Date: 20090319

Docket: T-161-07

Citation: 2009 FC 294

Ottawa, Ontario, March 19, 2009

PRESENT: The Honourable Madam Justice Snider

BETWEEN:

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

Plaintiffs

and

APOTEX INC.

Defendant

AND BETWEEN:

APOTEX INC.

Plaintiff by Counterclaim

and

SANOFI-AVENTIS CANADA INC.
SCHERING CORPORATION
SANOFI-AVENTIS DEUTSCHLAND GmbH
and RATIOPHARM INC.

Defendants by Counterclaim

REASONS FOR ORDER AND ORDER

[1] The action in Court File No. T-161-07 concerns a claim of infringement of Canadian Patent No. 1,341,206 (the '206 Patent) by Sanofi-Aventis Canada Inc. and Sanofi-Aventis Deutschland GmbH (collectively, Sanofi) and Schering Corporation (Schering). In its defence and counterclaim,

Apotex Inc. (Apotex) denies infringement and claims that the '206 Patent is invalid. After many months of productions of documents, discoveries and expert reports, the trial began on January 12, 2009. The 31-day evidentiary phase of the trial concluded on February 24. Final argument is scheduled to begin on April 6, 2009.

[2] On February 26 – two days after the completion of the evidentiary phase of the trial – Apotex brought a motion to admit further evidence into the trial. The approximately 3000 pages of evidence which Apotex seeks to be admitted consist of affidavits sworn in other Federal Court or Patent Office proceedings, transcripts from depositions taken on January 13 and 14, 2009 in the United States, together with videotapes of the depositions, and file history information for certain Canadian and US patents (collectively referred to as the Motion Documents). In the alternative to admitting the Motion Documents as evidence, Apotex requests that the Court order the issuance of a commission, letters rogatory or other document to examine certain persons who would be able to speak to the matters dealt with in such evidence. Novopharm Limited (Novopharm), the Defendant in companion Court File No. T-1161-07, supports Apotex in this motion. Sanofi and Schering object to the admission of this evidence.

[3] Although leave to re-open its case was not explicitly requested in this motion, Apotex agrees that it is seeking such leave to re-open. Accordingly, I have treated this motion as a motion by Apotex to re-open its case and to admit the further evidence.

[4] For the reasons that follow, I conclude that, with the exception of two Canadian patent file histories, the Motion Documents should not be admitted. Further, I decline to exercise my discretion

to order the issuance of a commission, letters rogatory or other document for the examination of witnesses outside Canada.

I. Nature of the Evidence

[5] I begin by reviewing the nature of the Motion Documents. As noted, the evidence falls into three broad categories. The first – and most important to Apotex – consists of affidavits by four individuals who were employed as scientists by Warner-Lambert Company (Warner-Lambert). These affidavits were sworn at various times between 1995 and 2006 in proceedings in Canada related to the drug quinapril. In their affidavits, Dr. Milton L. Hoefle, Mr. Sylvester R. Klutchko, Mr. George Bobowski and Dr. John D. Topliss speak to the work carried out in the Warner-Lambert laboratories in and around 1980. In the submission of Apotex, these documents do no more than set out "factual stuff"; in the affidavits, the employees merely set out what they did and what they wrote down in their notebooks.

[6] The second type of document consists of the transcripts and videotapes of the depositions of Dr. Hoefle, Mr. Klutchko and Mr. Bobowski conducted in the United States on January 13 and 14, 2009. The three former employees of Warner-Lambert were questioned by a U.S. attorney on behalf of Apotex, pursuant to an order dated January 11, 2009 of Judge Denise Page Hood of the United States District Court, Eastern District of Michigan, Southern Division. Counsel for Schering and Sanofi, on the invitation of Apotex, attended at and participated in the depositions.

[7] The third category of documents consists of various Canadian and U.S. patents and patent file histories. A number of such documents were attached to the affidavits already referred to or were exhibits produced during the depositions. Finally, Apotex seeks to admit a certified copy of the file history for Canadian Patent No. 1,341,330 (the '330 Patent), including the '330 Patent itself, and a certified copy of the file history for Canadian Patent No. 1, 205,476 (the '476 Patent), including the '476 Patent itself.

