

Date: 20080307

Docket: T-161-07

Citation: 2008 FC 320

Montréal, Quebec, March 7, 2008

PRESENT: The Honourable Madam Justice Snider

BETWEEN:

**SANOFI-AVENTIS CANADA INC. and
SCHERING CORPORATION**

Plaintiffs

and

APOTEX INC.

Defendant

AND BETWEEN:

APOTEX INC.

Plaintiff by Counterclaim

and

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

Defendants by Counterclaim

**REASONS FOR ORDER AND ORDER
(Motion for Relief from Implied Undertaking)**

I. Introduction

[1] Apotex Inc. (Apotex) is the Defendant and Plaintiff by counterclaim in Court File No. T-161-07 (the Ramipril Action). Apotex is also one of the Defendants and Plaintiffs by

counterclaim in Court File No. T-1548-06 (the Perindopril Action). In this motion, Apotex seeks relief from the implied undertaking rule that would allow it to use certain documents from the Ramipril Action in the Perindopril Action.

[2] Specifically, Apotex seeks relief in respect of the following documents (collectively referred to as the Ramipril Documents) which it has obtained during the discovery process in the Ramipril Action:

1. lab notebooks detailing the synthesis and testing of compounds related to captopril by Schering Corporation before the 17th National Medicinal Chemistry Conference in Troy, New York (the Pre-Troy Notebooks);
2. the semi-annual reports of Schering Corporation concerning the work performed with respect to ACE inhibitors spanning the times relevant to the Perindopril Action (the Semi-Annual Reports);
3. slides used at the 17th National Medicinal Chemistry Conference in Troy, New York, by Merck, Sharp and Dohme disclosing on June 18, 1980, “a group of carboxyalkyl proline derivatives which were potent non-sulfhydryl ACE inhibitors” (the Troy Slides);

4. the licence agreements between Schering Corporation and the Respondent Sanofi-Aventis Deutschland GmbH and subsequent agreements thereto (the Licence Agreements); and
5. transcripts from the examinations for discovery of Drs. Elizabeth Smith and Bernard Neustadt (the Ramipril Transcripts) for use in impeaching Dr. Smith and Mr. Anthony Creber at the trial of the Perindopril Action.

[3] For the reasons that follow, I am not persuaded that relief should be granted to Apotex and will dismiss the motion, except in respect of the Troy Slides.

II. **Background**

[4] The background to this motion is somewhat complex but necessary to understand the issues in this motion.

A. *The Conflict Proceedings leading to the 196 Patent and the 206 Patent*

[5] On October 1, 1981, ADIR, one of the Plaintiffs in the Perindopril Action, filed Canadian Application Number 387,093 (the 093 Application). Around the same time, other claimants filed their own patent applications for the issuance of patents covering overlapping compounds, including Schering Corporation (Schering) in Canadian Application Number 388,336 (the 336 Application) and Hoechst Aktiengesellschaft (Hoechst AG - the corporate predecessor to Sanofi-Aventis Deutschland GmbH (Sanofi Germany)) Canadian Applications Numbers 384,787 (the 787

Application) and 418,453 (the 453 Application). As provided for under the *Patent Act*, R.S.C. 1985, c. P-4, then in force, the Commissioner of Patents (the Commissioner) placed certain claims in the 093 Application into conflict with the claims of the other applications.

[6] As part of the conflict proceedings, the parties filed affidavit evidence before the Commissioner. Schering filed an affidavit of Dr. Elizabeth Smith (now publicly available), which documented the work done by Schering with respect to its claim to first inventorship of the applications in conflict (the Smith Affidavit). The Smith Affidavit indicated that Schering's work fell into two general phases. First, in the late 1970's, Schering sought to develop antihypertensive compounds which were more effective than captopril. Second, after June 18, 1980, Schering sought to develop antihypertensive compounds that were more effective than what later became known as enalapril. The Smith Affidavit also indicated that between these two phases a disclosure was made by Merck, Sharp, and Dohme (Merck) on June 18, 1980, of "a group of carboxyalkyl proline derivatives which were potent non-sulfhydryl ACE inhibitors" at the 17th National Medicinal Chemistry Conference in Troy, New York (the Troy Conference).

