Date: 20080716

Docket: T-703-08

Citation: 2008 FC 875

Toronto, Ontario, July 16, 2008

PRESENT: The Honourable Madam Justice Tremblay-Lamer

BETWEEN:

ELI LILLY CANADA INC.

Applicant

and

NOVOPHARM LIMITED and THE MINISTER OF HEALTH

Respondents

and

ELI LILLY and COMPANY LIMITED

Respondent/Patentees

REASONS FOR ORDER AND ORDER

[1] This is an appeal motion by Novopharm Limited (Novopharm) to set aside or vary

paragraphs 1 through 5 of the order of Prothonotary Tabib dated June 24, 2008.

[2] This appeal arises from an application respecting Canadian Patent No. 2,214,005 (the 005 Patent) which is owned by Eli Lilly and Company Limited.

[3] On March 18, 2008, Novopharm served a Notice of Allegation (NOA) in respect of the 005 Patent and its own 5 mg, 15 mg and 20 mg olanzapine orally disintegrating tablets. In response to the NOA, Eli Lilly Canada Inc. (Eli Lilly) commenced an application on May 2, 2008 pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, in order to determine whether Novopharm's allegations of non-infringement and invalidity are justified.

[4] On May 9, 2008, Eli Lilly served a Notice of Motion requesting a schedule for the application.

[5] On June 19, 2008 the motion was heard by Prothonotary Tabib and a decision was rendered on June 24, 2008 in which she ordered, *inter alia*, that:

- Novopharm's evidence on the issue of invalidity shall be served and filed no later than August 18, 2008.
- 2. Lilly's evidence shall be served and filed no later than October 2, 2008.
- Novopharm's evidence on non-infringement shall be served and filed no later than December 1, 2008.
- 4. Cross-examinations on affidavit shall be completed no later than 90 days following service and filing by Novopharm of a notice that it has filed all its evidence on non-infringement, or the expiration of the time provided in paragraph 3 of this order.

 The parties have leave to serve and file a requisition for hearing 10 days after the service of Novopharm's evidence on infringement or the expiration of time for doing so.

[6] The issue for determination on this motion is whether the above paragraphs 1 through 5 of the June 24 order should be varied or set aside and replaced.

[7] The present case deals with scheduling matters: the order of the presentation of evidence and the time allotted to each party to present evidence. Scheduling matters are discretionary in nature (*Bristol-Myers Squibb Company v. Apotex*, 2008 FC 824). It is well established that discretionary orders of prothonotaries should be left undisturbed unless the questions in the motion are "vital to the final issue of the case" or the prothonotary's order is "clearly wrong" (*Merck & Co. v. Apotex Inc.*, 2003 FCA 488, [2003] F.C.J. No. 1925 (QL), at para. 19).

[8] On the issue of the order of presentation of evidence, Novopharm submits that Prothonotary Tabib made significant errors in principle and improperly exercised her judicial discretion when, without jurisdiction or any basis for doing so, she imposed a schedule that departs significantly from the procedure required by sections 306 and 307 of the *Federal Courts Rules*, SOR/98-106 (the Rules).

[9] Pursuant to these provisions, an applicant shall serve and file its supporting affidavits and documentary exhibits within 30 days after the issuance of a notice of application and a respondent

shall serve and file any supporting affidavits and documentary exhibits within 30 days after service of the applicant's affidavits.

[10] While the aforementioned provisions explicitly set out the procedure to be followed in presenting evidence, there are also additional provisions in the Rules which provide for a measure of flexibility in their application and interpretation. Of particular importance, s. 385(1)(*a*), pertaining to the powers of a case management judge or prothonotary, establishes that they shall deal with all matters that arise prior to the trial or hearing of a specially managed proceeding and may "give any directions that are necessary for the just, most expeditious and least expensive determination of the proceeding on its merits". Section 3 also states that the Rules are to be interpreted and applied in such a way as "to secure the just, most expeditious and least expensive determination of every proceeding on its merits". Further, s. 55 allows the Court to vary a rule or dispense with compliance in special circumstances.

[11] In a recent line of cases, these provisions have been interpreted as permitting a case management prothonotary to vary the order of the presentation of evidence where he is satisfied that it is necessary for the just, most expeditious and least expensive determination of the proceedings (*Lundbeck Canada Inc. v. Ratiopharm Inc.*, 2008 FC 579; *Astrazeneca Canada Inc. v. Apotex Inc.*, 2008 FC 537, [2008] F.C.J. No. 681 (QL); *Abbot Laboratories v. Canada (Minister of Health)*, 2007 FC 1291, [2007] F.C.J. No. 1660 (QL); *Pharma v. Pharmascience Inc.*, 2007 FC 1196, [2007] F.C.J. No. 1568 (QL)).

