

Date: 20071114

Docket: T-1836-06

Citation: 2007 FC 1183

Ottawa, Ontario, November 14, 2007

PRESENT: The Honourable Justice Johanne Gauthier

BETWEEN:

**ALTANA PHARMA INC., and
ALTANA PHARMA AG**

Applicants

and

**NOVOPHARM LIMITED and
THE MINISTER OF HEALTH**

Respondents

REASONS FOR ORDER AND ORDER

[1] Novopharm appeals the portion of Prothonotary Milczynski's decision granting Altana an extension of time to file part of the affidavit of Dr. Senn-Bilfinger dated July 17, 2007 and the affidavit of Dr. Brian Fennerty in the form provided in Altana's motion record.

[2] The standard of review applicable on such an appeal is not in dispute. As the question raised in the motion before the Prothonotary is not vital to the final issue of the case, the Court will only intervene if the order is clearly wrong, in the sense that the exercise of discretion by Prothonotary Milczynski was based upon a wrong principle or upon a misapprehension of the facts

(*Merck & Co. v. Apotex* [2003] FCA 488 at para. 19, and *Z.I. Pompey Industrie v. ECU-Line N.V.* [2003], 1 S.C.R. 450 at para. 18). In its motion record, Novopharm submitted that the Prothonotary was clearly wrong in finding that the proposed evidence:

- a) was not available earlier and that Altana has a reasonable explanation for its delay;
- b) was relevant and admissible and would not prejudice Novopharm, and;
- c) should be subject to a different treatment than previously given to it by Justice Puine Blais in T-427-06.

[3] With respect to the first alleged error, it appears that the argument turns on Novopharm's interpretation of the following passage in the order:

“With respect to Senn-Bilfinger affidavit, I am satisfied with the explanation provided as to why the in vivo rat studies were not attached to Dr. Senn-Bilfinger's earlier affidavit. He was aware of the studies, knew they were important but could not, for various acceptable reasons, locate them until later.”

[4] According to Novopharm, the cross-examination of Dr. Senn-Bilfinger on his second affidavit indicates that even if he knew about them, those studies were not mentioned in his first affidavit and he did not start looking for them until months after he swore his said affidavit. Thus, the use of the words *“locate them until later”* above indicates that Prothonotary Milczynski misapprehended the evidence and wrongly believed that such search had started prior to the filing of Dr. Senn-Bilfinger's first affidavit.

[5] Having carefully considered the order, and the surrounding circumstances, the Court is not satisfied that Novopharm has established that Prothonotary Milczynski misapprehended the facts in respect of this finding.

[6] The facts as disclosed in the examination were not only clearly spelled out in paragraph 6 of Novopharm's written representations but also in paragraph 24 of Justice Pierre Blais' decision, to which Novopharm referred at length and which Prothonotary Milczynski discusses in detail in her order.

[7] The decision maker is presumed to have considered the material before her and Novopharm admitted that reference to such facts was also made during the two hours hearing before Prothonotary Milczynski.

[8] The Court finds that in fact, Novopharm is asking the Court to reassess the reasonableness of the explanation given by Altana and to conclude that because such explanation is not reasonable, the Prothonotary must have misapprehended the facts.

[9] This is not what the applicable standard of review calls for and in any event, the Court has not been persuaded that Prothonotary Milczynski could not come to her conclusion unless she really believed that Dr. Senn-Bilfinger had started to look for those studies before signing his first affidavit.

[10] Turning now to the third issue raised by Novopharm, the Court agrees with Prothonotary Milczynski's treatment of the decision of Justice Blais in T-427-06, (a different NOC proceeding between Altana and Apotex involving the same patent). The circumstances in that case were quite different than those before Prothonotary Milczynski. At the time Altana sought permission to file the additional affidavit of Dr. Senn-Bilfinger, Apotex had already filed its evidence. Thus, Justice Blais presumably refers to the test applicable pursuant to Rule 312 for the filing of reply evidence. There was also a clear prejudice to Apotex given that permission to file this evidence was sought only a few months before the hearing. In that respect, Prothonotary Milczynski did not misapprehend the facts nor did she err in law. There is no doubt that she was not bound by this earlier decision and could (in fact had to) properly exercise her own discretion based on the facts before her.

[11] The last issue raised in Novopharm's written material will be dealt with together with another question added, or more clearly identified, by Novopharm in the written representations filed after the hearing.

