Date: 20080721

Docket: T-1321-97

Citation: 2008 FC 892

Ottawa, Ontario, July 21, 2008

PRESENT: The Honourable Justice Johanne Gauthier

BETWEEN:

ELI LILLY AND COMPANY
and ELI LILLY CANADA INC.

Plaintiffs

- and -

APOTEX INC.

Defendant

AND BETWEEN: **APOTEX INC.**

Plaintiff by Counterclaim (Defendant)

- and -

ELI LILLY AND COMPANY
and ELI LILLY CANADA INC.

Defendants by Counterclaim (Plaintiffs)

and

SHIONOGI & CO. LTD.

Defendant by Counterclaim

AMENDED REASONS FOR ORDER AND ORDER

[1] **UPON** Apotex's motion for an order directing that the documents listed in "Schedule A" of its motion record (as amended by Apotex's letter of July 11, 2008) be treated confidentially and placed under seal pursuant to Rules 151 and 152 of the *Federal Court Rules*, made in writing;

[2] **HAVING** reviewed the material submitted by the parties, including the more recent correspondence, except for the lengthy list of portions of the transcript of this proceeding, which will be dealt with in a distinct order after Apotex has revised said list taking account the present order;

[3] **UPON NOTING** that earlier in this proceeding, the Court ruled that the confidentiality order issued to protect designated documents produced and exchanged prior to trial did not apply to documents filed as exhibits during the trial. Among other things, this is so because at the trial stage, Rule 151 requires that the Court individually review each of the documents for which an order is sought, to assess whether it meets the test set out by the Supreme Court of Canada in *Sierra Club of Canada v. Canada* [2002] 2 S.C.R. 522, which test does not apply to the pre-trial phase;

[4] Given that the Court now needs to apply this test, it is worth reproducing the most salient passages of the decision:

> 53. Applying the rights and interests engaged in this case to the analytical framework of *Dagenais* and subsequent cases discussed above, the test for whether a confidentiality order ought to be granted in a case such as this one should be framed as follows:

(a) A confidentiality order under Rule 151 should only be granted when:

(b) such an order is necessary in order to prevent a serious risk to an important interest, including a commercial interest, in the context of litigation because reasonably alternative measures will not prevent the risk; and

(c) the salutary effects of the confidentiality order, including the effects on the right of civil litigants to a fair trial, outweigh its deleterious effects, including the effects on the right to free expression, which in this context includes the public interest in open and accessible court proceedings.

54. As in *Mentuck*, I would add that three important elements are subsumed under the first branch of this test. First, the risk in question must be real and substantial, in that the risk is well grounded in the evidence, and poses a serious threat to the commercial interest in question.

55. In addition, the phrase "important commercial interest" is in need of some clarification. In order to qualify as an "important commercial interest", the interest in question cannot merely be specific to the party requesting the order; the interest must be one which can be expressed in terms of a public interest in confidentiality. For example, a private company could not argue simply that the existence of a particular contract should not be made public because to do so would cause the company to lose business, thus harming its commercial interests. However, if, as in this case, exposure of information would cause a breach of a confidentiality agreement, then the commercial interest affected can be characterized more broadly as the general commercial interest of preserving confidential information. Simply put, if there is no general principle at stake, there can be no "important commercial interest" for the purposes of this test. Or, in the words of Binnie J. in *F.N. (Re)*, [2000] 1 S.C.R. 880, 2000 SCC 35, at para. 10, the open court rule only yields "where the public interest in confidentiality outweighs the public interest in openness" (emphasis added).

56. In addition to the above requirement, courts must be cautious in determining what constitutes an "important commercial interest". It must be remembered that a confidentiality order involves an infringement on freedom of expression. Although the balancing of the commercial interest with freedom of expression takes place under the second branch of the test, courts must be alive to the fundamental importance of the open court rule. See generally Muldoon J. in *Eli Lilly and Co. v. Novopharm Ltd.*, (1994), 56 C.P.R. (3d) 437 (F.C.T.D.), at p. 439.

57. Finally, the phrase "reasonably alternative measures" requires the judge to consider not only whether reasonable alternatives to a confidentiality order are

> available, but also to restrict the order as much as is reasonably possible while preserving the commercial interest in question.

[5] **UPON CONSIDERING** that the only evidence filed in support of this motion consists of an affidavit of Dr. Bernard Sherman affirmed June 20 ,2008;

[6] In this affidavit, Dr. Sherman refers to four categories of documents. The first category, comprising documents numbered 1 to 26 on the list, is described as regulatory documents or extracts thereof prepared by Apotex and submitted to Health Canada. They all include, according to Dr. Sherman, confidential proprietary information of Apotex and its suppliers, the disclosure of which would prejudice both parties.

