

Date: 20080623

Docket: T-991-07

Citation: 2008 FC 787

Toronto, Ontario, June 23, 2008

PRESENT: The Honourable Mr. Justice Harrington

BETWEEN:

LUNDBECK CANADA INC.

Applicant

and

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

Respondents

and

H. LUNDBECK A/S

Respondent/Patentee

REASONS FOR ORDER AND ORDER

[1] This appeal from an interlocutory order of Prothonotary Morneau puts in issue the manner in which proof is adduced in applications before this Court, as opposed to actions. The skirmish is within the context of the *Patented Medicines (Notice of Compliance) Regulations*. Lundbeck Canada Inc. has applied for an order prohibiting the Minister of Health from issuing Apotex a Notice of Compliance with respect to its submission for tablets comprising Escitalopram Oxalate

until the expiry of H. Lundbeck A/S's Canadian patent 1,339,452 titled "Etanionomers of Citalopram and Derivatives Thereof".

[2] Pursuant to rule 300 and following of the *Federal Courts Rules*, Lundbeck filed its Notice of Application and then its evidence which takes the form of affidavits and documentary support. The respondent, Apotex, replied in kind. The next step, which has yet to take place, is the cross-examination on affidavits, followed by the filing of both parties' records, which will include memoranda of fact and law. The hearing on the merits is scheduled for this December.

[3] Although on notice, the Minister of Health takes no position and has not participated.

[4] Lundbeck moved to have some of Apotex's expert affidavits struck in whole or in part. Failing that, it asked that it at least be given leave to file affidavits in reply. Leave is required under rule 312. It also sought leave to reply to certain paragraphs of the Apotex affidavits notwithstanding that it did not move that those statements be struck.

[5] Prothonotary Morneau dismissed the motions outright. Although Lundbeck appealed the order in its entirety, at the hearing it resiled with respect to certain paragraphs of certain affidavits.

THE DECISION UNDER APPEAL

[6] It bears mentioning that Lundbeck originally brought on two separate motions. However, they were heard together by Prothonotary Morneau who issued one order, and so there is only one

appeal before me. In one motion, it sought an order striking out certain paragraphs and exhibits to the affidavits of Aidan Hollis, Peter Jenner, John Keana, Robert McClland and Timothy Ward, or in the alternative for an order granting leave to file evidence in reply thereto and, in any event, for an order granting it leave to file evidence in reply to certain other paragraphs. The basis of the motion is that the parameters of this application were established by Apotex in the Notice of Allegation (NOA) it gave under the PM (NOC) Regulations, and that the said affidavit material was neither responsive to Lundbeck's own affidavits nor within the scope of the NOA.

[7] In its other motion, it sought to strike the affidavit of Dr. Richard Kellogg, and the two exhibits accompanying same, in their entirety, together with identified paragraphs and exhibits of other experts called by Apotex who referred to Dr. Kellogg's report, more particularly certain paragraphs and exhibits to the affidavits of Drs. McClland, Ward and Keana. The test results exhibited thereto were not listed as prior art in the NOA and in fact were only completed after the NOA was served.

[8] Prothonotary Morneau refused to strike any part of any affidavit and refused to grant Lundbeck leave to file any further affidavit evidence. He held that the test for striking out parts of an affidavit under rule 307 is that absent special circumstances, such as an affidavit being clearly abusive or irrelevant, the decision to strike should be left to the applications judge. Having reviewed the material, it was not clear to him that Apotex's affidavit evidence was an expansion of the legal and factual basis of its NOA, or that it could not clearly be considered a reply to the Lundbeck affidavits filed under rule 306.

[9] As for granting leave to file reply affidavits under rule 312, he purported to apply *Atlantic Engraving Ltd. v. Lapointe Rosenstein*, 2002 FCA 503, 23 C.P.R. (4th) 5 which set out a four-part test: 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 or serious prejudice to the other side; and d) the evidence was not available at an earlier date or could not have been anticipated.

THE REVIEW STANDARD IN APPEAL

[10] The order of the Prothonotary was discretionary. It is well established that the Court should not interfere with such a decision unless: a) the questions raised are vital to the final issue in the case; or b) the order is “clearly wrong” in the sense that the exercise of discretion by the Prothonotary was based upon an incorrect principle of law or upon a misapprehension of the facts. In that event, the Court must exercise its discretion *de novo* (*Merck & Co. v. Apotex Inc.*, [2004] 2 F.C.R. 459, 30 C.P.R. (4th) 40 at paragraph 19; *Canada v. Aqua-Gem Investments Ltd.*, [1993] F.C.J. No. 103, [1993] 2 F.C. 425 at page 454).

[11] In my opinion, the order of Prothonotary Morneau was not vital to the outcome of the case.

[12] Except in one respect, I am of the opinion that he based himself neither upon an incorrect principle of law nor upon a misapprehension of the facts. However, I cannot agree with his analysis with respect to the affidavit of Dr. Richard Kellogg, and the exhibits attached thereto.