[12] At the hearing before the Court, it was unclear what part of the test Novopharm was arguing Prothonotary Milczynski had misapplied in her analysis. In its written material before Prothonotary Milczynski, Altana had originally presented its motion pursuant to Rule 312; which, as pointed out by Novopharm, more properly applies to the filing of reply affidavits. This test was developed to

ensure that parties do not split their case and it is clear that this is not an issue here as Novopharm had not yet filed its evidence in chief when Altana brought its motion.

[13] Thus, Novopharm indicated that, because Altana was effectively seeking an extension of the time set out by Prothonotary Milczynski, as case manager, for the filing of its evidence in chief, the Prothonotary had to apply the four-pronged test set out in *Canada (Attorney General) v. Hennelly* [1999] F.C.J. No. 846, that is that the party seeking an extension must show: a) a continuing intention to pursue the application, b) that the application has some merits, c) that a reasonable explanation for the delay exists and d) that no prejudice arises from the delay. But it also referred in its written representations to the two part test applicable to motions for an extension of the time for filing affidavits set out in *Mapei Inc. v. Flextile Ltd.* [1999] 59 C.P.R (3d) 211 (FCTD) (a) there must be a valid reason for the delay and b) the affidavit must provide the Court with evidence which is relevant and admissible).

[14] In her order, Prothonotary Milczynski only refers specifically to the four-pronged test because, as argued by Altana, this is what the parties had agreed to at the hearing before her. However, Novopharm denies having made such an agreement.

[15] Be it as it may, neither in the Notice of Appeal nor in its written material before this Court, did Novopharm argue that Prothonotary Milczynski had failed to

turn her mind to the two-pronged test; rather, it stated that she had erred in finding that the additional evidence Altana sought to file was relevant and admissible, particularly in light of the fact that the only evidence on this issue, Dr. Saibil's affidavit, showed that it clearly was not.

[16] To answer the Court's request for clarification, it was agreed that the parties would file additional submissions. It is in that context that Novopharm now argues that Prothonotary Milczynski erred by not applying *Mapei* and by failing to balance the reasons for the delay with the intrinsic worth of the proposed affidavits (relevance, admissibility and potential use to the Court of the said affidavits).

[17] The Court agrees with Altana that strictly speaking this ground of appeal was not mentioned in the Notice of Appeal in or the written representations of Novopharm. Nonetheless, the Court will deal with it to avoid any further dispute in this respect. The Court will however consider, among other things, the fact that the alleged failure of the Prothonotary to turn her mind to this two-pronged test was certainly not apparent on the face of the decision as Novopharm failed to identify the alleged failure before the hearing of the appeal. In fact, it appears that Novopharm assumed that she had considered it and simply misapplied it.

[18] It has often been said that parties cannot expect orders of case managing Prothonotaries on procedural matters to include detailed comments on each and every issue they raised.

[19] Here, as noted, Prothonotary Milczynski did not refer specifically to *Mapei* or the two-pronged test. However, a fair reading of her order indicates that she clearly considered the relevance, admissibility and usefulness of the evidence as such. For example, she did not grant Altana an extension to file a large portion of Dr. Senn-Bilfinger's affidavit, on the basis that said portion appeared to be an attempt to simply bolster what he had said before. She refused an extension in respect of Laura Meucci's affidavit because this evidence was inadmissible as hearsay. In so doing, she endorsed a similar earlier finding of Justice Blais in the case referred to above. In respect of the remainder of Dr. Senn-Bilfinger's affidavit, she noted that she did not have the same reasons as Justice Blais to question its relevance, given that the studies had been filed and the proposed expert commentary provided.

[20] All this to say that Novopharm has not persuaded the Court that when Prothonotary Milczynski concluded that she was satisfied that this new evidence should be filed as part of the applicant's evidence, she failed to turn her mind to the two-pronged test referred to in *Mapei*, or to weigh the reasons for delay against the intrinsic worth of the proposed evidence.

[21] It is also worth noting that the *Mapei* test is meant to be easier to meet than the four-pronged test of *Hennelly*, because the party seeking the extension does not have, in theory, to deal with the lack of prejudice and the overall merits of its application (*Strykiwsky v. Stony Mountain Institution*, 2000 F.C.J. No. 1404 at paras. 7-8).