[7] In six decisions dated August 8, 1996, the Commissioner made determinations related to inventorship of the claims in conflict and awarded some claims to Schering, some to ADIR and some to Hoechst AG.

[8] Six proceedings were then commenced by way of actions in the Federal Court which challenged the determinations of the parties' rights by the Commissioner. All of the proceedings were consolidated by the Order of Justice Joyal dated May 27, 1997, into Court File No. T-228-97.

[9] Subsequent to completion of discoveries in the consolidated action, the parties to the conflict agreed to settle on terms set out in Minutes of Settlement. The parties, based on the Minutes of Settlement, applied to the Court for an Order on consent. The Order that was issued by Justice Nadon on December 12, 2000 provided for an allocation of the claims of the competing applications. Ultimately, the result of the Order for ADIR was the issuance of the Canadian Patent No. 1,341,196 (the 196 Patent). The result for Schering was the issuance of Canadian Patent No. 1,341,206 (the 206 Patent).

B. *T-161-07: the Ramipril Action*

[10] By Statement of Claim dated January 26, 2007, Schering, Sanofi-Aventis Canada (Sanofi Canada) and Sanofi Germany (collectively referred to with Sanofi Canada as Sanofi) commenced the underlying action against Apotex alleging that Apotex has infringed the 206 Patent. In its pleadings in response, Apotex raises issues that relate to the conflict proceedings and the allocation of patents pursuant to the Order of Justice Nadon that gave effect to the Minutes of Settlement. Apotex also alleges that the plaintiffs in the Ramipril Action entered into an unlawful settlement agreement with ADIR, one of the plaintiffs in the Perindopril Action, for the purpose of limiting competition in the market for ACE inhibitors, contrary to s. 45 of the *Competition Act*, R.S.C. 1985, c. C-34 (referred to by Apotex as the Settlement Conspiracy Allegations).

C. *T-1548-06: the Perindopril Action*

[11] By Statement of Claim dated August 25, 2006, Les Laboratoires Servier, ADIR, ORIL Industries, Servier Canada Inc., Servier Laboratories (Australia) Pty. Ltd. and Servier Laboratories Limited (collectively referred to as Servier) commenced an action in Court File No. T-1548-06 against Apotex and Apotex Pharmachem Inc. (Pharmachem) claiming that Apotex and Pharmachem have infringed certain claims of the 196 Patent. In its pleadings in response, Apotex raises the same Settlement Conspiracy Allegations as it does in the Ramipril Action, alleging that ADIR entered into an unlawful settlement agreement with Schering and the predecessors to Sanofi Germany, for the purpose of limiting competition in the market for ACE inhibitors, contrary to s. 45 of the *Competition Act*. In this action, Apotex has also pleaded that Schering, and not ADIR, is the first and true inventor of the subject matter of the 093 Application.

D. *The Joinder Motions of Sanofi Germany and Schering*

[12] By Notice of Motion dated August 17, 2007, Sanofi Germany sought to be added as a Defendant by Counterclaim to the Perindopril Action. Schering filed a similar Notice of Motion on November 12, 2007. This Court dismissed both Sanofi Germany's and Schering's motions on November 19, 2007 (*Laboratoires Servier v. Apotex Inc.*, 2007 FC 1210).

E. *Discoveries in the Ramipril Action*

[13] On December 6-7, 2007, Apotex held examinations for discovery of Dr. Bernard Neustadt, a named inventor of the 206 Patent, in the Ramipril Action. On November 13-16, 19-21, and 27, 2007, Apotex held examinations for discovery of Dr. Elizabeth Smith, also a named inventor of the 206 Patent, in the Ramipril Action. During the examination for discovery of Dr. Smith, Schering produced the Troy Slides.

F. *The Forthcoming Trial of the Perindopril Action*

[14] The date for the trial of the Perindopril Action is fast approaching. The trial, originally to begin on February 25, is now set to commence on March 5, 2008.

