Date: 20080916

Docket: A-336-08

Citation: 2008 FCA 265

CORAM: **DESJARDINS J.A.**
EVANS J.A.
PELLETIER J.A.

BETWEEN:

APOTEX INC.

Appellant
(Respondent)

and

LUNDBECK CANADA INC.

Respondent
(Applicant)

and

THE MINISTER OF HEALTH

Respondent
(Respondent)

and

H. LUNDBECK A/S

Respondent
(Respondent/Patentee)

Heard at Toronto, Ontario, on September 15, 2008.

Judgment delivered at Toronto, Ontario, on September 16, 2008.

REASONS FOR JUDGMENT BY: EVANS J.A

CONCURRED IN BY: DESJARDINS J.A.
PELLETIER J.A

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REASONS FOR JUDGMENT

EVANS J.A.

[1] This appeal arises from an interlocutory order made in the course of an application by Lundbeck Canada Inc. for an order of prohibition, filed on May 31, 2007, under subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133. In this application, the applicant seeks to prohibit the Minister of Health from issuing a Notice of Compliance to Apotex Inc. for a proposed new generic drug, until the expiry of Canadian Patent No. 1,339,452 ('452 patent) held by H. Lundbeck A/S, the parent company of Lundbeck Canada Inc. The Lundbeck parties will be referred to in these reasons as Lundbeck.

[2] Apotex appeals from a decision of the Federal Court (2008 FC 787) in which Justice Harrington allowed, in part, an appeal from a decision of Prothonotary Morneau, dated March 6, 2008. In that decision, the Prothonotary, who is case managing Lundbeck's application for an order of prohibition, dismissed a motion by Lundbeck to strike an affidavit sworn by Dr. Richard Kellogg, together with its exhibits, and various paragraphs in, and exhibits to, three other affidavits referring to the Kellogg affidavit.

[3] Lundbeck cross-appeals from that part of Justice Harrington's order dismissing its appeal from the Prothonotary's decision to dismiss a second motion by Lundbeck to strike certain paragraphs and exhibits from four other affidavits. Lundbeck also requests that, whether or not it succeeds in its motion to strike, it be granted leave pursuant to rule 312 of the *Federal Courts Rules*, SOR/98-106, to file seven reply affidavits.

[4] Lundbeck's application for an order of prohibition has been set down to be heard for five days commencing December 8, 2008, less than three months from now. Cross-examination on the 17 affidavits pertaining to the validity of the '452 patent filed by the parties in this summary proceeding is underway and is expected to be completed by the end of September.

[5] I wish to emphasise at the outset a point reflected in the jurisprudence and often reiterated by this Court in interlocutory disputes, particularly, but not exclusively, in connection with those arising from NOC proceedings. Appellate courts (including courts of first instance when exercising an appellate function) are well advised not to interfere with discretionary rulings in interlocutory matters, especially of the kind in this case, unless satisfied that the issues in dispute are clearly material to the just disposition of the litigation and the ruling in question is fundamentally flawed.

[6] The fact that the *Federal Courts Act*, R.S.C. 1985, c. F-7, provides for appeals as of right in interlocutory matters from a Prothonotary to a Judge of the Federal Court, and then to the Federal Court of Appeal, is not an open invitation to subject discretionary decisions at first instance to close scrutiny. The interests of justice are normally best served in summary and, indeed, in other proceedings, by minimising delays in the determination of the substantive matter. Whenever possible, the resolution of ongoing evidential wrangles (and some procedural issues) should be left to be decided by the judge hearing the application, or conducting the trial.

1. Apotex's Appeal: the Kellogg Affidavit

Standard of review

[7] It is common ground that the order made by the Prothonotary in disposing of Lundbeck's motions was discretionary in nature and that the questions raised were not vital to the final issue in the case. Accordingly, the Judge was only entitled to intervene, and to exercise his discretion *de novo*, if satisfied that the order was clearly wrong, because it was based on a wrong principle or on a misapprehension of the facts: *Merck & Co. v. Apotex Inc.* (2003), 30 C.P.R. (4th) 40, 2003 FCA 488 at para. 19. A similar standard of review applies on an appeal to this Court from a discretionary decision in an interlocutory matter by a Judge of the Federal Court: *Z.I. Pompey Industrie v. ECU-Line N.V.*, [2003] 1 S.C.R 450 at para. 18.

[8] While I am not satisfied that the Judge made an error of law in his formulation of the appropriate standard of review, it is my opinion that he erred in concluding that the Prothonotary's order was "clearly wrong" in either of the senses described above. Hence, he was not entitled to strike the Kellogg affidavit in the exercise of his discretion and his decision cannot stand.

