Date: 20070914

Docket: T-427-06

Citation: 2007 FC 913

Ottawa, Ontario, September 14, 2007

PRESENT: The Honourable Madam Justice Snider

BETWEEN:

SOLVAY PHARMA INC. and ALTANA PHARMA AG

Applicants

and

APOTEX INC. and THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

[1] In this motion, the Applicants appeal the decision of Prothonotary Tabib dated June 15, 2007. In that decision, the Prothonotary denied the Applicants' motion to file affidavits from 10 experts in reply, although certain limited portions of the affidavit evidence were allowed.

[2] The background to this motion involves an application under s. 6 of the *Patented Medicine (Notice of Compliance) Regulations*, S.O.R./93-133 (the *Regulations*), filed March 9, 2006, in

which the Applicants seek to prohibit the Minister of Health from issuing a Notice of Compliance (NOC) to Apotex Inc. (Apotex) in respect of Apotex's pantoprazole product.

[3] Evidence in NOC proceedings is presented to the Court by way of affidavit, as provided for in Rules 306 and 307 of the *Federal Courts Rules*. In this case, after being granted significant extensions of time, the bulk of the Applicants' evidence – consisting of affidavits from 12 expert witnesses – was finally filed on August 4, 2006. On January 30, 2007, Apotex responded with affidavits from 10 expert witnesses.

[4] Pursuant to Rule 312, further affidavits may only be filed with the leave of the Court. Accordingly, the Applicants brought two motions to submit further affidavit evidence. The first of these two motions (Notice of Motion dated March 14, 2007) was heard by Prothonotary Tabib and is the subject of this motion of appeal. The second motion (Notice of Motion dated July 18, 2007) was heard by Justice Blais who dismissed the motion (see *Solvay Pharma Inc. v. Apotex Inc. and the Minister of Health*, 2007 FC 857).

[5] The issue before me is whether the Prothonotary erred in refusing to admit the greater portion of the reply affidavit evidence.

Standard of Review of Prothonotary Decisions

[6] The standard of review of decisions of prothonotaries of the Federal Court is well-established (see *Canada v. Aqua-Gem Investments Ltd. (C.A.)*, [1993] 2 F.C. 425; *Merck & Co. v.*

Apotex Inc. (2003), 30 C.P.R. (4th) 40 (F.C.A.)). Discretionary orders of prothonotaries should not be disturbed unless:

(a) the issue raised is vital to the final issues in the case; or

(b) the orders were clearly wrong in the sense of making a decision based upon a wrong principle or upon a misunderstanding or misapprehension as to the facts (*Merck*, above at para. 19).

[7] This motion does not deal with any matter that is vital to the final issues (such as, for example, a motion to strike). A motion to permit reply evidence is a procedural matter and, as noted in *Contour Optik, Inc. v. Viva Canada Inc.* (2005), 45 C.P.R. (4th) 31 at para. 27, aff'd 2007 FCA 81, "it will be rare indeed that a procedural matter will amount to a vital issue."

[8] That is not to say that the outcome of the motion is not important to the Applicants. However, the fact that something is important does not automatically make it "vital". Accordingly, my analysis will be restricted to determining whether Prothonotary Tabib's Order was clearly wrong in the sense of making a decision based upon a wrong principle or upon a misunderstanding or misapprehension as to the facts.

Principles Applicable to Reply Evidence

[9] What is at issue in the motion before me is whether Prothonotary Tabib properly exercised her discretion pursuant to Rule 312 of the *Federal Courts Rules*. The application of Rule 312 is

clearly discretionary as both a review of the language of the provision ("With leave of the Court, a party may…") and the case law reveal (*Mazhero v. Canada Industrial Relations Board*, 2002 FCA 295 at para. 5; *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FC 790 at paras. 15-16).

