

Date: 20071127

Docket: A-97-07

Citation: 2007 FCA 375

**CORAM: NOËL J.A.
SEXTON J.A.
TRUDEL J.A.**

BETWEEN:

**THE MINISTER OF HEALTH and
THE ATTORNEY GENERAL OF CANADA**

Appellants

and

CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

Respondent

Heard at Ottawa, Ontario, on November 14, 2007.

Judgment delivered at Ottawa, Ontario, on November 27, 2007.

REASONS FOR JUDGMENT BY:

SEXTON J.A.

CONCURRED IN BY:

**NOËL J.A.
TRUDEL J.A.**

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REASONS FOR JUDGMENT

SEXTON J.A.

[1] This is an appeal from the Order of Harrington J. (the “Motions Judge”), which dismissed the appellants’ motion to strike out the Canadian Generic Pharmaceutical Association’s (the “respondent”) Notice of Application without prejudice to the appellants taking the same position when the application for judicial review is heard on the merits.

[2] The respondent is seeking a judicial determination of the *vires* of a recently enacted amendment to section C.08.044.1 of the *Food and Drug Regulations* C.R.C., c. 870 by the *Regulations Amending the Food and Drug Regulations (New Data Protection Regulations)* (the “New Data Protection Regulations”). This appeal was heard concurrently with the appeal of the decision of Shore J. in *Apotex v. Canada (Governor in Council)* 2007 FC 232. In that case, this Court allowed the appeal and held that the question of Apotex’s standing should be allowed to be heard along with the merits of that case. For the reasons that follow, I would dismiss this appeal.

[3] The respondent is an industry association representing most Canadian generic drug manufacturers. Its drugs are approved by comparison with a drug which is already on the market, subject to patent rights as set out in the *Patented Medicine (Notice of Compliance) Regulations*.

[4] The decision to grant or refuse a motion to strike is a discretionary one. When the lower court judge has made a discretionary decision, it will usually be afforded deference by the appellate court. However, the latter will be entitled to substitute the lower court judge’s discretion for its own if the appellate court clearly determines that the lower court judge has given insufficient weight to relevant factors or proceeded on a wrong principle of law: *Elders Grain Co. v. Ralph Misener (The)*, 2005 FCA 139 at paragraph 13. This Court may also overturn a discretionary decision of a lower court where it is satisfied that the judge has seriously

misapprehended the facts, or where an obvious injustice would otherwise result: *Mayne Pharma (Canada) Inc. v. Aventis Pharma Inc.*, 2005 FCA 50, 38 C.P.R. (4th) 1 at paragraph 9.

[5] The Motions Judge did not proceed on a wrong principle of law in finding that the Application should not be struck, as it was not plain and obvious that the Canadian Generic Pharmaceutical Association did not have public interest standing. The test for public interest standing, as articulated by the Supreme Court of Canada in *Canadian Council of Churches v. Canada (Minister of Employment and Immigration)*, [1992] 1 S.C.R. 236 at paragraph 37 has three elements:

- There is a serious issue to be tried;
- The party has a direct interest or a genuine interest in the matter; and
- There is no other reasonable and effective manner in which to bring this issue to the Court.

No serious argument was made with respect to the first and second prongs of this test. The Motions Judge adequately addressed the third prong of this test, and I could find no overriding and palpable error in his conclusion that it was not plain and obvious that there was another reasonable and effective manner in which to bring this issue to the Court. This conclusion is in no way diminished by the result in the companion case to this appeal, *Apotex v. Canada (Governor in Council)* 2007 FCA 374, where this Court held that it was not plain and obvious that Apotex did not have standing to challenge the New Data Protection Regulations. Since there has been no final ruling on whether Apotex has standing to contest the *vires* of the New Data Protection Regulations, it cannot yet be said that it is plain and obvious that there is another manner in which to bring this issue to the Court.

[6] In light of my conclusion with respect to public interest standing, it is unnecessary to comment on the Motion Judge's finding that it was not plain and obvious that the Respondent was not "directly affected" within the meaning of section 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7.

[7] The Motions Judge also did not err in dismissing the appellants' motion "without prejudice" to raising the issue again when the Application is heard on the merits. While not cited by the Motions Judge, the Supreme Court of Canada noted in *Finlay v. Canada (Minister of Finance)*, [1986] 2 S.C.R. 607, 33 D.L.R. (4th) 321 at paragraph 16, that it is a matter of judicial discretion whether to determine the question of standing with final effect as a preliminary matter or to reserve it for consideration on the merits. In deciding that the matter of standing should not be decided now, he noted, at paragraph 25 of his decision that "An application for judicial review is supposed to be decided in a summary way. The Court discourages interlocutory motions in applications for judicial review." I can find no overriding and palpable error in the Motion Judge's discretionary decision to reserve the question of standing for consideration on the merits.

[8] I also find that the Motions Judge did not err in allowing the Canadian Research-Based Pharmaceutical Companies leave to intervene. I would note that this was not opposed by the Minister of Health, and not raised as a ground of cross-appeal by the respondent.

[9] For the above reasons, I would dismiss the appeal with costs.

"J. Edgar Sexton"

J.A.

"I agree
Marc Noël J.A."

"I agree
Johanne Trudel J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-97-07

**APPEAL FROM A JUDGMENT OR ORDER OF THE FEDERAL COURT DATED
FEBRUARY 9, 2007, DOCKET NO. T-1976-06**

STYLE OF CAUSE: THE MINISTER OF HEALTH and THE
ATTORNEY GENERAL OF CANADA v.
CANADIAN GENERIC PHARMACEUTICAL
ASSOCIATION

PLACE OF HEARING: Ottawa, Ontario

DATE OF HEARING: November 14, 2007

REASONS FOR JUDGMENT BY: Sexton J.A.

CONCURRED IN BY: Noël J.A.
Trudel J.A.

DATED: November 27, 2007

APPEARANCES:

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Mr. Edward Hore FOR THE RESPONDENT

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