[7] After an initial review of these documents, the Court indicated to Apotex's counsel that only a few of those documents appear to include substantive information. As a result, the list was significantly reduced. For some reason, it still includes documents that have already been the subject of a confidentiality order (TX-126, TX-129, TX-157, TX-168, TX-317, TX-167) when they were filed as exhibits during the testimony of Dr. Parra, the Health Canada representative who testified as to the content of the relevant Drug Master File. At that time, both parties agreed that all the documents filed by this representative should be treated confidentially to maintain the integrity of the regulatory system. The Court was also satisfied that generally, the public interest in maintaining the confidentiality of documents containing proprietary information filed with the

regulator on a confidential basis outweighs the public interest in open and accessible Court proceedings, in a private matter such as this one.

[8] This should not however be construed as a recognition that all the information included in such documentation is per se confidential.

[9] With respect to the remainder of documents in this category, TX-1538, TX-1539, TX-142 and TX-143, Lilly opposes the granting of the order requested. Nevertheless, having carefully reviewed said documentation, the Court is satisfied that it meets the test set out in *Sierra Club*, and these documents shall be treated pursuant to Rules 151 and 152.

[10] The second category of documents (27-46 and 96-106) has apparently not been reviewed by Dr. Sherman, for his affirmation that documents in this category contain confidential information pertaining to the synthetic process by which Apotex's cefaclor or cefaclor product is manufactured and by whom, is based on information and belief.

[11] At paragraph 6 of his affidavit, Dr. Sherman then goes on to make a very general statement that information pertaining to the synthetic process by which **an** active pharmaceutical ingredient is made is an **important trade secret** and represents proprietary information that is intimately connected to the commercial interests of Apotex and its suppliers. After affirming that information pertaining to Apotex' cefaclor formulations is equally sensitive to Apotex, Dr. Sherman then states that "[t]his information is not publicly available and is maintained on a strictly confidential basis."

It is not clear whether this last sentence refers only to Apotex's formulations, or whether it also refers to the general affirmation in respect of synthetic processes used by Apotex and its suppliers. If it is meant to apply to how the information is treated internally by each of Apotex's suppliers, there are no details or explanations as to how Mr. Sherman could objectively ascertain that this was effectively so with respect to the actual information contained in the documents of this category. It may well be that this is simply his subjective assessment of the situation. Be that as it may, it is clear for example that contrary to Dr. Sherman's assertion, the second document listed in this category (number 28, W-18), which reproduces the Kyong Bo process chart on a white board, does not contain information not publicly available or maintained in strict confidentiality; this process has been public for several years as "Appendix B" to the Statement of Claim filed by Lilly in 1997. In the circumstances, the weight that can be given to Dr. Sherman's statement is greatly diminished.

[12] Lilly also questioned the confidentiality of Apotex's second supplier's information, because it was in possession of a letter which described in great detail one of the processes used by this supplier (TX-160). Although this document, dated June 12, 1996, was not entered as an exhibit because counsel for Lilly could not ascertain by whom it was received at Lilly, it nonetheless raises some questions about the supplier's treatment of the information contained therein. Obviously, this again does nothing more than illustrate, in my view, the insufficiency of a bald assertion without any details of the basis upon which Dr. Sherman ascertained that the two suppliers of interest have treated the specific information at issue here as confidential.

[13] In this case, the Court is in a somewhat different position that in many other cases dealing with similar issues in that it has the advantage of having heard extensive testimony about the suppliers' processes. For example, both of the processes referred to as "D" and "E" appear to have been developed for the sole purpose of avoiding infringement of the patents at issue in this proceeding. And it is more or less undisputed that one of the processes described in the documents (process E) has little practical or commercial value now that all of the patents at issue in this proceeding have expired; it produces lower yields, resulting in higher production costs and an increased sale price. This certainly provides context to Dr. Sherman's affirmation that information about the specific processes is an **important** trade secret (para. 6) or that it constitutes "private and **valuable** confidential information (para. 11).

[14] Dr. Sherman also states that in providing Apotex with information **pertaining** to their processes to manufacture cefaclor, its suppliers insisted that it be treated confidentially, and that Apotex agreed to do so. Here again, this is a very general statement, and Dr. Sherman does not give any particulars as to how and when such agreements were reached. From the use of the word "insisted", one would reasonably assume that very specific discussions took place in that respect.

