

Date: 20060301

Docket: A-556-05

Citation: 2006 FCA 92

**Present: RICHARD C.J.
EVANS J. A.
SHARLOW J.A.**

BETWEEN:

**BIOVAIL CORPORATION and
LABORATOIRE DES PRODUITS ÉTHIQUES ETHYPHARM**

Appellants

and

**THE MINISTER OF NATIONAL HEALTH AND WELFARE and
RHOXALPHARMA INC.**

Respondents

Dealt with in writing without appearance of parties.

Order delivered at Ottawa, Ontario, on March 1, 2006.

REASONS FOR ORDER BY:

SHARLOW J.A.

CONCURRED IN BY:

**RICHARD C.J.
EVANS J.A.**

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REASONS FOR ORDER

SHARLOW J.:

[1] The respondent Rhoxalpharma Inc., through its successor in interest, Sandoz Canada Inc. (collectively “Rhoxal”) has filed a notice of motion seeking an order dismissing this appeal for mootness. The motion is opposed by the appellants (collectively “Biovail”). Biovail argues that the appeal is not moot and, in the alternative, that it should be heard even if it is moot. Biovail has also asked for an oral hearing of the motion.

[2] In my view, the issues raised by this motion are well settled, and an oral hearing would not assist the Court in disposing of it. This motion will be dealt with on the basis of the written submissions pursuant to Rule 369 of the *Federal Courts Rules*, SOR/98-106, in accordance with the usual practice of this Court.

[3] The appeal is from the order of a judge of the Federal Court dated October 19, 2005 (2005 FC 1424). That order dismissed the application of Biovail under the *Patented Medicines (Notice of Compliance) Regulations*, SOR 93/133, for an order prohibiting the Minister of Health from issuing a notice of compliance to Rhoxalpharma for certain diltiazem hydrochloride tablets until the expiration of the respondents Canadian Patent No. 2,242,224. Rhoxalpharma had applied for a notice of compliance for its product on the basis of a comparison with Biovail's diltiazem product, sold under the trademark "Tiazac".

[4] The application was dismissed because the judge found, based on his construction of the patent and his understanding of Rhoxal's product, that Rhoxal's non-infringement allegation was justified. On October 21, 2005, the Minister issued the notice of compliance to Rhoxal. Biovail filed its appeal on November 18, 2005. In the notice of appeal, Biovail asserts that the judge erred in his construction of the patent, and also erred in his determination of certain characteristics of the Rhoxal product.

[5] A long and unquestioned line of authority from this Court establishes that an appeal from an order dismissing an application for a prohibition order under the NOC Regulations becomes moot when the notice of compliance is issued: *Merck Frosst Canada Inc. v. The Minister of Health and Apotex Inc.* (1999), 240 N.R. 195 (F.C.A.) (leave to appeal dismissed, [1999] S.C.C.A. No. 313), *Pfizer Canada Inc. v. Apotex Inc.* (2001), 266 N.R.371 (F.C.A.), (leave to appeal dismissed, [2001] S.C.C.A. No. 111), *Novartis A.G. v. Apotex Inc.*, 2002 FCA 440, *AstraZeneca AB v. Apotex Inc.*, 2004 FCA 224, (leave to appeal dismissed, [2004] S.C.C.A. No. 391), *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2005 FCA 6.

[6] Biovail alleges that, due to certain questions that have recently been raised about the manufacturing facilities for Rhoxal's product, Rhoxal has not begun and cannot begin to market its product on the basis of the notice of compliance issued to it on October 21, 2005. Biovail argues that because Rhoxal cannot yet use its rights under the notice of compliance, this appeal is not moot.

[7] I am not prepared to determine whether Biovail's allegations are well founded, nor do I believe it is necessary for me to do so. In my view, even if there is some constraint on the ability of Rhoxal to take full advantage of its notice of compliance, this appeal would still be moot. The NOC Regulations provide a forum for a limited adjudication of certain issues relating to patents. The merits of the Minister's determination of bioequivalence between Rhoxal's product and Biovail's comparison product, and the Minister's determinations as to the safety and efficacy of Rhoxal's product, cannot be resolved in proceedings under the NOC Regulations.

[8] Biovail's alternative argument is that this appeal should be heard even if it is moot. The leading case on this point is *Borowski v. Canada (Attorney General)*, [1989] 1 S.C.R. 342. In my view, in this case the key question is whether there is a live controversy between the parties that could be affected in some practical way by a determination of an issue raised in the appeal.

[9] Biovail alleges that Rhoxal's product is not truly equivalent to Biovail's Tiazac product, that it does not meet certain manufacturing standards, that Rhoxal's product has certain dissolution and stability problems, and that Biovail is at risk of harm if the Rhoxal product is permitted to be sold in Canada because a substandard Rhoxal product would undermine public confidence in Biovail's product. In essence, Biovail is arguing that if its appeal is heard, it might succeed in keeping Rhoxal's product off the market, which will not only be in the public interest but will assist Biovail in protecting its position in the market.

[10] Assuming without deciding that the allegations of Biovail indicate the existence of an ongoing dispute between Biovail and Rhoxal with regard to Rhoxal's product, they do not in my view justify the hearing of this moot appeal. I am unable to see how the situation Biovail describes can be distinguished from any of the situations presented in the cases cited above (paragraph 5). Indeed, one might reasonably expect that the kind of dispute described by Biovail exists in many, if not all, cases where a generic drug manufacturer is permitted to compete with an established product.

[11] I would dismiss this appeal with costs, on the ground of mootness.

“K. Sharlow”

J.A.

“I agree
J. Richard C.J.”

“I agree
John M. Evans J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-556-05

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MOTION DEALT WITH IN WRITING WITHOUT APPEARANCE OF PARTIES

REASONS FOR ORDER BY: SHARLOW J.A.

CONCURRED IN BY: RICHARD C.J.
EVANS J.A.

DATED: March 1, 2006

WRITTEN REPRESENTATIONS BY:

Douglas N. Deeth
Heather E.A. Watts

FOR THE APPELLANTS

Marie Lafleur

FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Deeth Williams Wall LLP
Toronto, Ontario

FOR THE APPELLANTS

Fasken Martineau DuMoulin LLP
Montréal, Quebec

FOR THE RESPONDENTS