Date: 20071127

Docket: A-130-07

Citation: 2007 FCA 374

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

BETWEEN:

APOTEX INC.

Appellant

and

THE GOVERNOR IN COUNCIL,
THE MINISTER OF HEALTH and
THE ATTORNEY GENERAL OF CANADA

Respondents

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.

Date: 20071127

Docket: A-130-07

Citation: 2007 FCA 374

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

BETWEEN:

APOTEX INC.

Appellant

and

THE GOVERNOR IN COUNCIL,
THE MINISTER OF HEALTH and
THE ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR JUDGMENT

SEXTON J.A.

[1] This is an appeal by Apotex Inc. ("Apotex") from the Order of Shore J. (the "Motions Judge"), which allowed the respondents' motion to strike out Apotex's Notice of Application and dismissed the proceeding on the basis that Apotex had no standing to bring the application for judicial review.

[2] Apotex 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"). The respondents essentially argue that the judicial review of Apotex is premature: Apotex's Application should be struck as they are not currently affected by the New Data Protection Regulations, though they admittedly will be in the foreseeable future.

[3] This appeal concerns the question of when courts should decide preliminary issues in a Motion to Strike, as well as the relevant considerations regarding the issue of standing in a judicial review that is based primarily on *vires* grounds. For the reasons that follow, I would allow the appeal.

Background

[4] Apotex is a company that manufactures and distributes generic drugs. It is challenging the recently enacted New Data Protection Regulations, which were published on October 18, 2006. In its Notice of Application filed less than a month later, Apotex alleged that the New Data Protection Regulations are *ultra vires* its enabling legislation (subsection 30(3) of the *Food and Drugs Act*, R.S. 1985, c. F-27), and, to the extent should it be found that the New Data Protection Regulations are not *ultra vires*, the enabling legislation is also *ultra vires*.

[5] The operative portion of the New Data Protection Regulations is subsection C.08.004.1(3), which provides as follows (emphasis is my own):

(3) If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug,	(3) Lorsque le fabricant demande la délivrance d'un avis de conformité pour une drogue nouvelle sur la base d'une comparaison directe ou indirecte entre celle-ci et la drogue innovante :
(a) the manufacturer may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission in respect of the new drug before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug; and	a) le fabricant ne peut déposer pour cette drogue nouvelle de présentation de drogue nouvelle, de présentation abrégée de drogue nouvelle ou de supplément à l'une de ces présentations avant l'expiration d'un délai de six ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante;
(b) the Minister shall not approve that submission or supplement and shall not issue a notice of compliance in respect of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.	b) le ministre ne peut approuver une telle présentation ou un tel supplément et ne peut délivrer d'avis de conformité pour cette nouvelle drogue avant l'expiration d'un délai de huit ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante.

[6] The New Data Protection Regulations have two obvious effects: (1) a six-year ban on the filing of a generic Abbreviated New Drug Submission (ANDS) after the date of the first Notice of Compliance (NOC) issued to the innovator's drug; and (2) an eight-year ban on the issuance of an NOC to a generic product after the date of the first NOC issued to the innovative drug.

[7] Apotex is the largest Canadian generic drug manufacturer. Apotex, like most generic companies, typically designs and markets products that are bioequivalent to products already accepted by Health Canada as safe and effective. In an Affidavit by its President, Dr. Bernard Sherman, Apotex presented evidence that stated that the New Data Protection Regulations "directly affect the manner, timing and extent to which Apotex and other generic drug manufacturers can secure marketing approval for their drug products from the Minister of Health." In addition, Dr. Sherman stated that "These regulations will considerably delay Apotex's introduction of drug products, resulting in lost profits and greater drug development expenses."

[8] In his decision that is the subject of this appeal, the Motions Judge first analyzed whether Apotex had the standing required to bring the Application, and subsequently addressed the question of whether the Application should be struck out. The Motions Judge concluded that Apotex was neither directly affected by the New Data Protection Regulations, nor did it have public interest standing. Of note is the Motions Judge's suggestion for how Apotex would be able to obtain standing, located at paragraphs 25 and 27 of his decision (emphasis in original):

> There is no evidence that the Data Protection Regulations have been applied to impose any actual limitation on Apotex -- or on any other drug manufacturer seeking a notice of compliance. As in the cases described above, the possibility that Apotex may at some time in the future be affected by the Regulations does not give it standing now.
>
> […]
>
> At some future time, particularly given the known litigiousness of this industry, the appropriate case will arise in one of two situations. A generic drug manufacturer will make a submission for a notice of compliance for its version of a particular drug made by an innovator manufacturer, and the Minister will make a decision that implements the Data Protection Regulations. In one situation, the Minister may refuse to accept the submission, or to approve it, or to issue a notice of compliance. The generic drug manufacturer can then

> initiate a Judicial Review Application on appropriate grounds (including, if so advised, those raised here). In that Application, the Applicant would name as a Respondent the innovator manufacturer of the drug to which the generic drug is compared. In the second situation, the Minister may accept the submission, approve it, and issue a notice of compliance. The innovative drug's manufacturer can then, on appropriate grounds, initiate a Judicial Review Application. In that Application, the Applicant would name as a Respondent the generic manufacturer of the drug to which the notice of compliance is issued.

