Federal Court  Cour fédérale

Date: 20111213

Docket: T-1201-08

Citation: 2011 FC 1469

Ottawa, Ontario, December 13, 2011

PRESENT: The Honourable Mr. Justice Mandamin

BETWEEN:

SANOFI-AVENTIS CANADA INC.,
SCHERING CORPORATION AND
SANOFI-AVENTIS DEUTSCHLAND GmbH

Plaintiffs

and

LABORATOIRE RIVA INC. AND
PHARMASCIENCE INC.

Defendants

AND BETWEEN:

LABORATOIRE RIVA INC.

Plaintiff by Counterclaim

and

SANOFI-AVENTIS CANADA INC.,
SCHERING CORPORATION AND
SANOFI-AVENTIS DEUTSCHLAND GmbH

Defendants by Counterclaim

REASONS FOR ORDER AND ORDER

[1] The Defendants by Counterclaim, Sanofi-Aventis Canada Inc. and Sanofi-Aventis Deutschland ("Sanofi") bring this motion to set aside portions of the Order of Prothonotary Milczynski made on May 26, 2011 to the effect that Laboratoire Riva Inc. ("Riva") need not answer certain questions posed in examinations for discovery.

[2] In particular, Sanofi is appealing the following paragraphs of the May 26, 2011 Order as it relates to questions: 5, 125, 252, 252, 253, 254 and 267; as well as seeking answers to questions: 9-19 which had been withdrawn in view of the Prothonotary's ruling on question 5.

[3] The questions can be grouped into two categories as follows:

Category 1 – Questions relating to the cross-reference arrangement between Riva and Pharmascience

No.	Question
5	To produce any documents related to the decision to enter into the cross-license with Pharmascience.
9	To produce any documents related to the decision by Riva to enter into the cross-license arrangement with Pharmascience [relating to ramipril], including any presentations, forecasts, plans, budgets or decision documents.
10	To produce any communications, electronic or otherwise, relating to this agreement [the cross reference agreement on ramipril with Pharmascience], such as e-mails or other correspondence exchanged with either one of the Goodman's with respect to the arrangement.
11	To advise what Mr. Goodman told Mr. St-Denis [at the time Mr. St-Denis approached Mr. Goodman at Pharmascience] about those legal proceedings [the legal proceedings related to ramipril in which Pharmascience was involved].
12	Further, to advise whether Mr. Goodman or anyone at Pharmascience indicated to Riva the possibility that it [Pharmascience] would be unsuccessful in the Notice of Compliance proceeding.

13	To advise whether, as part of the agreement with Pharmascience in 2004, Pharmascience agreed to assist Riva with the conduct of any litigation related to ramipril.
14	To advise whether Pharmascience in fact assisted Riva in the conduct of any litigation related to ramipril.
15	To confirm that Pharmascience assisted Riva by finding expert witnesses, including a Dr. Christensen.
16	To advise whether Pharmascience was directing other litigation or any litigation involving Riva and ramipril.
17	To advise whether Pharmascience was, in 2004 or at any other time, funding litigation related to ramipril.
18	Riva Document 25: To produce, if it exists, a written cross-reference license [related to ramipril, written at any point].
19	Riva Document 25: Further, if there is an oral cross-reference license [related to ramipril], to advise of the terms related to the oral cross-reference license.

[Emphasis added]

Category 2: Questions relating to the ability of Pharmascience to supply Riva with ramipril

No.	Question
125	Riva Production 23: Regarding the drop-off in sales of the 10 mg strength, to provide Riva's knowledge as to the drop-off in sales of the 10 mg tablet for approximately the same period of time [June 2009 to February 2010]. Further, to make similar inquiries of Pharmascience to find out Pharmascience's information as to the explanation for the drop-off in sales of the 10 mg tablet beginning in the summer of 2009.
251	In particular, to advise whether additional investment would have been required by Pharmascience in equipment, employees or others [for Pharmascience to have adequate manufacturing capacity to manufacture and supply to Riva], assuming that Riva was the sole generic supplier of ramipril commencing in June 2004.
252	Regarding this investment [see item no. 251], to ask Pharmascience whether this investment would change if Riva's share of the generic market for ramipril was reduced, i.e. if there were multiple generics on the market.
253	Further to the above questions [see item nos. 251-252], if no additional investment would have been required, to provide Pharmascience's information on the reasons why additional investment was not required.
254	To ask Pharmascience, if additional investment would have been required [see item no. 251], whether that would have impacted on Pharmascience's pricing of bulk ramipril tablets sold to Riva.
267	To provide Riva's information on the length of time it would take

	Pharmascience to fill bulk orders for Riva in or about 2004.

[Emphasis added]

[4] Sanofi submits that:

a) Riva has counterclaimed for losses suffered by Riva during the period from June 18, 2004 when a Notice of Compliance (NOC) could have been issued to Riva in the absence of an application by Sanofi under the *PMNOC Regulations* and ending when the Federal Court dismissed the application on March 4, 2008.

b) Two questions are at the heart of this claim for lost sales:

(1) Could Riva have secured product to sell?