III. **Analysis**

A. *The Implied Undertaking of Confidentiality*

[15] The implied undertaking of confidentiality prevents the use of information obtained in discovery from being used other than in the litigation in which it was disclosed. Recognition of the rule was reinforced by the Supreme Court of Canada in *Lac d'Amiante du Québec Ltée v. 2858-0702 Québec Inc.*, [2001] 2 S.C.R. 743. The rule has been explicitly and consistently recognized by the Federal Court (see, for example, *Canada v. ICHI Canada Ltd.*, [1992] 1 F.C. 571

at 579 (T.D.); *Merck and Co. v. Apotex Inc.*, [1997] F.C.J. No. 1852 at para. 27 (T.D.) (QL); *Visx Inc. v. Nidek Co.* (1998), 80 C.P.R. (3d) 437 (T.D.)).

[16] The rationale behind the rule was succinctly stated by Justice Joyal in *Merck*, above at para. 18:

In *Goodman v. Rossi*, the Ontario Court of Appeal explains that there are two rationales for the implied undertaking rule. Firstly, the discovery process represents an intrusion into the right of privacy which a person has with respect to his or her documents and a necessary corollary to this intrusion is that it should not be permitted to extend beyond that which is necessary for securing justice in the proceeding in which the discovery takes place. Secondly, the rule is said to promote full discovery by avoiding the disincentive to production which the risk of collateral use might cause.

[17] In other words, the rule serves the interests of justice in two ways, by preserving a litigant's right to privacy and by encouraging parties to make full disclosure on discovery (see also *Lac d'Amiante*, above at para. 60; *Goodman v. Rossi*, [1995] O.J. No. 1906 at para. 36 (C.A.)).

B. *Relief from the Implied Undertaking of Confidentiality*

[18] The implied undertaking of confidentiality, however, is not absolute. Limits to the rule were explicitly recognized by the Supreme Court of Canada in *Lac d'Amiante*, above, where the Supreme Court indicated that the courts retain the power to relieve persons of the obligation where it is in the interests of justice. More specifically, the test was framed by Justice LeBel as a balancing exercise

which requires the court to weigh the prejudice that would be suffered if relief were not granted against the prejudice that would result if the sought-after information were to be disclosed:

The courts must therefore assess the severity of the harm to the parties involved if the rule of confidentiality were to be suspended, as well as the benefits of doing so. In cases where the harm suffered by the party who disclosed the information seems insignificant, and the benefit to the opposing party seems considerable, the court will be justified in granting leave to use the information. Before using information, however, the party in question will have to apply for leave, specifying the purposes of using the information and the reasons why it is justified, and both sides will have to be heard on the application. The court will determine whether the interests of justice in the information being used in the relations between the parties and, where applicable, in respect of other persons, outweigh the right to keep the information confidential. A number of factors, which cannot be listed exhaustively, will be taken into consideration. Disclosure of all or part of an examination, or of exhibits produced during an examination, may then be approved, in cases where there is an interest at stake that is important to the justice system or the parties (*Lac d'Amiante*, above at para. 77; see also *Goodman*, above at paras. 65-66).

[19] Justice LeBel cautioned, however, that the courts should avoid exercising their power to relieve a party from the implied undertaking too routinely, as to do so would compromise the usefulness, and potentially even the existence, of the rule (*Lac d'Amiante*, above at para. 76; see also *Goodman*, above at para. 64).

[20] The test for relief from the implied undertaking rule was also articulated by Justice Rothstein, as he then was, in *Visx*, above at para. 3. In Justice Rothstein's view, two factors must be considered before relief from the undertaking may be granted: (i) the existence of special circumstances; and (ii) the weighing of the injustice between the parties between granting or denying the application for relief from the rule. This test has been followed by two cases in the

Federal Court (*Kirkbi AG v. Ritvik Holdings Inc.*, [2000] F.C.J. No. 1793 at para. 31 (T.D.) (QL); *Letourneau v. Clearbrook Iron Works Ltd.*, 2003 FC 949). However, upon closer review, I do not find that the *Visx* test adds anything to the more general test identified in *Lac d'Amiante*, above. In particular, neither *Visx*, nor the cases that follow, clearly distinguish between the factors that must be considered at the “special circumstance” stage versus the interest of justice stage. Accordingly, the Court will consider all the surrounding circumstances in the case at bar to determine whether the interests of justice will be served by granting relief.