[9] Of note in the decision below is the brief reference made to the decision of *Canadian Generic Pharmaceutical Association v. Canada (Governor in Council)* 2007 FC 154, a case also involving the *vires* of the New Data Protection Regulations, in which Harrington J. refused to grant a Motion to Strike against the Canadian Generic Pharmaceutical Association, and also granted Canada's Research-Based Pharmaceutical Companies leave to intervene. In that decision, Harrington J. declined to ultimately adjudicate on the issue of standing, deciding to leave it to the merits of the application for judicial review. He observed at paragraph 26:

> It seems to me that the Association has raised serious issues. It is not plain and obvious to me that it lacks standing in its own right, or as informally representing a class of litigants, or that public interest mitigates against giving it standing. Consequently I shall dismiss the motion, without prejudice to the respondents taking the same points when the application for judicial review is heard on the merits.

[10] The Motions Judge made reference to Harrington J.'s decision, but otherwise did not address Harrington J.'s reasons in the decision below. The appeal of Harrington J.'s decision is being heard concurrently with the case at bar.

Issues

[11] Before any of the issues are addressed, it needs to be emphasized that, above all else, this is an appeal of a motion to strike. It is not an appeal of a preliminary determination of a question of law. Thus, there is really only one question: is it plain and obvious that the application for judicial review is bereft of success?

[12] With this in mind, that question can be divided into four issues:

- What is the standard of review?
- What is the test for allowing a motion to strike?
- Was it plain and obvious that Apotex was not "directly affected" by the New Regulations?
- Was it plain and obvious that Apotex was not entitled to public interest standing?

[13] It is not always appropriate for motions to strike to be the context to make a binding decision on a question of standing, especially when the motion is to strike out an application for judicial review. Rather, a judge should exercise her discretion as to whether it would be appropriate in the circumstances to render a decision on standing, or whether a final disposition of the question should be heard with the merits of the case. Evans J. (as he then was) briefly discussed the considerations a judge should take in exercising her discretion in *Sierra Club of Canada v. Canada (Minister of Finance)* [1999] 2 F.C. 211 (T.D.) ("*Sierra Club*") at paragraph 25 (emphasis added):

> In my view, a court should be prepared to terminate an application for judicial review on a preliminary motion to strike for lack of standing only in very clear cases. At this stage of the proceeding, the court may not have all the relevant facts before it, or the benefit of full legal

> argument on the statutory framework within which the administrative action in question was taken. To the extent that the strength of the applicant's case, and other factors, are relevant to the ground of discretionary standing, the Court may not be in a position to make a fully informed decision that would justify a denial of standing.

I agree with Evans J. that this discretion should be exercised sparingly. This is affirmed by the principle that applications for judicial review are supposed to be decided summarily, and that interlocutory motions are to be avoided. This, indeed, as will be discussed below, explains why the test for the motion to strike on an application for judicial review is that the Application would be "bereft of success."

[14] As a result, I conclude that the Motions Judge erred by commencing his analysis with a preliminary determination on the question of standing. The Motions Judge failed to explicitly exercise his discretion to make a preliminary determination of standing, as permitted in *Finlay v. Canada (Minister of Finance)*, [1986] 2 S.C.R. 607, 33 D.L.R. (4th) 321 at paragraph 16 and *Sierra Club*, *supra*, at paragraph 26. If a judge does not exercise her discretion to consider a preliminary question of law at the outset, then all legal issues considered in a motion to strike must be subsumed within the legal test for a motion to strike. Thus, absent a clear exercise of judicial discretion, it is not correct to make a final decision on standing and then decide on the motion. Rather, the legal standard to grant a motion to strike must inform all legal questions.

Analysis

1) What is the standard of review?

[15] The respondents correctly point out that 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.

2) What is the test for allowing a Motion to Strike?

[16] A motion to strike an application for judicial review is a judicial tool which should be used in very exceptional cases and should only succeed if the application for judicial review is so clearly improper as to be bereft of any chance of success: *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.* [1995] 1 F.C. 588 (C.A.); *Bouchard v. Canada (Minister of National Defence)* (1999) 187 D.L.R. (4th) 314, 255 N.R. 183 (F.C.A.) at paragraph 12; *Syntex (U.S.A.) L.L.C. v. Canada (Minister of Health)* 2002 FCA 289, 292 N.R. 147, 20 C.P.R. (4th) 29 at paragraph 5; *Scheuneman v. Canada (Attorney General)* 2003 FCA 194 at paragraph 7. In the context of an action (as opposed to an application), the test for a motion to strike, as laid out by the Supreme Court of Canada for summary judgment in *Hunt v. Carey Canada Inc.* [1990] 2 S.C.R. 959, 74

D.L.R. (4th) 321 is whether it is "plain and obvious" that the pleadings disclose no reasonable cause of action. Without commenting on the appropriateness of applying a test for striking out an action to a motion to strike out an application, the language used in the *Hunt v. Carey* test is useful in framing the legal issues to be decided in this case.