[10] The Courts have provided some guidance to prothonotaries and judges on how to apply this discretion. As stated in a number of decisions (see, for example, *Eli Lilly and Co. v. Apotex Inc.* (1997), 76 C.P.R. (3d) 15 at 18-19 (F.C.T.D.)), the test for admitting additional evidence requires that the evidence:

1. Serve the interests of justice;

2. Assist the Court in making its final determination; and

3. Does not cause substantial or serious prejudice to the other party.

[11] A fourth factor was added by the Court of Appeal in *Atlantic Engraving Limited v. Lapointe Rosenstein* (2002), 23 C.P.R. (4th) 5 at 8-9 (F.C.A.) and requires that "the evidence sought to be adduced was not available prior to the cross-examination of the opponent's affidavits". This fourth test element has been accepted in the context of NOC proceedings (see *Pfizer Canada Inc. v. Canada (Minister of Health)* [2007] 2 F.C.R. 371 at paras. 20-21, 2006 FC 984; *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FC 506.

[12] The jurisprudence does not prescribe how these four elements are to be weighed. Further, because each decision is discretionary and will be fact-specific, there may be other factors that may be relevant in any given case. Thus, it is fair to say that each case will involve a different weighing depending on the individual circumstances before the decision maker. The obligation of the judge or prothonotary is to consider the relevant factors against all of the facts before him or her.

Reasons of the Prothonotary

[13] The Applicants sought to introduce 10 affidavits in reply to those submitted by Apotex. The reasons provided by Prothonotary Tabib are quite detailed. In pages 3 to 12 of her Order, after setting out three general opening paragraphs, she carefully reviews all aspects of each of the 10 affidavits. On a paragraph by paragraph basis and in detail, she describes the evidence and sets out the factors upon which she determined whether the paragraph would be allowed or not. In some cases, the evidence was allowed; however, for most of the evidence, the request was refused.

[14] The primary focus of this motion is on the first two paragraphs of the reasons, which are as follows:

> The Applicants have already filed as part of their evidence pursuant to Rule 306, the affidavits 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's evidence, in a matter where the parties have already engaged each other on the issue of delays.
>
> While the determinations I have made with respect to whether leave should be granted to file the various affidavits or parts thereof are essentially based on whether the material is necessary, would assist the Court in determining the issues before it

> or was available at an earlier date, the fact that the parties may well already have exceeded the limits provided in Section 7 of the *Canada Evidence Act* as to the number of experts they may call on any one issue, without having sought prior leave, and the significant delay on the part of the Applicants in bringing the present motion have been generally weighed in considering whether granting leave would serve the interests of justice or might cause prejudice to the other party.

[15] In the Applicants' view, these general comments indicate that the Prothonotary was exercising her discretion based upon wrong principles or a misapprehension of the facts. The principal errors alleged by the Applicants are that:

1. The Prothonotary erred by relying on the fact that the Applicants "may" have exceeded the limits set out in the *Canada Evidence Act*;

2. The Prothonotary misapprehended the facts when she stated that there had been "significant delay" on the part of the Applicants in bringing their motion and erred by relying on this "delay"; and

3. The Prothonotary applied an incorrect test for considering whether reply evidence could be filed by requiring that the material in the affidavits be "necessary" and by ignoring that any prejudice to Apotex must be significant or serious.

[16] The first problem that I see is that the Applicants are not reading the reasons of the Prothonotary as a whole or in the context of NOC applications and the particular facts of this case. I first note that the paragraphs in question were clearly not intended to be a statement of the law on

when reply evidence would be permitted in an NOC proceeding. This is amply demonstrated by the paragraph the follows the cited passage where the Prothonotary states that:

> I will also note that the parties are in general agreement as to the legal principles applicable to the within motion, such that it is not necessary for me to discuss these principles, but merely to apply them to the facts of the case.

[17] The Prothonotary's understanding of the correct test is well set out in the detailed analysis of the record before her, which analysis follows the general statements. While the Applicants may not agree with the weight that she places on some of the factors for each of her findings, they cannot argue that she ignored any evidence or that, in the specific analyses, she referred to any irrelevant factors.