[21] The jurisprudence on the implied undertaking of confidentiality identifies a number of factors that should be considered in order to determine whether relief should be granted:

- The use to which the party seeks leave to put the discovered material. For example, whether relief is sought in order to use the documents in another proceeding or whether relief is sought for a commercial purpose unconnected with litigation (John B. Laskin, Q.C., “The Implied Undertaking in Ontario” (1990) 11 Adv. Q. 298 at 314-315 [Laskin]);
- If the sought-after relief is connected with litigation, whether the parties in the proceeding for which the discovery took place (the Original Proceeding) are the same or similar as the parties in the proceeding in which the documents will be used (the Companion Proceeding) (*Gleadow v. Nomura Canada Inc.*, [1996] O.J. No. 668 at para. 9 (S.C.J.));

- If the sought-after relief is connected with litigation, whether the issues or factual background in the Original Proceeding are the same as in the Companion Proceeding (*Gleadow*, above at para. 10; *Merck & Co. v. Apotex Inc.*, 2004 FC 1723 at para. 8 [*Merck 2*]; Laskin at 315). However, this factor alone does not warrant granting relief (*Letourneau*, above at para. 8);
- Whether the discovered material is inherently confidential (Laskin at 315);
- Whether the documents obtained through discovery were once publicly available but are now no longer publicly available through no fault of the party seeking relief (*Kirkbi AG*, above at para. 31);
- If the sought-after relief is connected with litigation, whether the party seeking relief in the Original Proceeding wishes to establish a witness has given inconsistent versions of the same fact in the Companion Proceeding (*Lac d'Amiante*, above at para. 77);
- If the sought-after relief is connected with litigation, whether the Original Proceeding and the Companion Proceeding are protected by orders of confidentiality (*Merck*, above at para. 24);
- Whether granting relief will result in dissemination of the information beyond the parties who already have access to it (*Merck 2*, above at para. 8; Laskin at 315);

- Whether a third party claim is likely to be initiated against the party who gave the discovery (Laskin at 316);
- If the sought-after relief is connected with litigation, whether the purposes of the Companion Proceeding can be accomplished by the Original Proceeding (*Goodman*, above at para. 68);
- If the sought-after relief is connected with litigation, whether the information sought is otherwise compellable (*Merck*, above at para. 27, *Merck 2*, above at para. 8); and
- If the sought-after relief is connected with litigation, whether granting relief affects third parties (for example, it results in the commencement of legal proceedings against third parties) (*Merck*, above at para. 22; *Merck 2*, above at para. 8).

C. *Application of Principles to the Motion before the Court*

[22] Applying these principles to the facts before me, I find the following factors favour relief from the implied undertaking covering the Ramipril Documents:

- The issue of an unlawful conspiracy is common to both actions;
- The Perindopril Action is protected by a confidentiality order (*Merck*, above at para. 24);

- Apotex will not be using the Ramipril Documents to launch a legal proceeding against a third party (*Merck 2*, above at para. 8);
- The Ramipril Documents are most likely relevant to the Perindopril Action; and
- Apotex's efforts to locate the Troy Slides in the public sphere have been unsuccessful despite the documents being formerly available to the public.

[23] Furthermore, I note that the potential prejudice to Sanofi and Schering is of a general nature and, while significant, is present whenever a party requests to be relieved from the implied undertaking of confidentiality where companion proceedings involving similar issues exist. Given that Apotex is not seeking any damages from either Sanofi or Schering in the Perindopril Action, I do not find the potential tactical advantage that Apotex might gain from using the Ramipril Documents to be of a particularly egregious nature. With respect to the Troy Slides, I can see no prejudice whatsoever to Sanofi and Schering.

[24] Notwithstanding the above, I am not persuaded that Apotex should be granted relief with respect to the Ramipril Documents, other than the Troy Slides. Even assuming all of these documents are relevant, I have numerous problems with Apotex's motion. I turn to the factors that militate against granting the requested relief.

