

Date: 20071119

Docket: A-440-07

Citation: 2007 FCA 368

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

BETWEEN:

**ABBOTT LABORATORIES and
ABBOTT LABORATORIES LIMITED**

Appellants

and

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

Respondents

Dealt with in writing without appearance of parties.

Order delivered at Ottawa, Ontario, on November 19, 2007.

REASONS FOR ORDER BY:

SHARLOW J.A.

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REASONS FOR ORDER

SHARLOW J.A.

[1] The respondent Apotex Inc. has moved for an order dismissing this appeal for mootness. The appellants (collectively “Abbott”) oppose the motion and have asked for an oral hearing. The motion arises in circumstances that are routine in the context of appeals from proceedings under the *Patented Medicines (Notice of Compliance) Regulations* (the “NOC Regulations”). I am not persuaded that an oral hearing would be helpful. I would dispose of this motion under Rule 369.

[2] The relevant circumstances are as follows. Abbott is an innovator drug manufacturer that markets a drug called Biaxin. Apotex, a generic drug manufacturer, filed an abbreviated new drug submission seeking a notice of compliance for its generic version of Biaxin. In order to obtain its notice of compliance, Apotex was required to address certain listed patents. It did so by serving Abbott with a notice of allegation raising issues of invalidity and non-infringement. Abbott commenced an application under the *NOC Regulations* for an order prohibiting the Minister of Health from issuing a notice of compliance to Apotex until after the expiry of the patents in issue. That application was dismissed by Justice O'Reilly on July 17, 2007 (2007 FC 753). The dismissal of the application required the Minister to issue a notice of compliance to Apotex for its generic version of Biaxin once all conditions relating to safety and efficacy were met (*Apotex Inc. v. Canada (Attorney General)* (C.A.), [1994] 1 F.C. 742). Those conditions apparently were met because the notice of compliance was issued on July 27, 2007. On October 1, 2007, Abbott filed a notice of appeal of the decision of Justice O'Reilly.

[3] The only remedy that could have been obtained by Abbott in its application in the Federal Court was an order prohibiting the Minister of Health from issuing a notice of compliance to Apotex for its generic version of Biaxin. Once the prohibition application failed and the Minister issued the notice of compliance that was the subject of that proceeding, the case became moot. That point has been made in numerous cases, most recently in *Eli Lilly Canada Inc. v. Novopharm Limited*, 2007 FCA 359, at paragraph 24. It follows that the motion to dismiss must be granted unless the Court exercises its discretion to hear this appeal despite its mootness: *Borowski v. Canada (Attorney General)*, [1989] 1 S.C.R. 542.

[4] In most cases involving a moot appeal from the dismissal of a prohibition application under the *NOC Regulations*, this Court does not exercise its discretion to hear the appeal. Usually, the key factor in such cases is judicial economy. A prohibition application, regardless of its outcome, does not put an end to any substantive dispute between the parties as to the validity or infringement of the patent or patents in issue. In practical terms, the effect of a dismissal of a prohibition application is analogous to the dismissal of an application for an interlocutory injunction, in the sense that the applicant retains the right to pursue a claim for infringement.

[5] The jurisprudence discloses only one example of a situation in which this Court exercised its discretion to hear a moot appeal from the dismissal of a prohibition application: *Abbott Laboratories v. Apotex Inc.*, 2007 FCA 153. Numerous issues were raised in the appeal in that case, including a question as to whether the principle in *Hoffmann-La Roche & Co. Ltd. v. Commissioner of Patents*, [1955] S.C.R. 414, was still good law. The same point was about to be argued in a number of other prohibition applications in the Federal Court involving strikingly similar circumstances. The appeal was heard on that single point (and dismissed).

[6] In this case, Abbott is arguing essentially that the decision sought to be appealed may have a collateral consequence for Abbott that would justify the continuation of the appeal. The alleged collateral consequence arises from another prohibition application commenced by Abbott against a generic drug manufacturer, Sandoz, which has moved under paragraph 6(5)(b) of the *NOC Regulations* to dismiss that application as an abuse of process, relying on the decision of Justice O'Reilly in this case. Abbott argues that it would be unfairly prejudiced in that case if this appeal is not permitted to continue because the dismissal of its application in that other case might succeed

even though Justice O'Reilly's decision in this case is arguably wrong in law. In support of that argument, Abbott cites *Sanofi-Aventis Canada Inc. v. Novopharm Limited*, 2007 FCA 163 (leave to appeal refused October 25, 2007, Supreme Court of Canada File No. 32105). Apotex argues that, as it has no interest in the Sandoz proceedings, it is unfair to Apotex to give the possible outcome of that case any weight in determining whether this moot appeal should be heard. I agree with Apotex on that point.

[7] However, there is another reason why the argument of Abbott should not prevail. The apparent premise of Abbott's argument is that *Sanofi-Aventis* shifts the balance of rights under the *NOC Regulations*. Abbott suggests that, because *Sanofi-Aventis* gives generic drug manufacturers an advantage over innovator drug manufacturers in respect of motions under paragraph 6(5)(b) of the *NOC Regulations* to dismiss prohibition applications as an abuse of process, innovator drug manufacturers should have a corresponding advantage in the exercise of this Court's discretion to hear moot appeals from judgments dismissing prohibition applications.

[8] I express no opinion on the merits of the Sandoz dismissal motion. However, I acknowledge that the jurisprudence of the Federal Court and this Court, culminating in *Sanofi-Aventis*, may have caused the remedy in paragraph 6(5)(b) of the *NOC Regulations* to appear to be more robust than might have been foreseen by innovator drug manufacturers. Even if that is the case, the possibility of a successful paragraph 6(5)(b) motion in another proceeding normally should bear no weight in the exercise of the discretion of this Court to hear a moot appeal from a judgment dismissing a prohibition application. On that point I agree with the decision of this Court in *Eli Lilly Canada Inc.*

(cited above) (see in particular paragraph 42 of the reasons of Justice Sexton, writing for the majority).

[9] For these reasons, I would grant with costs the motion of Apotex to dismiss this appeal, and I would dismiss the appeal with costs.

“K. Sharlow”

J.A.

“I agree.
J. Richard, Chief Justice”

“I agree.
C. Michael Ryer J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-440-07

STYLE OF CAUSE: Abbott Laboratories and Abbott
Laboratories Limited v.
Apotex Inc. and The Minister of
Health

MOTION DEALT WITH IN WRITING WITHOUT APPEARANCE OF PARTIES

REASONS FOR ORDER BY: SHARLOW J.A.

DATED: November 19, 2007

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