[15] There was only one written agreement produced during the trial (TX-1656, which will be further discussed later on), but it covers a process which is described as the proprietary information of Apotex.

[16] Dr. Sherman does not explain either what would have been covered by the undertaking described at paragraph 7. Did it apply only to technical data provided to enable Apotex to file regulatory documentation and to answer its queries in that respect in the ordinary course of business?

[17] At this stage, it is also worth noting that Apotex did not provide any details as to which passages in any of the documents listed (which include a number of expert reports) would fall within the description of "information pertaining to the process to manufacture cefaclor". There is in fact a disconnect between the affirmation of Dr. Sherman, and the compilation by someone other than him of the list of documents containing information which was agreed would be kept confidential. In order for the Court to give weight to Dr. Sherman's affirmation, he would have had to have reviewed the documents himself in order to satisfy himself that they indeed contain information that falls within what he understood to be the agreement.

[18] On the basis of the record before it, the Court is not prepared to accept that documents such as Kyong Bo's two page letter to Apotex (filed as TX-622) provided in answer to Apotex's in-house counsel's query regarding the basis of the supplier's allegation that it obtained the right to use the "Shionogi process" is "process information pertaining to the manufacture of cefaclor" that would be covered by the so-called "confidentiality undertaking" described in paragraph 7 of the affidavit.

[19] There was an argument at one point that the very name of Apotex's supplier should be treated confidentiality. It is not clear whether this position has been abandoned totally (there is nothing else that would justify the inclusion of document 29); if it has not, it bears mention that the name Kyong Bo has been identified in the public record as a supplier of Apotex since at least 1997 and that its other supplier's name has been mentioned in at least one past order of this Court (Hugessen J., dated July 26, 2000) and in minutes of the Court that are publicly available. The Court finds that Apotex has not met its burden of establishing, on a balance of probabilities, the existence of a serious risk. Thus the public interest in open and accessible Court proceeding must prevail.

[20] Turning to exhibit TX-1656, it is a one-page contract (with a one-page appendix) signed in March 1998, that is, several months after the supplier in question had started to supply Apotex with cefaclor. It cannot be subject to the undertaking described in paragraph 7 of Dr. Sherman's affidavit, given that the process it describes is not, according to Dr. Sherman, the supplier's proprietary information. In effect, the contract expressly provides that the supplier undertakes to keep the process confidential and to use it only for the purpose of producing cefaclor for Apotex, and Dr. Sherman himself testified at the trial that he marked the appendix with the notation "confidential property of Apotex Inc." [1]

[1] If as argued by Apotex's experts, process "E" is essentially the same as process "D", the question is raised as to whether process "E" is also the property of Apotex, and not that of its supplier.

[21] Dr. Sherman does not specify in his affidavit how or why the very fact that Apotex contracted with this supplier, which clearly advertises that it produces cefaclor, would cause a serious risk to its commercial interest. In fact, the contract itself, although it deals with the issue of confidentiality, does not provide that its terms (as opposed to the process in Appendix A) are to be kept confidential.

[22] As argued by Lilly, it is also difficult to understand how the reference to the use of teachings of patents that are all in the public domain, as well as the description of a process which Apotex's experts testified was all part of the prior art (Appendix A), could constitute confidential information the disclosure of which would prejudice Apotex. This is particularly so when one considers the evidence referred to earlier with respect to the impracticality and commercial value of said process, now that the patents at issue have all expired and Apotex' competitors all have access to these superior and less costly processes to produce cefaclor. The situation in that respect is now very different from circumstances which prevailed in 1998 when the contract was concluded and the notation added.

[23] The weakness of the evidence produced in support of the motion in that respect, assessed in light of the evidence adduced at trial, leads me to conclude that Apotex has not established on a balance of probabilities that it meets the first part of the test in respect of this document.

[24] With respect to TX-135, the Court is satisfied that this information (identifying the specific solvent used by Kyong Bo) was disclosed to Apotex solely for the purpose of regulatory filings and should be treated confidentially. It goes beyond the more general information disclosed in W-18.

[25] Although the context in which the process description in TX-158 was provided is not as clear, and the evidence of a serious risk is weak given the nature of the information, the Court is nonetheless prepared to accept that this information meets the applicable test.

[26] With respect to W-17, the title on the white board will be expunged, not because the name of the supplier is confidential (as discussed), but because this constitutes an alternative measure which prevents any serious risk to the commercial interests evoked by Apotex. In effect, the very general description of compounds in W-17 discloses no more than what is already in the public domain through the various patents at issue in this case.