[22] The second condition in the two-pronged test appears to be an adaptation of the second requirement originally set out in *Grewal v. Canada (Minister of Employment and Immigration)*, 1985 2 FC 263 (F.C.A.) that the Court look at whether the position taken by the party seeking the extension has “some merit” (*Stanfield v. Her Majesty the Queen*, 2005 FCA 107 at para. 3). But whether one considers and weight four or only two factors, as mentioned recently in *Canada (Minister of Human Resource Development) v. Hogervorst*, 2007 FCA 41, [2007] F.C.J. 37 (QL) at para. 33, ultimately these factors are only tools to determine how justice may best be done between the parties. This is why, in appropriate cases, even a weak explanation for the delay or no explanation at all will not prevent the granting of the extension sought.

[23] With respect to the “intrinsic worth” of the new affidavits, and the Prothonotary’s finding that the evidence was admissible and relevant, the Court cannot agree with Novopharm that Prothonotary Milczynski could not reach the

conclusion she has because Dr. Fennerty's affidavit was not sworn and the only evidence before her was that of Dr. Saibil.

[24] As noted in *Prouvost S.A. v. Munsingwear (C.A.)*, 2 1992 FC 541, the Court needed a draft of Dr. Fennerty's affidavit to assess its admissibility, relevance and potential use for the Court.

[25] Admissibility is a question of law and given the admission of Altana as to why these studies were being produced, that is, merely as an aide-memoire or to corroborate Dr. Senn-Bilfinger's evidence that the inventor had this information in mind at the relevant time, Prothonotary Milczynski's finding is not clearly wrong.

[26] The relevance of the evidence has to be assessed primarily on the basis of the pleadings. The relevant portions of the NOC were reproduced in the motion material before Prothonotary Milczynski and as case manager she was intimately familiar with the issues raised by the parties in their pleadings.

[27] Even Novopharm noted, in paragraph 75 of its written representations before the Prothonotary that the proposed evidence goes to a very contentious issue between the parties.

[28] At this stage of proceeding, when looking at the relevance of the evidence proposed, the Court (here, Prothonotary Milczynski) is not called upon to determine the exact parameters of the question this evidence is set to answer or the ultimate weight that should be given to conflicting evidence. Nor is the test meant to provide an opportunity to Novopharm to cross-examine Altana's expert on this issue prior to the filing of its evidence in chief.

[29] It may well be that at the end of the day, the new evidence will prove insufficient considered alone or with the rest of the evidence in this file to meet Altana's burden of proof. This may even be as a result of Dr. Saibil's opinion if it is filed by Novopharm as part of his evidence in chief but it was not for Prothonotary Milczynski nor is it for this Court to decide this point.

[30] Based on the evidence of Dr. Senn-Bilfinger, particularly paragraph 36, it was open to Prothonotary Milczynski to find that Altana's position had some merit. It was also open to her, based on the importance of the contested issue, the admissibility of the evidence and having regard to the explanation given, that this evidence should be filed as part of the Applicant's evidence.

[31] That said, even if the Court were to assume that Novopharm has established that it should exercise its discretion *de novo*, because for example it is not clear that Prothonotary Milczynski applied the two-pronged test, the Court would have come

to the same conclusion as Prothonotary Milczynski and granted the extension of this evidence. In coming to that conclusion, among other things, the Court does accepted the explanation given for the delay in filing Dr. Senn-Bilfinger's evidence in respect of the studies, even if it is clearly a weak one. In respect of the evidence of Dr. Fennerty, obviously his opinion on the impact of such information could not be given before Altana was made aware that the inventors had this information in mind.

[32] The Court also finds that at this stage, this evidence is admissible and although its ultimate impact on the ability of the inventors to soundly predict the utility of the invention is contested, it would be relevant, important and useful for the Court to have the information available to it in order to decide this application on the merits. Obviously and as mentioned, this finding is not intended to bind in any way the judge hearing the merits be it in respect of the weight to be given to the evidence or otherwise.

ORDER

THIS COURT ORDERS that:

1. The appeal is dismissed with costs.

“Johanne Gauthier”

Judge

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: T-1836-06

STYLE OF CAUSE: ALTANA PHARMA INC ET AL v. NOVOPHARM LIMITED ET AL

PLACE OF HEARING: TORONTO

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REASONS FOR ORDER: GAUTHIER, J.

DATED:

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