Date: 20070828

Docket: T-427-06

Citation: 2007 FC 857

Ottawa, Ontario, August 28, 2007

PRESENT: The Honourable Mr. Justice Blais

BETWEEN:

SOLVAY PHARMA INC. and
ALTANA PHARMA AG

Applicants

and

APOTEX INC. and
THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

[1] This is an application by Solvay Pharma Inc. and Altana Pharma AG (the applicants) to file the supplemental affidavit evidence of Dr. Jorg Senn-Bilfinger and the affidavit of Laura Meucci attaching, as exhibit A, a letter received from Health Canada on August 2, 2007 pursuant to Rule 312 of the *Federal Courts Rules*, SOR/2004-283.

BACKGROUND

[2] By notice of application dated March 9, 2006, the applicants commenced the within proceeding seeking an order pursuant to section 6 of the Regulations prohibiting the Minister from issuing a Notice of Compliance (NOC) to Apotex for its pantoprazole product.

[3] By virtue of the applicants' commencement of the application, a 24-month statutory injunction was imposed on Apotex prior to it being entitled to market and sell its own enteric-coated tablets comprising pantaprazole sodium. That presumptive injunction expires on March 9, 2008.

[4] The applicants' evidence in support of their case was due on April 10, 2006.

[5] The applicants' request for a more than six months extension of time was partially granted as the applicants now had until July 14, 2006 to file their evidence.

[6] Later on, by notice of motion dated June 21, 2006, the applicants sought another extension of time which was denied by Madam Protonotary Milczynski.

[7] Finally, the parties agreed that the applicant could get an additional three weeks to serve and file their evidence. The evidence was filed on August 4, 2006, including an affidavit of Dr. Jorge Senn-Bilfinger sworn August 1, 2006.

[8] The applicants sought another extension of time to file additional evidence which was the affidavit of Dr. Corbin; Apotex provided its consent and obtained an extension of time until January 31, 2007 to respond to the evidence of the applicants.

[9] Apotex served its evidence upon the applicants on January 30, 2007.

[10] By notice of motion dated March 14, 2007, the applicants sought leave to file reply evidence.

[11] The applicants proposed to file ten new affidavits, including one of Dr. Senn-Bilfinger to be sworn in April 2007 in reply to Apotex's evidence. The drafts of all ten affidavits were delivered by the applicants on April 10, 2007, which is, as noted by the respondents, exactly one year after the applicants' evidence was first due.

[12] In the decision dated June 15, 2007, Madam Prothonotary Tabib granted leave only for a partial reply evidence for a total of six paragraphs from three of the ten affidavits. Leave to file any portion of the second Senn-Bilfinger affidavit was denied.

[13] By notice of motion dated July 18, 2007, the applicants again seek leave to file reply evidence.

[14] This is the motion before the Court now.

ANALYSIS

[15] The third Senn-Bilfinger affidavit attaches two research reports (Research Report No. 32/91 and Research Report No. 101/91) as exhibits. The third Senn-Bilfinger affidavit and the reports purport to address Apotex's allegations concerning sound prediction.

[16] It is not usually permitted to file reply evidence.

[17] The Court has established some basic principles to allow such reply evidence. In *Wayzhushk Onigum Nation v. Kakeway* (2000), 182 F.T.R. 100, Prothonotary Hargrave held at paragraphs 5-7:

> In my view, the 1998 Federal Court Rule 312 allows the filing of a supplementary affidavit in limited instances and special circumstances, for to do otherwise would not be in the spirit of judicial review proceedings which are designed to obtain quick relief through a summary procedure. While the general test, as reflected in Eli Lily, Abbott Laboratories and Bayer A.G. (supra) is whether the additional material will serve the interests of justice, will assist the court and will not seriously prejudice the other side, it is also important that any supplementary affidavit neither deal with material which could have been made available at an earlier date, nor unduly delay the proceedings. To this I would add two further observations.
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> First, supplemental material is meant to provide additional factual evidence to meet the respondent's case: see for example Vrabek v. Minister of National Revenue, [1997] N.R. Uned. 39; [1997] 2 C.T.C. 261, at pp. 262-263 (F.C.A.). Moreover, a reply affidavit is to meet the other sides case, not merely to confirm the deponent's initial evidence.
>
> Second, a motion to file reply affidavit evidence ought to be brought promptly, for not only is judicial review, by the use of an application, a summary procedure designed to get a hearing with a minimum of delay, but also, and equally important, delay will often be a bar to a discretionary remedy.

[18] In an application under the *Patent Medicines Regulations,* supplemental affidavits should be allowed only in very limited circumstances. It cannot be used to introduce additional legal arguments. Justice Paul Rouleau in *Abbott Laboratories, Ltd. v. Nu-Pharm Inc. et al.* (1998), 82 C.P.R. (3d) 216 at paragraph 11 held:

> Judicial review and more particularly the patent medicines regulations require that these applications are to be conducted summarily and expeditiously. To allow the respondents to file a third affidavit from the same expert containing some 62 pages will not contribute in any way to a better understanding or clarification of the issues.