[27] Exhibit TX-159 is Apotex's supplier's answers to queries from Apotex' in-house counsel, who was trying to determine whether the supplier's process was likely to infringe certain of the patents at issue. Apotex had originally claimed a legal privilege on this document (for litigation purposes) and obtained an order in that respect, but decided sometime before trial to waive said privilege. The document provides information about tests that were performed and certain parameters that were measured for comparison with data in the Lilly patents.

[28] Here again, the evidence is not sufficient to establish that the characteristics of the compound tested by the supplier is information that falls within the description at paras. 6 or 7 of Dr. Sherman's affidavit. The Court is willing however to expunge from the document information directly describing the actual manufacturing process, at page 2, beginning with the phrase "please note" through page 4 inclusive, as well as to delete the two words appearing before "complex" in the first sentences of paragraphs 1(1), 2, 3, and 4.

[29] With respect to documents nos. 96 to 105, these are all expert reports that deal with much more than the information described in Dr. Sherman's affidavit. Again, as Apotex took the position that no reasonable alternatives existed than to seal these reports in their entirety, it did not specify which paragraphs it considered would create a serious risk to its commercial interests.

[30] In my view, it would be contrary to the principle of open and transparent justice to seal a whole report simply because an appendix or a paragraph contains what Dr. Sherman describes as "private and valuable information" the disclosure of which would prejudice Apotex.

[31] Thus each document was individually assessed and only the portions which passed the applicable test will be expunged or sealed (in the case of appendices). In document 105 (A-15), which deals only with the validity of the patents at issue, no potentially confidential information was found.

[32] Finally, the Court notes that it has already issued an order pursuant to Rule 151 in respect of TX-340 (both parties were in agreement in that respect).

[33] This brings us to the last two categories of documents, the first of which consists of documents provided by one of Apotex's suppliers shortly prior to trial to be introduced into evidence by two of that supplier's employees scheduled to testify at trial. The others (G-1 to G-35) are documents submitted by Glopec, the Canadian agent of that same supplier, after receiving a subpoena from Lilly as well as Apotex.

[34] Dr. Sherman attached to his affidavit three letters. The first, from the supplier's legal counsel, is addressed to both Lilly and Apotex. It states that the testimony and the documents to be produced "at least in part" will deal with "details of the manufacture of cefaclor which constitute trade secrets intimately connected with [the supplier's] commercial interests." It is to be noted that at the time of this letter, the documents in question had yet to be assembled by the supplier's counsel, who was requesting confirmation that the testimony as well as the documents would be subject to the terms of a valid protective order. It also appeared that the supplier's counsel would likely attend the trial.

[35] Apotex confirmed that it would cooperate (presumably by designating these documents under the existing order and by filing this motion) and that it was content to see these documents protected. Lilly did not respond at all and currently objects to the granting of this motion, particularly in light of the evidence offered in support, which in its view is clearly insufficient to support the order sought.

[36] By this date, the Court had already advised the parties that it had serious doubts that any confidentiality order issued before trial would apply during the trial phase. The best that could be agreed to was to protect the confidentiality of the documents not filed as exhibits or to seek an order from the Court which is the only body that can actually grant such an order.

[37] It is evident that the supplier was in a better position than Apotex to provide the detailed evidence necessary to support a motion for confidentiality. The supplier could have, but did not, make any representations or motion to obtain the order now sought.

[38] As to Glopec, its solicitor advised both parties by e-mail that his client's file contains confidential information of the manufacturer and supplier and that "accordingly" it must be treated as confidential. Although the solicitor mentions that the documents are provided on the express understanding that they are subject to the protective order that is in effect, it is clear that absent a motion from Glopec to the Court on the morning Mr. Singh was scheduled to testify, his client was bound to answer the subpoenas issued by the parties. It appears that neither party responded to this e-mail.

[39] Be that as it may, it is not clear if Apotex is arguing that this correspondence in itself creates a confidentiality undertaking akin to the one discussed in *Sierra Club*, and that this avoids the need for the supplier itself to establish that the information contained in the documentation is of such a nature that its preservation constitutes an important interest that warrants protection.

[40] I do not believe that this is so, for it appears to me that the context in which such an undertaking is made must be considered. That said, the Court does not need to rule in this respect for even if it was so, there is still the need to establish that the risk is "real and substantial" and poses a "serious threat" to the commercial interest in question.