II. Admission of the documents

A. *What is the test?*

[8] I do not think that there is any disagreement among the parties as to the overall test for the re-opening of a case and the admission of the documents. In simple terms, the task before me is to determine whether the admission of the Motion Documents, at this stage of the trial, would cause more harm than good. If it would, the evidence will be kept out.

[9] Beyond this general question, the parties disagree somewhat with respect to the legal tests that Apotex must meet in order to succeed in this motion. On the one hand, they agree that, in addition to the threshold issue of relevance, there are four relevant factors that should be considered: 1) whether the evidence is necessary, 2) whether it is reliable, 3) whether Apotex has acted with due diligence, and 4) whether there will be prejudice to the parties.

[10] However, Schering and Sanofi also allege that Apotex must, in addition, seek leave of the Court to re-open the trial by satisfying the legal test, as identified by the Supreme Court of Canada in *671122 Ontario Ltd. v. Sagaz Industries Canada Inc.*, 2001 SCC 59, [2001] 2 S.C.R. 983. This 2-part test asks:

1. Would the evidence, if presented at trial, probably have changed the result?

2. Could the evidence have been obtained before trial by the exercise of reasonable diligence?

[11] In my opinion, the *Sagaz* analysis unnecessarily complicates the present matter. For one, the test may not be directly applicable because the *Sagaz* decision dealt with a motion to lead fresh evidence after judgment had already been rendered. This is clearly distinguishable from the present case where judgment has not been rendered; the parties have not yet even entered into final arguments. Moreover, the two considerations that are encapsulated by the *Sagaz* test are covered by the four factors that were identified by the parties.

[12] Another approach would be to consider this evidence to be hearsay. The evidence likely meets the broad definition of hearsay as it consists of out-of-court statements that are offered for the truth of the matter asserted (*R. v. Starr*, [2000] 2 S.C.R. 144). Under the principled approach to the hearsay rule, the Court should apply a principled approach to the question of admissibility of hearsay evidence. The questions of reliability and necessity must be examined. Once again these factors are included in the list of factors identified above.

B. *Is the evidence relevant?*

[13] I am prepared to accept for purposes of this motion, without deciding, that the evidence would be relevant to the issues of obviousness and first inventorship. This factor favours admitting the evidence.

C. *Is the evidence necessary?*

[14] Apotex submits that admission of the Motion Documents is warranted on the facts of this case. Apotex points to its strenuous efforts to obtain evidence through the use of U.S. Court procedures— efforts that were delayed by the actions of Pfizer, Inc. (successor to Warner-Lambert). The procedures culminated in the depositions of three witnesses in Michigan. Given that these three witnesses are unavailable to appear in our trial, the test of "reasonable necessity" is, in Apotex's view, met.

[15] The problem with Apotex's submission on this point is that there are other procedures for bringing evidence into the Federal Court without resorting to this procedure which avoids the underlying premise of our courts that evidence should be taken orally.

[16] I am also concerned that Apotex's prior inaction in introducing the documents in its case in-chief, despite having had possession of certain of the affidavits, seriously undermines its assertion that the evidence is necessary.

[17] Overall, this factor favours not admitting the evidence.

D. *Is the evidence reliable?*

[18] Apotex points to a number of facts which, in its opinion, establish the reliability of the evidence:

- The affidavits constitute sworn or affirmed testimony, in some cases on more than one occasion;

- The affidavits were not produced for a particular situation/litigation and do not relate to work for which the affiants would not have had an incentive to overstate the nature or extent of their work;

- The evidence in the depositions was not provided on a voluntary basis;

- The depositions were recorded visually and audibly, thereby alleviating concerns about being able to observe demeanour; and

- Counsel for Schering and Sanofi were present at the depositions and were given the opportunity to object and to pose questions.