[19] The Court of Appeal also discussed the question of filing reply evidence in *Atlantic Engraving Ltd. v. Lapointe Rosenstein* (2002), 23 C.P.R. (4th) 5 at paragraph 9:

> Further, an applicant, in seeking leave to file additional material, must show that the evidence sought to be adduced was not available prior to the cross-examination of the opponent's affidavits. Rule 312 is not there to allow a party to split its case and a party must put its best case forward at the first opportunity. […]

[20] On that subject, the applicants' counsel points out that the cross-examinations have not occurred yet. Nevertheless, the clock is ticking and the hearing of the case is already fixed for December. There is at least another motion pending and the time is very limited for cross-examinations on affidavits given the high number of affidavits that were filed on both sides.

[21] Madam Prothonotary Tabib in her decision dated June 15, 2007, held at page 2:

> The Applicants have already filed their evidence pursuant to Rule 306, the affidavit of twelve expert witnesses, while Apotex has responded with some ten expert witnesses. By their motion, the Applicants would add supplementary evidence from ten experts, one of whom is a new expert who has not yet filed any evidence in this

> case. The proposed affidavits would add a total of 87 pages of affidavit evidence, excluding exhibits, to a case that already has a surfeit of expert evidence. The Applicants' within motion was filed nearly ten weeks after the delivery of Apotex' evidence, in a matter where the parties have already engaged each other of the issue of delays.

[22] Suffice it to say that this large volume of technical evidence already filed is subject to cross-examination. If the Court allows filing of two other documents, this will increase the duty of the respondent and somehow limit his capacity to face this new evidence at the last minute.

[23] The applicants are right when they say that the interests of justice are better served if the Court has all relevant information before it. Nevertheless, it has to be done pursuant to the rules and there are limits. The affidavit of Laura Meucci attaching a letter received from Health Canada dated July 30, 2007 is in response to a letter sent by the applicants on July 17, 2007 referring to other documents that were not filed. The applicants want to file this document which amounts to introducing an opinion by an associate director of the office of Patented Medecines and Liaison. This correspondence was exchanged only a few weeks ago and the letter cannot, in any way, be considered as evidence. It is not an affidavit, and the documents referred to in it are unknown. Hence, it is hearsay. In my view, that is sufficient to reject the application to file this letter as evidence.

[24] Regarding the two reports that the applicants want to introduce, those documents have existed since 1991. Pursuant to Dr. Senn-Bilfinger's affidavit, when he signed his first affidavit on August 1, 2006 he advised counsel that the documents attached to his initial affidavit were the only

ones in his possession. Later on, Dr. Senn-Bilfinger tried to locate those reports and has been unable to find them on his own. Pursuant to his affidavit in May 2007, it was only with the assistance of a company information research specialist that the reports were finally located. Dr. Senn-Bilfinger now believes that those two researches would be relevant to these proceedings. Despite the fact that those researches were located in May 2007, he waited until the end of June when a scheduled meeting with counsel occurred to bring copies of these reports.

[25] As suggested by counsel for Apotex, the documents are not filed nor commented on by an expert. The detailed scientific nature of the documents and the absence of expert consideration make me doubt the impact or relevance of the documents on this case.

[26] In addition, I am considering the prejudice that could be created to Apotex if those documents were filed. Dr. Senn-Bilfinger mentioned that he made a mental note to himself at the time he wrote the first affidavit; he recalled that the reports supported certain of his statements in his first affidavit. Nevertheless, it was not mentioned in the affidavit and it is only when he finally located them, almost a year later, that he seeks to introduce them. That is, only a few months before the hearing and just a few weeks before the cross-examinations would be done. The reports were available at an earlier date; it is unfortunate that they could not be located earlier.

[27] I am of the opinion that Apotex will suffer a prejudice if they now have to take those reports and ask their experts to examine these documents and see whether there is an impact and whether they should reply to it in any way or use the cross-examination process to do that. Given the time

constraint they could suffer a prejudice. We should remember that the 24-month injunction is there and, not only should the hearing be completed on schedule, but a judgment should be rendered also in due time to avoid any prejudice to any of the parties.

[28] Therefore, I have no hesitation to conclude that this motion to file reply evidence should be dismissed. Costs in favour of the respondents.

ORDER

THIS COURT ORDERS that

1. This motion to file reply evidence be dismissed.

2. Costs in favour of the respondents.

"Pierre Blais"

Judge

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-427-06	
STYLE OF CAUSE:	SOLVAY PHARMA INC. and ALTANA PHARMA AG	Applicants
	v. APOTEX INC. and THE MINISTER OF HEALTH	Respondents
PLACE OF HEARING:	Toronto, Ontario	
DATE OF HEARING:	August 13, 2007	
REASONS FOR ORDER AND ORDER:	BLAIS J.	
DATED:	August 28, 2007	

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