[41] The documents identified as Satpute-1 and Satpute-2 contain no "details of the manufacture of cefaclor" by this supplier. They refer to old pilot batches of product made by a process which was not found practical by the supplier. They also reflect discussions in the context of developing the "non-infringing process" discussed in TX-1656. At best, it could be argued that these pertain broadly to the process described in that contract; thus they should not be treated any differently. For the many reasons explained earlier I find that the evidence is simply insufficient to enable the Court to conclude to the existence of a serious risk to an important interest.

[42] In contrast, Satpute-3 does contain details of a manufacturing process for the key intermediate used in making cefaclor. The Court is satisfied that this information should be treated confidentially. However this conclusion does not apply to the first page of this document which contains no technical information outside of a reference to the name of the intermediate. There is insufficient evidence before the Court to conclude that this information is regarded and treated by the supplier as a "proprietary trade secret," and certainly no indication that the disclosure of this information alone would create a serious risk to any important commercial interest.

[43] Once again, more detailed evidence from the supplier itself would have been required to support such a conclusion, given that this compound and its name appear to be in the public domain.

[44] I also find that there is no justification for the issuance of an order of confidentiality in respect of Patil-1, Patil-4, Patil-5, Patil-6, Glopec-1 to Glopec-13, Glopec-28, Glopec-29, Glopec-30, Glopec-32, Glopec-33, which are essentially one page letters containing no information of the nature described in the letter of the supplier's legal counsel or in Dr. Sherman's affidavit (para. 6 to 11).

[45] However, I have concluded that Patil-2, Patil-3, Patil-7, Patil-9, Patil-10, and Glopec-15, Glopec-16, and Glopec-35 (except first page of these last five exhibits) contain material information about the supplier's process and that Apotex has met the test to obtain the order sought.

[46] For the same reason given with respect of the first page of Satpute-3, I find that Glopec-31, Glopec-34, Glopec-14, and the first page of Glopec-15 and the first page of Patil-10, should not be the subject of an order of confidentiality.

[47] I believe that I have now covered all of the documents remaining on Apotex's list.

[48] Apotex did not seek costs and indicated that it opposed any such attempt by Lilly. The Court considers that no costs should be granted on this motion, but reserves Lilly's right to refer to it when arguing the issue of costs at the end of this proceeding.

ORDER

THIS COURT ORDERS that

(a) This motion is granted in part. The following exhibits or identified portions thereof shall be treated confidentially in accordance with Rules 151-152:

TX-1538;
TX 1539;
TX-141;
TX-142;
TX-143;
TX–134 (letter dated July 21, 1995);
TX-135;
TX-158;
Patil-2;
Patil-3;
Patil-7;
Patil-9 (except first page);
Patil-10 (except first page);
Glopec–15 (except first page);
Glopec-16 (except first page);
Glopec–35 (except first page);
Satpute-3 (except first page);

(b) Also, the indicated portions of the following documents shall be expunged from the copies kept in the public record and certain appendices sealed as follows:

TX-159: Page 2, beginning with the phrase “please note”, through page 4 inclusive (expunged), as well as the two words appearing before “complex” in the first sentences of paragraphs 1(1), 2, 3, and 4

Glopex-19: *idem.*

Glopec-17: on p. 1, the first sentence under the heading “With regard to Step V”, and all of p. 2;

Glopec-18: *idem.*

Glopec-20: Schematic diagram at paragraph A);

Glopec-21: *idem.*

Glopec-22: Paragraphs A, B, and D (expunged);

Glopec-23: From the phrase “With regard to Step IIIA” up to the words “and while” at line 6 of the paragraph beginning “With regard to Step IIIb”(expunged);

Glopec-24: *idem.*

Glopec-25: On p.1, the first paragraph under the heading “With regard to step IIIb” (expunged)

E-1: paragraphs 59 – 93 (expunged) and exhibits B, C, D, E (sealed)

A-1: *idem.*

E-2: exhibits 1, 2 (sealed)

E-3: exhibits B and C (sealed)

E-5: paragraphs 36-39 (expunged) and exhibits B and C (sealed)

E-11: paragraph 11, the citation at paragraph 13 (expunged), exhibits B, C, D (sealed)

TX-1764: paragraph 24, first sentence of paragraph 47 (expunged)

“Johanne Gauthier”

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1321-97
STYLE OF CAUSE:	Eli Lilly and Company et al. **v.** Apotex Inc.

MOTION DEALT WITHOUT APPEARANCE OF PARTIES

REASONS FOR ORDER AND ORDER BY:	GAUTHIER J.
DATED:	July 21, 2008

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