[19] The fact that the affidavits were sworn or affirmed in prior proceedings is of some – but not significant – comfort on the question of reliability. My more serious problem with the affidavits is that I have no evidence before me that the truth of those affidavits was tested in the earlier proceedings. Further, I have no way of testing whether the affiants had an incentive to exaggerate or misstate the contents of the affidavits. Taken to its extreme, if the Court accepts that the swearing or affirmation of an affidavit is sufficient to establish reliability of the truth of the contents, there would be no need for *viva voce* evidence at trial.

[20] Apotex submits that the contents of the affidavits and the depositions contain "factual stuff", such as what the scientists did and what they wrote down in their laboratory notebooks. Although this may be the case, it does not necessarily follow that reliability of the evidence need not be tested. Surely, facts may be disputed – even simple ones such as dates and who said what.

[21] Apotex also relies on the fact that the depositions were recorded in a manner that allows the Court to assess the demeanour of the witnesses. I have reviewed the transcripts of the depositions and I am not convinced that they overcome the problems of not having the witnesses before the Court. I observe that the witnesses appeared to be confused on a number of occasions. It is possible that this confusion could be quickly cleared up during a proper Court appearance (even by way of videoconference) with full examination-in-chief and cross-examination.

[22] Moreover, I am not persuaded that Schering and Sanofi were provided with meaningful rights to participate in the depositions despite having been invited. Their participation was considerably handicapped by the fact that they were advised of the depositions less than two days

before they took place. I understand that no documents were provided in advance to either Schering or Sanofi. Given that the trial in Toronto was sitting on both days of the depositions, the lead counsel on the files for Schering and Sanofi were unable to attend the depositions, leaving the task to counsel who – although obviously qualified – would have had far less familiarity with the issues at trial. I conclude that the rights of participation offered to Schering and Sanofi provide little comfort on the question of reliability. The rights can, in no way, be characterized as equivalent to the ability to cross-examine in a trial.

[23] Considering the problems with the reliability of the evidence, I conclude that this factor favours not admitting the Motion Documents. This conclusion would extend to the various documents that were appended to the affidavits and the deposition exhibits.

E. *Did Apotex exercise due diligence?*

[24] As I have earlier noted, Apotex asserts that it proceeded with all due diligence to obtain the evidence that it now wishes to admit. Apotex submits that it acted reasonably by giving notice to the Court and the opposing parties throughout the trial that it might later attempt to admit evidence related to proceedings that were developing in the U.S. Because of the difficulties encountered in the U.S. proceedings, Apotex alleges that they were left with no choice but to proceed with the Motion Documents at the time that it did.

[25] There are serious flaws in Apotex's reasoning on this point.

[26] Apotex has (or ought to have known) about the earlier affidavits of the witnesses that were sworn between 1995 and 2007. They are all part of publicly available Federal Court records or records of the Patent Office. It appears that Apotex's focus, in its U.S. proceedings, was initially to pursue documents it thought were in the possession of Pfizer, Inc. It was only when every possible door slammed on these efforts that "Plan B" was pursued; only then did Apotex contemplate the admission of the evidence now before me. Even the depositions were taken with a view to returning to the United States District Court, Southern District of New York to seek a reconsideration of that Court's quashing of an earlier subpoena.

[27] At the commencement of the evidentiary phase of the trial, Apotex was well aware that there was evidence from former Warner-Lambert scientists that was potentially relevant to the pleaded issues at trial. Apotex was in possession of most, if not all, of this evidence. Yet, throughout the entirety of the evidentiary phase, it did not seek to introduce this evidence in its case in-chief.

[28] In my view, Apotex chose, as a matter of strategy, not to introduce this evidence at the appropriate time at trial. It chose, as a matter of strategy, to pursue a course of action that effectively split its case and deprived the opposing parties of an opportunity to challenge this evidence.

[29] I agree with Apotex that delay, in and of itself, is not a ground for denial. However, on the facts before me this factor of due diligence weighs heavily against Apotex.

F. *Will prejudice be suffered if the evidence is admitted?*

[30] Both Sanofi and Schering submit that they would be prejudiced by the admission of the Motion Documents at this stage. Apotex submits that neither Sanofi nor Schering has adduced evidence to prove their assertion that they would suffer prejudice if the Motion Documents were admitted. In the absence of such evidence, Apotex argues that their claims of prejudice should be given little weight by this Court.