[18] Evidence of the careful analysis by the Prothonotary is that certain parts of the evidence were allowed. It is evident throughout – whether she allowed or disallowed the evidence – that the Prothonotary was assessing the evidence in light of the correct legal principles. I also note that, in the detailed analysis, the Prothonotary makes no mention whatsoever of the Applicants' delay in bringing the motion or of s. 7 of the *Canada Evidence Act*. This indicates that, in the context of individual determinations, little, if any, weight was placed on these two considerations.

[19] So, but for the first two paragraphs, the conclusion of any reviewing judge would almost certainly be that the Prothonotary did not make a decision based upon a wrong principle. The question remains, however, whether the first two general paragraphs cited above show that, without any further express reference, the Prothonotary was, indeed, applying irrelevant considerations or wrong principles throughout her decision.

Section 7 of the *Canada Evidence Act*

[20] The Applicants submit that the Prothonotary erred by taking into account that the Applicants "may" have exceeded the limits set out in the *Canada Evidence Act*. I agree that it would be an error for the Prothonotary to take this into account without a clear determination that the Applicants had acted contrary to the *Canada Evidence Act*.

[21] However, in my view, this is not what the Prothonotary did. Rather, I read this sentence as a reference to the volume of evidence filed to date. In other words, she is stating that the volume of the evidence – which, incidentally, may have exceeded the limits of the *Canada Evidence Act* – was a general factor to be weighed in determining whether the reply should be allowed. The volume of evidence may affect the ability of parties to manage the NOC process within the relevant time limits and is, in my view, a relevant factor.

[22] The reference to s. 7 of the *Canada Evidence Act* by the Prothonotary was not needed; it adds nothing to the decision. However, when I read the specific analysis on each part of the proposed reply, it is apparent that no weight was placed on the possible breach. There is not a single reference to s. 7. Thus, while the Prothonotary's words may have been ill-chosen, there is no clear error.

Delay

[23] The Applicants submit that the Prothonotary based her decision on a wrong principle or misapprehension of the facts in weighing the delay of the Applicants in bringing the motion. They point out that the delay was not ten weeks as stated by the Prothonotary, but only six weeks from

the time they were served with Apotex's expert affidavits to the time when they brought the Notice of Motion. In their view, this is not an unreasonable length of time to bring the Notice of Motion.

[24] It is well-known that, due to the statutory stay imposed on Apotex by the *Regulations*, the application must be heard and decided by the Court during a two-year window; in this case, that would be by March 9, 2008. To the extent that delays cause this date to be extended, Apotex will be prevented for a longer period from bringing its product to market (or from being told that it cannot do so). Thus, in general, delay is a relevant and important consideration with particular impact on Apotex as the responding party.

[25] The road to the hearing of this particular application has not been easy. There have been many procedural motions and motions for extensions of time. At the stage when the Prothonotary heard the motion in question, a schedule had been ordered, by Order dated March 27, 2007, that provided for the completion of cross-examination by September 30, 2007 and a five-day hearing to commence on December 10, 2007. It is reasonable to conclude that further reply would cause stress to the timetable and possibly require an extension of the two-year statutory stay. At this stage, any delay is a relevant and important consideration.

[26] When the Prothonotary referred to the ten-week delay in filing the "within motion", she was obviously referring to the filing of the motion record. Her calculation of this time was factually correct. The ten weeks included the weeks from the filing of Apotex's evidence to the filing of the Notice of Motion. In the context of this NOC application, it is clear that the Prothonotary considered that the Applicants could have brought its Notice of Motion more quickly. Given the importance of

time at this stage of the proceedings (even two or three weeks could have a serious impact on the schedule), it was not unreasonable for the Prothonotary to take the delay into account. Further, from my review of the specific conclusions by the Prothonotary, I am not persuaded that delay can be isolated as a determinative factor in any of the specific conclusions.

