. Sharpe, *Injunctions and Specific Performance*, 3rd edn. (Canada Law Book Inc.; 1999; Aurora).

_. We are not persuaded that the Motions Judge misunderstood either the nature of the pleadings, or the relevant law. In our opinion, the assertions in paragraphs 19 and 20 do not disclose the facts normally necessary to obtain an injunction *quia timet*: a high probability that an infringement will otherwise occur and that the infringement is imminent. The Motions Judge accordingly would allow paragraph 20 to remain in the pleadings only if reworded so that it asserted a past or present infringement.

_. A clear intention to commit a future infringement by Apotex" continuing to sell lisinopril after its pre-patent inventory had been exhausted cannot be inferred from the fact that Apotex did not have enough pre-patent inventory to enable it to supply demand until the expiry of the "350 patent, nor from Apotex" refusal to respond to a letter from the appellants seeking an undertaking that it would give up its NOC when its pre-patent inventory was exhausted. Accordingly, in the absence of other facts, neither the facts asserted in paragraphs 19 and 20, nor their supporting particulars, allege that an infringement of the "350 patent is sufficiently probable to justify the grant of an injunction *quia timet* .

_. However, by upholding the Motions Judge's order we do not intend to preclude the appellants from relying on Apo-lisinopril's designation as a listed drug under the *Ontario Drug Benefit Act* to prove a past or present infringement. Nor do we intend to preclude the possibility that the appellants may seek to amend their pleadings with respect to the injunction *quia timet* should the facts so warrant.

_. For these reasons, the appeal will be dismissed with costs.

"John M. Evans"

J.A.

FEDERAL COURT OF CANADA

Names of Counsel and Solicitors of Record

DOCKET: A-346-97

STYLE OF CAUSE: MERCK & CO., INC., MERCK FROSST CANADA
INC., ZENECA LIMITED and ZENECA PHARMA INC.

Appellants

(Plaintiffs)

- and -

APOTEX INC.

Respondent

(Defendant)

DATE OF HEARING: WEDNESDAY, JUNE 28, 2000

PLACE OF HEARING: TORONTO, ONTARIO

REASONS FOR JUDGMENT

OF THE COURT BY: EVANS J.A.

Delivered at Toronto, Ontario on Wednesday, June 28, 2000

APPEARANCES: Mr. J. Nelson Landry

For the Appellants (Plaintiffs) Merck & Co., Inc. and Merck Frosst
Canada Inc.

Mr. Sheldon Hamilton

For the Appellants (Plaintiffs) Zeneca Limited and Zeneca Pharma Inc.

Mr. D. M. Scrimger

For the Respondent (Defendant)

SOLICITORS OF RECORD: Ogilvy Renault

Barristers & Solicitors

1981 McGill College Avenue, Suite 1100

Montreal, Quebec

H3A 3C1

For the Appellants (Plaintiffs) Merck & Co., Inc. and Merck Frosst
Canada Inc.

Solicitors of Record ...cont"d

Smart & Biggar

Barristers & Solicitors

438 University Avenue, Suite 1500

Toronto, Ontario

M5G 2K8

For the Appellants (Plaintiffs) Zeneca Limited and Zeneca Pharma Inc
Goodman Phillips & Vineberg

Barristers & Solicitors

250 Yonge Street, Suite 2400

Toronto, Ontario

M5B 2M6

For the Respondent (Defendant).

FEDERAL COURT OF APPEAL

Date: 20000628

Docket: A-346-97

BETWEEN:

MERCK & CO., INC., MERCK FROSST CANADA INC., ZENECA LIMITED and ZENECA PHARMA INC.

Appellants

(Plaintiffs)

- and -

APOTEX INC.

Respondent

(Defendant)

**REASONS FOR JUDGMENT
OF THE COURT**