Issue and Analysis

[9] In its lengthy Notice of Allegation (NOA), Apotex alleged that the '452 patent was invalid on several grounds, including anticipation. In support of this ground the NOA stated:

> Furthermore, testing results have confirmed that separation of citalopram using conventional techniques (as described herein) available prior to June 13, 1987 [i.e. when the '452 patent was filed] results in substantially pure (+) – citalopram.

[10] Lundbeck's core objection to the Kellogg affidavit is that Dr. Kellogg's report was signed, and some of the tests referred to in it were conducted, after the issue of Apotex's NOA. Lundbeck says that Apotex is not permitted to rely on facts outside the scope of its NOA in order to support an allegation that the patent is invalid.

[11] Lundbeck also says that the statement in the NOA that "testing results have confirmed …" is insufficient because it does not identify the tests in question. However, the Prothonotary found that the NOA sufficiently disclosed the existence of test results on the separation of citalopram. Lundbeck did not ask Apotex for clarification or for the identity of the person who had conducted the tests, but was content to file affidavits responding to the NOA. In these circumstances, I attach no importance to this point.

[12] Hence, the question to be decided in this appeal is whether the Prothonotary's order was "clearly wrong" because the Kellogg affidavit, and the test procedure and results described in an exhibit to the affidavit, improperly expand the scope of the NOA. I am not persuaded that the Prothonotary did so err.

[13] First, Dr. Kellogg had produced relevant test results prior to the issue of the NOA. Second, the results subsequently obtained simply confirmed the earlier results, and could legitimately have been regarded by the Prothonotary as not being "additional facts" beyond those set out in the NOA. Third, since it is common ground that Apotex was not required to include Dr. Kellogg's report in its NOA, the fact that it was completed after the NOA was issued does not render it irrelevant to this proceeding.

2. Lundbeck's Cross-Appeal

Standard of review

[14] The part of the order in dispute in the cross-appeal is also discretionary and does not pertain to a question vital to the final issue in the case, since it involves the striking of affidavits, as well as a request by Lundbeck for leave to file additional affidavits. It is therefore subject to the same standard of review as the part of the order appealed by Apotex.

[15] In my opinion, Justice Harrington was correct to conclude that Prothonotary Morneau had committed no reversible error in dismissing Lundbeck's motion.

Issue and Analysis

[16] Lundbeck says that the paragraphs in question should be struck because they contain facts that are beyond the scope of the Apotex's NOA. However, the Prothonotary concluded that the disputed paragraphs in the affidavits related to facts contained in either the NOA or the affidavits filed in support of Lundbeck's attempt to disprove the allegation that the '452 patent is invalid. I am not persuaded that this conclusion was "clearly wrong" in law or was based on a misapprehension of the facts. As Justice Heneghan aptly said in *GlaxoSmithKline Inc. v. Genpharm Inc.* (2003), 30 C.P.R. (4th) 360, 2003 FC 1248 at para. 59:

> The affidavit evidence filed by the Respondent was responding to the evidence and argument filed by the Applicants. … [T]his must be permitted to allow for the adversarial process to function properly.

[17] Nor am I satisfied that the Prothonotary made any error warranting the intervention of this Court in his formulation or application of the criteria for the exercise of discretion when he

dismissed Lundbeck's request for leave to file additional affidavits in response to those of Apotex's experts. None of the affidavits adduced before the Prothonotary were "final drafts", and some were only "partial drafts". Cross-examination provides an adequate opportunity for Lundbeck to challenge the evidence contained in the affidavits filed by Apotex.

[18] I note that on both of the above issues, Justice Harrington, exercising his discretion *de novo* out of an abundance of caution, concluded that the Prothonotary was correct.

3. Conclusion

[19] For these reasons, I would allow Apotex's appeal and dismiss Lundbeck's cross-appeal, both with costs.

"John M. Evans"
J.A.

"I agree
Alice Desjardins J.A."

"I agree
J.D. Denis Pelletier J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-336-08

(APPEAL FROM THE ORDER OF THE HONOURABLE MR. JUSTICE HARRINGTON OF THE FEDERAL COURT, DATED JUNE 23, 2008 IN FEDERAL COURT FILE DOCKET NO. T-991-07.)

STYLE OF CAUSE:	APOTEX INC. v. LUNDBECK CANADA INC. and THE MINISTER OF HEALTH and H. LUNDBECK A/S
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	September 15, 2008
REASONS FOR JUDGMENT BY:	Evans J.A.
CONCURRED IN BY:	Desjardins JA. Pelletier J.A.
DATED:	September 16, 2008

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