[27] On the question of delay, the Applicants also submit that prejudice should not be weighed as a factor where cross-examination has not yet taken place (*AB Hassle v. Canada (Minister of National Health and Welfare)* (1995), 61 C.P.R. (3d) 492 at 493 (F.C.T.D.), aff'd 64 C.P.R. (3d) 78 (F.C.A.); *AB Hassle v. Apotex Inc.* (2003), 30 C.P.R. (4th) 519 at 527 (F.C.); *Novopharm v. Canada* (1995), 61 C.P.R. (3d) 82 at 88 (F.C.A.)). What the cases put forth by the Applicants demonstrate is that there may be situations where the prejudice to the Applicants or Court justify the admission of affidavit of documents. However, they do not indicate that Prothonotary Tabib clearly erred by considering the effect of delay caused by the Applicants (*Wayzhushk Onigum Nation v. Kakeway* (2000), 182 F.T.R. 100 at para. 7). Nor do they indicate that the prejudice to the Court or the Applicants must always be considered. Indeed, there are numerous cases where such prejudice has not been cited as a factor for consideration by the Court (see, for example, *Eli Lilly*, above; *Atlantic Engraving*, above).

[28] In sum, the Prothonotary did not clearly err by taking the Applicants' delay – even though not very long – into account.

Application of incorrect legal principles

[29] As I understand the third alleged error, the Applicants are submitting that the Prothonotary misstated the test for when reply evidence will be permitted when she stated in the second paragraph that "the determinations I have made . . . are essentially based on whether the material is necessary, would assist the Court in determining the issues before it or was available at an earlier date". The problem with this assertion is that the passage recited was not intended to be a statement of the totality of relevant legal principles. When read in context, the words that concern the Applicants can be interpreted as a "shorthand" version of the test to be applied. The paragraph containing the offending words is a general statement addressing certain concerns of the Prothonotary and was not meant to be a complete statement of the applicable legal principles. As stated in the third paragraph, the Prothonotary did not feel a need to set out or discuss the relevant legal principles, since there was no disagreement.

[30] More importantly, a review of the individual findings does not turn up any occasion when the Prothonotary erred by requiring the affidavits to be "necessary" or by incorrectly understanding the concept of "prejudice". I am satisfied that the Prothonotary did not misapply the legal principles.

Specific alleged errors

[31] In sum, having regard to the totality of the reasons, I am not persuaded that the Prothonotary applied any incorrect principles or had regard to irrelevant considerations. Having reviewed the reasons in light of the specific concerns raised by the Applicants, I am also satisfied that Prothonotary Tabib did not misapprehend the facts and was not clearly wrong in respect of any of

her specific conclusions. I do not intend to revisit each of those conclusions except with respect to two particular proposed reply affidavits which were argued in detail before me.

(a) *Reply survey evidence of Dr. Chakrapani*

[32] An issue in the NOC proceeding is whether Apotex's product monograph would induce doctors and pharmacists to infringe the patent in issue. With respect to this issue, the Applicants included, in its affidavits filed on August 4, 2006, survey evidence of Dr. Corbin. Apotex responded with the affidavit of Mr. Klein, in which he criticized the survey design and methodology of Dr. Corbin. In its proposed reply, the Applicants put forward an affidavit of Dr. Chakrapani, who responds to the criticisms. The Applicants' argument to the Prothonotary and to me, on appeal, is that this evidence, from an objective third party, is necessary to get all of the necessary information before the Court. Further, the extent of the criticisms of Mr. Klein could not have been anticipated.