[12] Novopharm cites the case of *Merck & Co. v. Apotex Inc.*, 2003 FCA 438, [2003] F.C.J. No. 1725 (QL) wherein the Federal Court of Appeal, in the context of discovery rights, stated that the "general words" of sections 3 and 385 of the Rules are not sufficient to override a party's other specific rights that have been clearly spelled out elsewhere in the Rules. Novopharm submits that this principle is equally applicable in the present case where the specific language of sections 306 and 307 of the Rules should not be subordinate to the general language of sections 3 and 385.

[13] However, as stated by Prothonotary Aronovitch in *Lundbeck*, above, at para. 20, rule 307 confers a procedural rather than a substantive right and the "inversion of the order of evidence also does not work a procedural inequity where the respondent can show that it requires a right of reply, and has the opportunity to do so".

[14] I would also add that reversing the order of evidence was explicitly contemplated by the Practice Directive of this Court effective January 7, 2008. Thus, I am of the view that Prothonotary Tabib had the jurisdiction to reverse the order of the presentation of evidence.

[15] Novopharm submits in the alternative, that if Prothonotary Tabib did have jurisdiction to reverse the order of the presentation of evidence she acted upon a wrong principle and made an error of law in failing to consider or properly consider the factors set out in the prior jurisprudence on the subject.

[16] The jurisprudence reveals that in determining whether a reversal of the order of presentation of the evidence is appropriate, the primary consideration is that it must be for "the purpose of achieving the least expensive and most expeditious determination of the issues on the merits in a manner that remains just". (*Pharma*, above, at para. 8). Accordingly, reversing the order should not affect "the substantive rights of the parties and the fairness of their procedural rights". (*Lundbeck*, above, at para. 19; *Pharma*, above, at para. 8). Further, when reversing the order, "substantial savings in time, expense and resources, both of the Court and of the parties would have to be expected". (*Pharma*, above, at para. 20; see *Astrazeneca*, above at para. 10).

[17] After reviewing Prothonotary Tabib's order, I am satisfied that she understood the facts surrounding the present litigation and considered all relevant factors. As Justice Evans stated in *Sawridge Band v. Canada*, 2006 FCA 228, [2006] F.C.J. No. 956 (QL), at para. 21:

(...) this Court is very reluctant to interfere with decisions made by a judge in the course of managing a matter prior to trial, particularly one as complex, lengthy and difficult as this one. As a result of living with the matter over time, the case management judge will have acquired an overall understanding of it which an appellate court, on the basis of hearing an appeal on a particular issue, cannot possibly match in either depth or breadth.

[18] Prothonotary Tabib, as the case management prothonotary, was particularly well positioned to apprehend the circumstances of this case. She has managed other proceedings between these parties and with other respondents regarding the patents for olanzapine and thus understands the approaches taken by the parties and the complex factual matrix involved. Through her experience she has developed a level of expertise in these matters.

[19] Turning now to the Prothonotary's decision, after having read the written record and heard oral submissions from both parties, Prothonotary Tabib determined that a reversal of the order of presentation of the evidence was appropriate. In her reasons she indicated that based on the particular facts, the just, most expeditious and least expensive determination of the issues in this application will likely be achieved if Novopharm files its evidence on its allegation of invalidity first, that Eli Lilly then files its evidence on invalidity and non-infringement at the same time, and that Novopharm's evidence on non-infringement be delivered last. She also specifically addressed the appreciable savings in time and costs for the parties and for the Court which would result by requiring Novopharm to file its evidence on invalidity first, as the issues would thus be substantially narrowed.

[20] Accordingly, I can find no error of law in the decision in question, nor can I find anything clearly wrong in the Prothonotary's exercise of her wide grant of discretion.

[21] Concerning the issue of the time allocated to the parties to file their materials, I similarly find that Prothonotary Tabib was not clearly wrong. She accepted most of the uncontested evidence put forward by Dr. Bugay and was satisfied that a period of 105 days was reasonably necessary for Eli Lilly to serve and file its evidence on infringement. Further, she accepted the representations of counsel for Novopharm at the hearing that a period of 60 days would be reasonably necessary to serve and file its affidavits on invalidity, if it were required to do so before the applicant filed its evidence, and also that it would require 60 days following service of Eli Lilly's evidence on infringement in which to respond.

[22] For the foregoing reasons, the appeal of the Prothonotary's order is dismissed

<u>ORDER</u>

THIS COURT ORDERS that the appeal of the prothonotary's order is dismissed.

"Danièle Tremblay-Lamer" Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:

T-703-08

STYLE OF CAUSE:

ELI LILLY CANADA INC.

and

Applicant

NOVOPHARM LIMITED ET AL

Respondents

PLACE OF HEARING: TORONTO, ONTARIO

DATE OF HEARING: 14-JUL-2008

REASONS FOR ORDER AND ORDER BY:

TREMBLAY-LAMER J.

DATED:

DISMISSED (14-JUL-2008)

WRITTEN REASONS RENDERED:

July 16, 2008

APPEARANCES:

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