[13] Dr. Kellogg's affidavit is dated 5 December 2007. In it, he states that he was provided by one of Apotex's co-counsel with copy of two U.S. patents and asked to carry out or supervise certain resolutions and separations based on open literature available in June 1988. The accompanying notes and report indicate that the work began 10 April 2007 and finished 21 May 2007.

[14] The report was relied upon by other experts called by Apotex to support the following proposition in Apotex's NOA where it states:

Furthermore, testing results have confirmed that separation of Citalopram using conventional techniques (as described herein) available prior to June 13, 1987 results in substantially pure (+) – Citalopram.

[15] That NOA is dated 20 April 2007. It comprises forty-three (43) pages of text and an additional seventeen (17) pages of a schedule in which 170 items of "prior art" are listed.

[16] Perhaps on 20 April, Apotex had reason to believe the testing then going on would support its case, but the simple fact remains that the test was not complete, and so cannot be called "prior art". It is, at best, "subsequent art".

[17] Had Apotex waited until the report was actually in existence, it could have been invoked. I agree with the Prothonotary that it would not have been absolutely necessary to refer to it in the text of its NOA, but it would have had to list it as prior art. The PM (NOC) Regulations require a detailed statement of the basis in fact and law to support the allegation that a patent is invalid, or that

it will not be infringed, or whatever other grounds are alleged with a view of obtaining a Notice of Compliance from the Minister before a listed patent has expired (*Bayer AG v. Canada (MNHW)*, [1993] F.C.J. No. 1106, 51 C.P.R. (3d) 329).

[18] As noted in *AB Hassle v. Canada (MNHW)*, [2000] F.C.J. No. 855, 7 C.P.R. (4th) 272 at paragraph 23, the entire factual basis is to be set forth in the NOA rather than be revealed piecemeal as the need arises. To the extent prior art is relied upon, it must be identified.

[19] Consequently, I cannot share the Prothonotary's opinion that the section of Apotex's NOA referred to above sufficiently discloses the existence of test results. If there are such results, it is certainly not the Kellogg report, which did not exist at the time.

[20] To allow the affidavit to stand, even giving Lundbeck a right to reply, would be to allow Apotex to split its case. The Kellogg report goes beyond the NOA and it would be patently unfair to allow it to remain in the record (*Mayne Pharma (Canada) Inc. v. Aventis Pharma Inc.*, 2005 FCA 50, 2005 F.C.J. No. 215).

[21] I do not think that this misapprehension of the Kellogg Report permeated the rest of Prothonotary Morneau's decision, but to be on the same side I have decided to consider the matter *de novo*.

[22] It is certainly not at all clear to me whether the remaining affidavits go beyond the NOA and the Lundbeck affidavits. To the extent that reports are mentioned that are not listed in the NOA, Apotex must be given a fair opportunity to respond to Lundbeck's affidavits. One does not know how the person who has listed a patent may react to an NOA, and so the issuer thereof cannot fully anticipate all that might be set out in the applicant's affidavits. It is not at all clear to me that the affidavits bring new points into issue, or raise confusion.

[23] One of the reasons these matters are usually left to the applications judge is that in the fullness of time, with the benefit of transcripts of cross-examinations and argument on all points in issue, that judge is in, at that time, a much better position to appreciate the relevance of the statements under attack, the weight which should be given to them, and their context. If Apotex has split its case, or if some of the allegations in its NOA are too vague, then it is open to the applications judge, on a full record, to so find, without the need of still more affidavits.

[24] Following *Atlantic Engraving*, I do not see circumstances which are such that justice would be better served by permitting further affidavits, which quite possibly would lead to further motions to file affidavits in reply and more cross-examinations. Apotex made its bed in its NOA and Lundbeck in its Notice of Application and its affidavits. They should lie in them.

ORDER

THIS COURT ORDERS that the appeal from the order of Prothonotary Morneau, dated 6 March 2008, is allowed in part:

1. The affidavit of Dr. Richard Kellogg and the two exhibits thereto are struck in their entirety.
2. The following paragraphs and exhibits of the experts called by Apotex who refer to the Kellogg report are struck:
 - a. Paragraph 91 and exhibit 2 to the affidavit of Dr. McClland;
 - b. Paragraphs 26-29 and exhibit 3 to the affidavit of Dr. Ward; and
 - c. Paragraph 117 and exhibits 3 and 4 to the affidavit of Dr. Keana.
3. The balance of the appeal is dismissed.
4. Costs in the cause.

"Sean Harrington"
Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-991-07

STYLE OF CAUSE: LUNDBECK CANADA INC. v.
THE MINISTER OF HEALTH AND APOTEX INC.
AND H. LUNDBECK A/S

PLACE OF HEARING: Vancouver, British Columbia

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DATED: June 23, 2008

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