3) Was it plain and obvious that Apotex was not "directly affected" by the New Regulations?

[17] Subsection 18.1(1) of the *Federal Courts Act*, R.S.C. 1985, c. F-7, limits the right of judicial review to individuals "directly affected" by the matter:

An application for judicial review may be made by the Attorney General of Canada or by anyone directly affected by the matter in respect of which relief is sought.	Une demande de contrôle judiciaire peut être présentée par le procureur général du Canada ou par quiconque est directement touché par l'objet de la demande.

[18] The Motions Judge concluded that, at the instant moment, Apotex was not directly affected by the New Regulations. He stated at paragraph 21 of his Reasons:

> The Data Protection Regulations specify particular limitations on certain manufacturers that seek a notice of compliance for a new drug. Until the situation arises in which a manufacturer has sought a notice of compliance and the Minister has acted on it, or refused to act on it, pursuant to the Data Protection Regulations, the "matter" will have no direct effect, and no party will be directly affected. Until then, neither the issue nor the Applicant is properly before the Court.

[19] This assertion ignores both the wording of the New Data Protection Regulations as well as the context of Apotex's Application. It is unclear how Apotex could possibly seek a Notice of Compliance in the first place. In order to obtain a Notice of Compliance, the NOC Regulations require Apotex to file, *inter alia*, a New Drug Submission ("NDS") or ANDS. However, the New

Data Protection Regulations prohibit Apotex from filing an NDS or ANDS until six years after the date of the first NOC issued to the innovator's drug. Moreover, there is no Ministerial discretion as to whether the Minister can issue a NOC. The Regulations provide that the Minister "shall not issue" an NOC within the eight year period after the innovator's NOC has issued.

[20] In the words of the appellant, "…Apotex is *currently* subject to a direct legislative prohibition" (emphasis in original). Moreover, a generic drug manufacturer, including Apotex, may be less inclined to develop generic drugs if it knows that the Minister will not carry out a comparison study because of the new Regulations. This has impacts that exist in the present, and are not hypothetical. It was not plain and obvious that the prohibition did not affect Apotex's legal and commercial interests; I fail to comprehend how the Motions Judge concluded otherwise.

[21] Moreover, it should be pointed out that this is a *vires* challenge. It is unclear why there is a need of a factual context in the first place. V*ires* challenges often necessarily occur in a factual vacuum. In this case, the challenge is concerned with the enactment of regulations pursuant to an enabling provision. The factual scenario envisioned by the Motions Judge would in no way assist in the adjudication of such questions as the power to enact regulations, or any federalism arguments with respect to the enabling provision.

[22] Without deciding this issue on the merits, it seems to us that Apotex has a very strong argument with respect to being "directly affected" by the New Data Protection Regulations, and hence it is not plain and obvious that the Application for Judicial Review is bereft of success.

4) Was it plain and obvious that Apotex was not entitled to public interest standing?

[23] Seeing that this appeal can be disposed on the conclusion that it was clearly not plain and obvious that Apotex was not directly affected by the New Data Protection Regulations, I need not address this issue.

Conclusion

[24] In conclusion, it was not plain and obvious that Apotex was not directly affected by the New Data Protection Regulations. I would note that in their Memorandum of Fact and Law, Apotex did not request that in allowing the appeal the issue of standing should be decided as a preliminary question. Rather, Apotex only wanted a reinstatement of its Application. I would thus allow the appeal, and remit the matter to be decided by the Judge ultimately hearing the Application, without prejudice to the respondents taking the same points when the application for judicial review is heard on the merits. The appellant shall have its costs in this Court and in the Court below.

"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-130-07
APPEAL FROM A JUDGMENT OR AN ORDER OF THE FEDERAL COURT DATED NOVEMBER 22, 2006, DOCKET NO. T-2047-06.	
STYLE OF CAUSE:	APOTEX INC. v. THE GOVERNORE IN COUNCIL, THE MINISTER OF HEALTH and THE ATTORNEY GENERAL OF CANADA
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:

Mr. Nando Deluca Mr. Miles Hastie	FOR THE APPELLANT
Mr. F.B. Woyiwada Mr. David Cowie	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Goodmans LLP Toronto, Ontario	FOR THE APPELLANT
John H. Sims, Q.C. Deputy Attorney of Canada Ottawa, Ontario	FOR THE RESPONDENTS