(2) Would Riva have faced competition in the market?

c) Sanofi has been precluded from fully exploring these issues on discovery.

[5] Sanofi submits that the Prothonotary clearly erred in not requiring Riva to answer the questions as they are proper and relevant to pleaded issues in this action, are neither unreasonable nor unnecessary, and are not unduly onerous. Further, the questions in issue do not call for speculation or opinion.

Standard of Review

[6] A Prothonotary's decision to allow or disallow a question on discovery is a matter of discretion. On appeal, a discretionary order of a Prothonotary is reviewed *de novo* where it raises an issue vital to a final issue in the case or it is clearly wrong, in the sense that the exercise of discretion by the Prothonotary was based upon a wrong principle or upon a misapprehension of the facts. Where a Prothonotary has fallen into an error of law that prevented the proper exercise of discretion, the decision is clearly wrong. *Merck & Co. v Apotex Inc*, 2003 FCA 488 at para 19; *Hayden Manufacturing Co. v Canplas Industries Ltd.*, (1998), 161 FTR 57 at para 8 (F.C.T.D.);

[7] Relevance is a matter of law, not discretion. *Apotex v Sanofi-Aventis Canada Inc.*, 2011 FC 52 at para 17.

Deference

[8] This Court has held that a ruling on relevance involves an exercise of discretion, and a high level of deference should be accorded to such decisions. *AstraZeneca Canada Inc. v Apotex Inc.*, 2008 FC 1301 at paras 19-23; *Apotex Inc. v GlaxoSmithKline Inc.*, 2009 FC 378 at para 5.

[9] The absence of written reasons by the Prothonotary does not necessarily mean that this appeal should proceed as a hearing *de novo*. Absent establishing that a Prothonotary's decision was clearly wrong, this Court ought not to exercise its discretion *de novo*. *Apotex Inc. v*

Wellcome Foundation Limited, 2008 FCA 131 at paras 3-4; *Abercrombie & Fitch Co. v Giant Tiger Stores Ltd.*, 2009 FC 492 at para 9.

[10] The Court has recognized that a case manager is intimately familiar with the history and details of the complex matters. *Apotex Inc. v Sanofi-Aventis Canada Inc.*, 2011 FC 52 at para 15.

[11] The Prothonotary considered the questions now under appeal in the context of the information set out below:

a) the present counterclaim involves Riva's claim of damages pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations* (Riva Counterclaim at paras 85, 86A, 87, 88A);
b) Riva is seeking compensation for the damages it suffered from lost profits on lost sales of ramipril capsules in Quebec from June 2004 to March 2008 (the "Exclusionary Period") (Riva Counterclaim at paras 85, 86A, 87, 88A);
c) Riva cross-referenced the Abbreviated New Drug Submission ("ANDS") of Pharmascience Inc. ("Pharmascience") (Riva Counterclaim at paras 8-9, 15);
d) commercial agreements were made between Riva and Pharmascience, including agreements relating to (i) Pharmascience's supply to Riva supplier of ramipril capsules; and (ii) Pharmascience's distribution of ramipril capsules across Canada (Riva Prods. 25-26);

e) Riva and Pharmascience have sold ramipril capsules in Quebec and Canada, respectively (Transcript from the Examination for Discovery of Andre St-Denis held on February 1, 2011 at 86-87)

f) Sanofi has alleged that Riva was not in a position to market ramipril during the Exclusionary Period (Sanofi Defence to Counterclaim at para 90); and

g) the pleadings of the parties, the transcripts from the examinations for discovery of Riva's representative and specific references therein; and the documents of the parties.

Relevance

[12] Sanofi makes the broad assertion that the Prothonotary erred in law or misapprehended the facts with respect to the relevance of the questions under review.

[13] The test for relevance is not limitless. To meet the test, it must be fairly shown that it is reasonable to suppose that a document or answer contains information that will directly or indirectly enable a party to advance its case or to damage that of another party. The "train of inquiry" test for relevance is always subject to the "overriding discretion of a prothonotary or judge to control abuses of the discovery process". *AstraZeneca Canada Inc. v Apotex Inc.*, 2008 FC 1201 at paras 12 and 17; *Apotex Inc. v Bristol-Myers Squibb Co.*, 2007 FCA 379 at para 30.

[14] If a question is determined to be relevant, the prothonotary must weigh the relevance of that question against several factors, including, but not limited to, the degree of relevance, the generality/breadth of the question, the onerousness of providing an answer, and whether the

question is fair or abusive. *AstraZeneca Canada Inc. v Apotex Inc.*, 2008 FC 1301 at paras 16-18; *GSC Technologies Corp. v Pelican International Inc.*, 2009 FC 223 at paras 9, 11-12; *T-Mobile USA, Inc. v Telus Corporation*, 2010 FC 45 at paras 4-5.