[25] Some of the obvious responses to Apotex's request are as follows:

1. The mere fact that Apotex has alleged a common conspiracy does not justify granting relief (*Letourneau*, above at para. 8).
2. The named parties in the Perindopril Action are not the same as the parties in the Ramipril Action (*Gleadow*, above at para. 9).
3. Apotex points to the confidentiality order in place in the Perindopril Action. However, I take judicial notice that such orders are not rare in pharmaceutical patent actions and the presence of one here does not add much, if any, weight to Apotex's argument for relief.

[26] The impact on Servier, even though it is not a party to the Ramipril Action, must also be considered. As the Plaintiff and Defendant by Counterclaim to the Perindopril Action, it is self-evident that Servier is one of the "parties involved" (*Lac d'Amiante*, above at para. 77). For this motion, Apotex has selected groups of documents from the discovery process in the Ramipril Action. As a third party, Servier is unable to review the entire discovery record to determine whether there are other documents or transcript references that might assist it in responding to Ramipril Documents that would now become available in the Perindopril Action. In this, I see the potential for serious prejudice to Servier. In response, Apotex asserts that it has only "selected" entire groups of documents (for example, all of the semi-annual reports and all of the pre-Troy lab notebooks). Even accepting that this is true, I do not find this explanation to be sufficient to

dissipate the potential prejudice. There may be other documents outside these defined “groups” that could assist Servier. While Servier may have tools at its disposal to overcome the potential prejudice (although none have been described), the late hour of this motion closes that possibility. Apotex has not persuaded me that Servier would not suffer any prejudice; indeed, I believe that it is more likely than not that Servier would, at best, be at a disadvantage and, at worst, be seriously prejudiced.

[27] Further, the importance of this potential prejudice or disadvantage to Servier is heightened, in my view, by the fact that other means could have been pursued by Apotex to obtain the Ramipril Documents. Sanofi and Schering have highlighted at least five different ways – including methods explicitly spelled out in the *Federal Courts Rules*, S.O.R./98-106 – in which Apotex could have obtained the Ramipril Documents while still preserving the implied undertaking of confidentiality.

Briefly, Apotex could have:

1. Used r. 233(1) of the *Federal Courts Rules* to seek the documents from a third party;
2. Sought leave to examine a non-party by r. 238(1) of the *Federal Courts Rules*;
3. Included Schering and Sanofi as parties to its counterclaim;
4. Consented to Schering and Sanofi being joined as a party; or
5. Asked Dr. Michel Vincent questions relating to the Troy Conference.

[28] I acknowledge the arguments of Apotex that each of these avenues might pose problems. Nevertheless, it is not convincing that Apotex did not seek the information earlier and through one or more of the other means that could have brought the issue and the Ramipril Documents (or at least some of them) squarely into the Perindopril Action without the need for the extraordinary relief from the implied undertaking rule. A party should not be rewarded for its failure to use such obvious alternative procedures (*Merck*, above at para. 27).

[29] Nor is it an adequate excuse that the Perindopril Action has proceeded at such a fast pace that Apotex is unable to obtain the Ramipril Documents through other means. This Court has been involved with the Ramipril Action ever since the injunction motion in December 2006. At that time, the parties were advised of the availability of the February 2008 dates for trial. With the support of all parties, the challenge of the trial date was accepted – with, as I distinctly recall, great enthusiasm on the part of Apotex. At no time, has Apotex sought a later trial date. It is simply not acceptable for Apotex to use the timing of the trial as an excuse for obtaining relief from its implied undertaking.

[30] Apotex submits that it needs the Ramipril Documents to pursue the issues of anti-competitiveness and inventorship. The problem with this argument is that Apotex, without access to the Ramipril Documents, has managed to produce many expert reports and conduct extensive discovery. While it may have been at some disadvantage from not having the Ramipril Documents, Apotex cannot say that it was prevented from preparing what appears to be a well-documented record on the issues. While the absence of the Ramipril Documents may present difficulties to Apotex, I cannot conclude that the Ramipril Documents are “necessary” within the meaning contemplated by the jurisprudence (see, for example, *Lac d'Amiante*, above at para. 76).