[31] In my opinion, a number of considerations give rise to prejudice.

- Given the importance of cross-examination to the trial process, I view the process proposed by Apotex in this case to be inherently prejudicial. I do not think that Sanofi and Schering need to identify the specific areas where they would choose to exercise this right. The fact is that they would be deprived of a fundamental right with respect to 3000 pages of evidence.

- Apotex's proposed procedure fails to take into consideration the fact that Sanofi and Schering would also be deprived of any ability to respond the Motion Documents. Once again, there is inherent prejudice.

- It is also too late to cross-examine Apotex's expert witnesses on the matters raised by the Motion Documents.

- I am also concerned with the integrity of our judicial process. All parties, who are currently in the process of preparing final argument, would now have 3000 more pages to consider without the benefit of seeing how the evidence would be presented if Apotex were to conduct an examination-in-chief or how cross-examination would affect the evidence. This may well affect the quality of the final arguments that are put before this Court.

[32] In sum, I am satisfied that there is prejudice to Sanofi and Schering.

G. *Conclusion on admissibility*

[33] Considering all of the factors, I am not persuaded that the Motion Documents (subject to the exception discussed below) should be admitted. In the most general of terms, the harm of admitting the evidence outweighs the good of letting it into the trial at this stage.

III. The File Histories of the '330 Patent and the '476 Patent

[34] In my view, the situation with respect to the file histories and patents for the '330 Patent and the '476 Patent is somewhat different. I am prepared to accept that these documents satisfy the threshold for relevance to the issues of obviousness and first inventorship.

[35] Pursuant to s. 13(2) of the *Patent Act*, R.S.C., 1985, c. P-4, "every court, judge and person shall…admit in evidence, without further proof and without production of the originals [such

documents]". Accordingly, the file histories of the '330 and the '476 Patent would, generally, be admissible into evidence. The question still remains as to whether I should exercise my discretion to re-open the evidentiary portion of the trial to do so.

[36] As I have ruled in admitting the file history of the '206 Patent, upon request by Schering, the file history will be of limited use. The file history simply demonstrates, without further proof, that the documents therein were placed on the file of the Patent Office on the dates that appear on any Patent Office stamps on any of the documents and have been kept on that file. However, the file wrapper does not and cannot speak to the truth of any matter contained in any document in the file history.

[37] For this reason, unlike the balance of the Motion Documents, I can see no significant prejudice to Sanofi or Schering in admitting the file histories. I will allow the admission of the certified copies of the file history for each of the '476 Patent and the '330 Patent and the relevant patents into these proceedings.

IV. Letters of Request and Commission

[38] In the alternative to the admission of the additional evidence, Apotex submits that the Court should use the procedures set out in the *Federal Courts Rules* (See r. 271 and 272) to allow for the taking of trial evidence of four witnesses – Mr. Bobowski, Dr. Hoefle, Mr. Klutchko and Mr. Ernest Nicolaides (the Warner-Lambert witnesses) – in Michigan or Colorado.

[39] The issuance of a commission to obtain evidence is an extraordinary procedure which should only be granted where special circumstances and the proper administration of justice requires it (*Canada (Minister of Citizenship and Immigration) v. Seifert*, 2004 FC 1010, 257 F.T.R. 91 at para. 10, reconsidered on other grounds 2004 FC 1711, 49 Imm. L.R. (3d) 40, aff'd 2005 FCA 105, 332 N.R. 79, leave to appeal to S.C.C. refused [2005] S.C.C.A. No. 230). The decision to set up a commission is discretionary. In adjudicating between the parties on such a discretionary matter, the Court must not only consider the rights of the parties but the effects that its decision might have on the administration of justice generally (*Canada (Minister of Citizenship and Immigration) v. Fast*, 2001 FCT 594, 206 F.T.R. 58 at para. 15 (T.D.)). On the facts before me, I am not satisfied that the issuance of a commission is warranted.