[33] On the admission of Dr. Chakrapani's affidavit, the Prothonotary concluded that "the disadvantages of introducing limited evidence through the affidavit of a new expert, outweigh any potential usefulness of this evidence being brought in the form of supplementary affidavits". Her reasons were as follows:

- A second opinion on the survey design and methodology "could and should have been brought at first instance";

- The introduction of a new expert would add to the time and complexity of the proceeding;

- The contents of the proposed affidavits are, for the most part, “argumentative and unhelpful”;

- The facts or opinions in this particular affidavit are not necessary to the determination of the issues before the Court; and

- Any useful or helpful facts or opinion go to very basic premises and principles of survey design implementation and could be brought to light in cross-examination.

[34] While it is true that the jurisprudence shows that reply evidence of this nature has been permitted (see *Pfizer Canada Inc. v. Canada (Minister of Health)* 2006 FC 790 at paras. 11, 51; *AB Hassle v. Apotex* (2003), 30 C.P.R. (4th) 519 at 527 at para. 32 (F.C.)), that does not mean that this type of evidence will always be admitted. As amply demonstrated by her reasons, Prothonotary Tabib was aware of, and did apply, the general test for the admission of affidavit evidence as defined in *Atlantic Engraving*. None of the cases cited by the Applicants purport to override the test; rather they suggest that the admission of reply affidavits which clarify survey methodology may be relevant in some circumstances.

[35] In effect, the Applicants are seeking a re-weighing of the factors. They have not shown any clear error on the part of Prothonotary Tabib.

(b) *Reply from Dr. Fennerty*

[36] Another issue in the NOC proceeding is sound prediction. The Applicants submit that paragraphs 23 to 36 of the proposed reply evidence of Dr. Fennerty respond to evidence from Apotex's expert, Dr. Howden, that raises allegations of unsound prediction that were not contained in the Notice of Allegation (NOA). In their view, the NOA simply states that *H.pylori* does not reside in the more acidic environments of the gastrointestinal tract - an allegation which is vague and meaningless. Apotex's expert, Dr. Howden, by raising the more specific allegation that the luminal part of the stomach is a place where *H.pylori* does not reside, raises an argument that is not in the NOA.

[37] Prothonotary Tabib obviously was of the view that, by introducing a new basis for addressing the issue of sound prediction, "the Applicants are effectively splitting their case"; on this basis, she denied the request. In reaching this determination, it is clear that she considered and rejected the Applicants' argument that the allegation addressed by the proposed reply was not raised in the NOA. Quite simply, she concluded that the NOA was not inadequate and that the Applicants could have put the proposed reply evidence in their initial affidavit evidence. On the facts, I can see no clear error.

Conclusion

[38] In conclusion, I am not persuaded that there is any error in the decision of Prothonotary Tabib that warrants the granting of this motion. Her decisions to refuse the admission of certain of the proposed reply affidavit evidence were not clearly wrong.

[39] The motion will be dismissed with costs to Apotex in any event of the cause. In the circumstances, I see no reason to grant Apotex's request for costs at an increased scale. Costs will be assessed in accordance with column III of Tariff B of the *Federal Courts Rules*.

ORDER

THIS COURT ORDERS that:

1. The motion is dismissed; and

2. Costs of this motion are awarded to Apotex, in any event of the cause, to be assessed in accordance with column III of Tariff B of the *Federal Courts Rules*.

"Judith A. Snider"

_____

Judge

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-427-06
STYLE OF CAUSE:	SOLVAY PHARMA INC. ET AL v. APOTEX INC. ET AL
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	September 5, 2007
REASONS FOR ORDER AND ORDER:	Snider, J.
DATED:	September 14, 2007

APPEARANCES:

Kevin Sartorio	FOR THE APPLICANTS
David Lederman	FOR THE RESPONDENT, APOTEX INC.

SOLICITORS OF RECORD:

GOWLING LAFLEUR HENDERSON LLP Barristers and Solicitors Toronto, Ontario	FOR THE APPLICANTS
GOODMANS LLP Barristers and Solicitor Toronto, Ontario	FOR THE RESPONDENT, APOTEX INC.