[31] Finally, it should not be forgotten that the “discovery process represents an intrusion into the right of privacy” of the discovered parties (*Merck*, above at para. 18). That right should not be easily set aside lest it become meaningless.

[32] While the above reasons are sufficient to dispose of Apotex’s motion with respect to all the Ramipril Documents, other than the Troy Slides, I also note the following problems with respect to certain individual documents:

- The Licence Agreements: Servier is not a party to the Licence Agreements. While the pleadings in the Ramipril Action make specific reference to the Licence Agreements, no such reference is contained in the Perindopril Pleadings. Accordingly, the question of the relevance of these particular documents remains in question, even though Apotex has gone to considerable lengths to demonstrate that the Licence Agreements are evidence of a “three-way trade” among ADIR, Sanofi and Schering.
- The Pre-Troy Notebooks and the Semi-Annual Notebooks: Apotex claims that these materials contain information that has been “generically disclosed”. However, “documents and information given under compulsion of this Court are confidential until they become part of the public record” (*N.M. Paterson & Sons Ltd. v. St. Lawrence Seaway Management Corp.*, 2002 FCT 1247 at paras. 7-9). Apotex has submitted no evidence that these documents are part of the public record. Indeed, the

Affidavit of Andrew Lapierre indicates at paragraph 24 that the majority of the Semi-Annual Reports have not been disclosed to the public.

- The Ramipril Transcripts: The use of discovered documents may justify relief from the implied undertaking where they are used to impeach a witness who has already given evidence and that evidence is inconsistent with an earlier statement (*Lac d'Amiante*, above at para. 77 citing *Wirth Ltd. v. Acadia Pipe & Supply Corp.* (1991), 79 Alta. L.R. (2d) 345). In the case at bar, as neither Dr. Smith nor Mr. Creber has given any evidence yet, Apotex's motion is premature. Should that situation arise, this Court would entertain a further request for relief from the undertaking. Further, if a party is granted relief on the basis of speculation that witnesses may contradict themselves in some future testimony, relief from the rule would be granted as a matter of course; the rule would be rendered meaningless. I also agree that Mr. Creber, as counsel to Schering during the discovery of Dr. Neustadt, gave statements with respect to his client's position. It is unclear how those statements could be used to impeach Mr. Creber, if indeed he were called to testify.

[33] The Troy Slides are inherently different from the balance of the Ramipril Documents. They are not confidential documents. Rather, the Troy Slides were available to anyone who attended the related session at the Troy Conference. Moreover, it appears, they were disseminated afterwards. Given that 28 years have passed since the conference, it is not surprising that Apotex has been unable to locate copies of the slides from other sources, in spite of their efforts to do so. Neither

Sanofi nor Schering made any submissions of prejudice if the undertaking were to be released for the Troy Slides. Accordingly, I am prepared to grant Apotex's request for relief for the Troy Slides in this Order.

Conclusion

[34] In sum, except with respect to the Troy Slides, I am not persuaded that the interests of justice in the information that is sought to be used outweigh the rights of the parties to keep the information confidential. For these reasons, the motion will be dismissed for all but the Troy Slides. As Sanofi and Schering have been almost entirely successful in their response to Apotex's motion, they are entitled to their costs in any event of the cause. Although each of Sanofi and Schering seeks costs on an elevated scale, I can see nothing that would warrant anything other than the normal scale.

ORDER

THIS COURT ORDERS that

1. Apotex is granted relief from the implied undertaking rule with respect to the Troy Slides and may use the Troy Slides in the Perindopril Action (Court File No. T-1548-06);
2. the motion for relief from the implied undertaking rule is dismissed with respect to all other Ramipril Documents; and
3. costs are awarded to Sanofi and Schering in any event of the cause.

“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
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PLACE OF HEARING: Montréal, Quebec

DATE OF HEARING: February 28, 2008

**REASONS FOR ORDER
AND ORDER:** SNIDER, J.

DATED: March 7, 2008

APPEARANCES:

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Mr. J. Sheldon Hamilton

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