[40] To begin, I note that two factors are in favour of the granting of Apotex's request. I will accept, without deciding, that the anticipated testimony of the Warner-Lambert witnesses would be, at least at a very low threshold, relevant to the issues of obviousness and first inventorship. I am also satisfied that the Warner-Lambert witnesses, as residents of the United States could not be forced to appear in this Court.

[41] Nevertheless, I note the significant problems with the issuance of a commission, in this case and at this time, in these proceedings.

[42] The timing of this request, coming after the close of evidence and a short time before the scheduled commencement of final argument, is extremely problematic. There is no question that the issuance of a commission would thwart the trial schedule. Subpoenas would have to be issued in the

relevant jurisdictions, the individuals might or might not object, acceptable timetables and travel arrangements would have to be made; all of this will take time. There is a serious danger that the trial that was to be concluded by April 15, 2009 would drag on for months.

[43] Apotex appears to suggest that the additional evidence could be dealt with separately. Frankly, I cannot see how a separation of this evidence into a separate phase could work without placing undue burden on the parties and the Court.

[44] As discussed above, Apotex has known for months that it would like to rely on the evidence that these persons might be able to give and also that it was having little success in its attempts to use U.S. legal procedures to obtain certain evidence from Pfizer, Inc. This is not a case where the existence of a witness has only come to light; Apotex has (or ought to have had) knowledge of the affidavits that were sworn by the Warner-Lambert witnesses in earlier proceedings. There was nothing to prevent Apotex from requesting the issuance of a commission prior to trial. This path was successfully followed by Apotex in a previous case (the perindopril trial).

[45] On a minor point, I note that Apotex did not directly ask any of the Warner-Lambert witnesses (other than Dr. Nicolaides) to come to Canada to testify. Thus, while I am satisfied that the Warner-Lambert witnesses cannot be forced to testify in Canada, I am not persuaded that Apotex did everything that it could to persuade the witnesses to testify in person at this trial.

[46] In sum, I am of the view that the issuance of a commission at this time in the trial would seriously and negatively affect the administration of justice. Accordingly, having regard to r. 271

and all of the facts in this case, I am not prepared to order the trial of the Warner-Lambert witnesses out of Canada.

V. Conclusion

[47] For the above reasons, Apotex's motion will be dismissed, subject to the exception that the '330 and '476 Patents and their file histories will be admitted on the terms described above. The evidence admitted by this Order will also be evidence for the purposes of Court File No. T-1161-07.

[48] Schering seeks elevated costs. While Sanofi and Schering are entitled to their costs, I do not believe that the circumstances warrant elevated costs.

POSTSCRIPT

[1] These Reasons for Order are un-redacted from confidential Reasons for Order which were issued on March 19, 2009 pursuant to the Second Amended Protective Order dated February 28, 2008.

[2] The Court canvassed counsel for the parties whether they had concerns if the reasons were issued to the public without redactions. On March 23, 2009, the parties advised they were in agreement that there are no portions of the confidential Reasons for Order that should be redacted or otherwise edited.

ORDER

THIS COURT ORDERS that:

1. the '330 and '476 Patents and their file histories will be admitted as exhibits in this trial and in the trial of T-1161-07, on the terms described herein;

2. the balance of the motion is dismissed;

3. a copy of these Reasons for Order and Order is to be placed in Court File No. T-1161-07; and

4. costs are awarded to Sanofi and Schering, in any event of the cause, in accordance with Column III of Tariff B.

"Judith A. Snider"
Judge

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-161-07
STYLE OF CAUSE:	SANOFI-AVENTIS CANADA INC. and SCHERING CORPORATION Plaintiffs and APOTEX INC. Defendant and APOTEX INC. Plaintiff by Counterclaim and SANOFI-AVENTIS CANADA INC. and SCHERING CORPORATION SANOFI-AVENTIS DEUTSCHLAND GmbH and RATIOPHARM INC. Defendants by Counterclaim
PLACE OF HEARING:	Ottawa, Ontario and Toronto, Ontario by videoconference
DATE OF HEARING:	March 17, 2009
REASONS FOR ORDER AND ORDER:	SNIDER, J.
DATED:	March 19, 2009

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