The Refusal Questions

[15] In Question No. 5 Sanofi sought production of "any documents related to the decision to enter in to the cross-license with Pharmascience. When Riva's refusal regarding Question No. 5 was maintained by the Prothonotary, Sanofi withdrew Questions 9-19 "in view of the Court's ruling on Item No. 5".

[16] I am satisfied the documents sought by Sanofi, "any documents related to the decision to enter into the cross-license with Pharmascience", are not relevant because they are overtaken by the actual cross-reference agreements between Riva and Pharmascience. Moreover, these agreements provide that Pharmascience, as an independent contractor, does not have any power to bind Riva with any third party and all financial obligations associated with Pharmascience are the sole responsibility of Pharmascience. Finally, any presentations, forecasts, plans and budgets related to the decision to enter the agreements would merely be hypothetical and speculative.

[17] I am satisfied the Prothonotary properly exercised her discretion in maintaining the refusal to answer Question 5.

Withdrawn Questions Cannot be Appealed

[18] Sanofi withdrew Questions 9-19 "in view of the Court's ruling on Item No. 5". If Sanofi wished to maintain it was entitled to answers to these questions it should have put them to the Prothonotary who is in the best position to assess their relevance. Sanofi did not and it has not set out any compelling reasons why it should be able to resile from its withdrawal of these questions.

[19] It is trite law that one can only appeal an order, not the reasons or the preamble to the order. *Procter & Gamble Pharmaceuticals Canada Inc. v Canada (Minister of Health)*, 2002 FCA 290 at para 7; *Bauer Nike Hockey Inc. v Easton Sports Canada Inc.*, 2006 FC 1084 at para 57.

[20] The Prothonotary's Order was not made in respect of Questions 9-19 since they were withdrawn by Sanofi. They were in the preamble to the Order where it was noted that they were withdrawn by Sanofi. Since no order was made in respect of the withdrawn Questions 9-19, they are not properly the subject matter of an appeal of the Order by Prothonotary Milczynski.

[21] I conclude Sanofi's appeal in respect of the withdrawn Questions 9-19 must be dismissed on the basis that Sanofi can neither resile from its withdrawal of these questions nor appeal questions that were not the subject matter of the appeal.

Relevance

[22] Questions 125, 251-257 and 267 were before the Prothonotary. However, I consider these questions either not relevant or of little relevance.

[23] Question 125 is directed to third party information (i.e., a drop in sales in IMS data) which is not Riva's data. Sanofi has had the opportunity to ask questions regarding actual sales information of Riva.

[24] Questions 251-254 relate to the investment that may have been made by Pharmascience and costs incurred by Pharmascience. Pharmascience is not a party to Riva's section 8 claim. Also, these questions are not relevant to the calculation of *Riva's* lost profits because they relate solely to costs that Sanofi alleges may have potentially been incurred by Pharmascience. However, pursuant to the cross-reference agreements between Riva and Pharmascience, Pharmascience's costs are solely those of Pharmascience.

[25] Question 267 seeks the length of time it would take Pharmascience to fill bulk orders for Riva in 2004. This is of dubious relevance and amounts to a fishing expedition by Sanofi since it is a tangential exploration of Pharmascience production of ramipril rather than deliveries to Riva.

[26] In my view, even if the questions are minimally relevant, the Prothonotary properly exercised her discretion in maintaining the refusals.

Conclusion

[27] The Prothonotary was fully familiar with the claims and issues raised in the pleadings by the parties, the case history and the specific issues before her when she denied Sanofi's refusals motion.

[28] I find Sanofi voluntarily withdrew Category One questions, and Sanofi is not to be entitled to resile on its withdrawal in a motion appealing the Order. Further, the withdrawn Questions were not subject to the Order and are not proper subject matter in this appeal motion.

[29] I also find the Prothonotary exercised her discretion and reasonably decided that Questions 5, 125, 252, 253, 254 and 256 did not require answers.

[30] Sanofi is seeking to have Riva ask Pharmascience about matters that are of little or no relevance to Riva, particularly so having regard to the provisions in the cross-reference agreement that specify Pharmascience cannot act to bind Riva in respect of any third party (i.e. Sanofi) or place Riva under any obligation for Pharmascience costs.

[31] The Order is well-supported by the factual and procedural history of the case and the representations and arguments that were before the Prothonotary. I do not see, on the basis of the extensive material before the Prothonotary, any error in the exercise of her discretion.

ORDER

THIS COURT ORDERS that:

1. This motion is dismissed with costs payable to Riva in any event of the cause.

"Leonard S. Mandamin"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1201-08
STYLE OF CAUSE:	SANOFI-AVENTIS CANADA INC. ET AL. V. LABORATOIRE RIVA INC. ET AL.
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	AUGUST 29, 2011
REASONS FOR ORDER AND ORDER:	MANDAMIN J.
DATED:	DECEMBER 13, 2011

APPEARANCES:

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Christopher Tan	FOR THE DEFENDANTS (PLAINTIFFS BY COUNTERCLAIM)

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