

Federal Court



Cour fédérale

Date: 20100120

Dockets: T-371-08
T-372-08

Citation: 2010 FC 65

Toronto, Ontario, January 20, 2010

PRESENT: The Honourable Mr. Justice Hughes

Docket: T-371-08

BETWEEN:

**ASTRAZENECA CANADA INC. and
ASTRAZENECA AKTIEBOLAG**

Applicants

and

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

Respondents

Docket: T-372-08

AND BETWEEN:

**ASTRAZENECA CANADA INC. and
ASTRAZENECA AB**

Applicants

and

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

Respondents

REASONS FOR ORDER AND ORDER

[1] This is a motion brought by the Applicants, AstraZeneca et al. by way of an appeal from the Order of Prothonotary Aalto dated December 18, 2009, in each of these two proceedings. In particular, the Applicants seek to set aside that Order in which:

1. The Prothonotary refused to strike out the Affidavit of John Hems and portions of Apotex's evidence listed in Schedule A, or, in the alternative, for leave to argue the propriety of this evidence at the hearing of these applications;
2. The Prothonotary refused to permit the Applicants to file, by way of reply evidence, a further affidavit of Dr. Stephen Davies in each of these two proceedings.

[2] The Prothonotary provided eight pages of Reasons for his decision in these respects.

[3] It is well understood, having regard to appeals of this kind, that this Court should not disturb an Order of a Prothonotary unless the matter is vital to a final issue in the proceeding, or that the Order was clearly wrong as being based upon a wrong principle or misapprehension of the facts (*Merck & Co. v. Apotex Inc.* (2003), 30 C.P.R. (4th) 40 (F.C.A.)).

[4] As to the facts, the Applicants chose to place before the Prothonotary only an affidavit from a law clerk which provided copies of certain correspondence between the solicitors for the parties and copies of some of the materials in the Court Record in these proceedings. There is no substantive affidavit attesting to any factual basis for striking the Hems' affidavit or allowing the

further Davies' affidavit to be filed. Counsel for the Applicant relies on argument and inferences drawn from the Record in these proceedings to substantiate a basis for the request to strike Hems and allow Davies.

[5] As to the law, there is no provision, as such, in the Federal Courts Rules for striking out evidence before the hearing of an application or for allowing evidence to be filed in reply to evidence filed by a respondent in application proceedings. In similar instances, Orders to such effect have been granted but an exceptional basis for doing so must be established on a case-by-case basis.

[6] First, in respect of striking out the Hems' affidavit and related portions of the Apotex evidence, the Applicants' position, notwithstanding complex arguments of Counsel, is that these portions constitute a withdrawal of certain statements made in Apotex's Notice of Allegation and that somehow, AstraZeneca is prejudiced, particularly should events transpire in certain ways in respect of any section 8 claim Apotex may wish to make under the Patented Medicines (Notice of Compliance) Regulations. S.O.R./93-133, as amended. Essentially, the situation is that, in its Notice of Allegation, Apotex stated that it would be obtaining the essential ingredient for its medicine either from supplier A or supplier B, each of which made the ingredient in a somewhat different way. Hems' affidavit says that Apotex will not be seeking to obtain the ingredient from supplier A, but only from supplier B.

[7] The Applicants argue that they "might" not have launched these proceedings if only supplier B was to be the source of the ingredient and, if they were to persist in the present proceedings only with respect to supplier B, they may lose and be exposed to a section 8 claim. All of this is

speculative. There is no evidence to support these speculations. Apotex is not changing its Notice of Allegation; it is removing one of the grounds for the allegations as to non-infringement. There will be less for the Applicants and the Court to address – it is not a different matter, just less. Any ramifications as to section 8 can be argued, if necessary, at a later time. I agree with the Prothonotary's conclusions at page 5 of his Reasons:

With respect, there is no provision in the Regulations which prevents a party from changing a fact such as this. In effect, Apotex is simplifying the case and narrowing the issues. To take AstraZeneca's position to extreme, Apotex would be compelled to deal with a factual premise upon which they no longer rely in the course of the hearing and argue it as if they were going to use Nosch as a supplier. This would be a wasteful and useless exercise. Apotex have now committed to a position regarding the Nosch material from which it cannot resile. If AstraZeneca is prejudiced by virtue of having prepared its expert affidavits on the basis of the use of the Nosch material, such prejudice can be compensated for in costs at the time of the hearing.

[8] With respect to the proposed Davies' reply affidavit, Applicants' counsel argues that the affidavit addresses two matters. The first is the propriety of certain tests, said to replicate prior art, put in evidence by Apotex; the second is addressed to what has been characterized as an "optical purity" issue, which AstraZeneca argues was not put into play in Apotex's Notice of Allegation.

[9] As to the propriety of the replication by Apotex's affiants of certain prior art, the Applicants argue that they were caught by surprise and could not have anticipated this evidence at an earlier time when they put in their evidence in chief. There are two reasons why this assertion is not appropriate. First, the order in which evidence was to be provided by the parties was the subject of a previous Order of the Prothonotary, which was upheld on appeal by this Court. Applicants were well aware as to how evidence was to be presented and in which order. Second, if the Applicants

were caught by surprise, there was no evidence to this effect before the Prothonotary. Therefore, the Prothonotary was not in error when he concluded, at page 7 of his Reasons:

[1] *Since the three affidavits are not being struck, is AstraZeneca entitled to file reply evidence? The tests for permitting reply evidence are well-known:*

- (a) *the evidence to be adduced will serve the interests of justice;*
- (b) *the evidence will assist the Court;*
- (c) *the evidence will not cause substantial prejudice to the other side;*
- (d) *the evidence was not available at an earlier date.*

(See, Atlantic Engraving v. Lapointe Rosenstein (2002), 23 C.P.R. 4th) 5 (F.C.A.)

In this case I am not satisfied that any compelling case has been made out to satisfy these tests. There is nothing in the Apotex affidavits that is new in the sense that it was unanticipated or could not have been dealt with initially nor will the evidence assist the Court. AstraZeneca cannot rationally believe that having had their clinicians conduct the tests in Examples 4 and 5 that Apotex would not also undertake a similar proves. The evidence of Dr. Davies in the proposed reply affidavit, while relatively short, in large part is speculative, repeats information that is already in the record, or can be dealt with in cross-examination. In my view, reply is not warranted in this case.

[10] As to whether Apotex has gone beyond the allegations made in its Notice of Allegation, the Applicants are free to make this argument, if appropriate, at the hearing of these applications on their merits. There is no need for Davies' affidavit in this regard, as the argument is one of law.

[11] Therefore, the appeal is dismissed with costs to Apotex. The Minister of Health did not appear and no costs for or against the Minister are awarded.

ORDER

THIS COURT ORDERS that:

1. The motion, by way of an appeal in each of these proceedings from Prothonotary Aalto's decision dated December 18, 2009, is dismissed; and
2. Apotex is entitled to costs of each motion as against the Applicants.

"Roger T. Hughes"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS: T-371-08 and T-372-08

STYLE OF CAUSE: AstraZeneca Canada Inc. et al. v. Apotex Inc. and The
Minister of Health

PLACE OF HEARING: TORONTO, ONTARIO

DATE OF HEARING: January 18, 2010

**REASONS FOR ORDER
AND ORDER:** HUGHES J.

DATED: January 20, 2010

APPEARANCES:

Ms. Yoon Kang FOR THE APPLICANTS
Ms. Tracey Stott

Mr. Andrew Brodtkin FOR THE RESPONDENT APOTEX INC.
Mr. Daniel Cappe

No one appeared FOR THE RESPONDENT THE
MINISTER OF HEALTH

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