

Date: 20060817

Docket: T-1232-05

Citation: 2006 FC 984

OTTAWA, Ontario, August 17, 2006

PRESENT: The Honourable Mr. Justice Teitelbaum

BETWEEN:

PFIZER CANADA INC.

Applicant

and

THE MINISTER OF HEALTH and APOTEX INC.

Respondents

and

SANOFI-AVENTIS DEUTSCHLAND GmbH

Respondent/Patentee

REASONS FOR ORDER AND ORDER

[1] The present motion arises within an application for prohibition under the *Patented Medicines (Notice of Compliance) Regulations*. Apotex Inc. (“Apotex”) served a Notice of Allegation (“NOA”) on June 3, 2005 alleging non-infringement of Canadian Patent No. 2,023,089, held by Pfizer Canada Inc.’s (“Pfizer”). Apotex also made arguments as to the patent’s invalidity. Pfizer initiated proceedings on July 18, 2005 seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance (“NOC”) to Apotex in respect of its proposed Apo-Quinapril

tablets. Pfizer filed evidence with the Court on November 24, 2005, including a Confidential Affidavit of Dr. Mansoor Husain. Apotex then served and filed its evidence on April 7, 2006, including a Confidential Affidavit of Dr. Gordon W. Moe.

[2] Pfizer alleges that Dr. Moe's affidavit aggressively critiques Dr. Husain's evidence. Pfizer brought a motion for (among other things) leave to file a reply affidavit of Dr. Husain pursuant to Rule 312 of the *Federal Courts Rules*. Pfizer alleges that the reply affidavit consists exclusively of responses to Dr. Moe's criticisms. By Order dated June 16, 2006, Prothonotary Tabib declined to grant Pfizer leave to file Dr. Husain's reply affidavit. Pfizer presently brings a motion requesting that the Court set aside the Prothonotary's Order and grant it leave to file the reply affidavit.

II. The Prothonotary's Decision

[3] The Prothonotary's reasons for declining to grant Pfizer leave to file its reply affidavit are as follows:

In my view, the decision of this Court in *Abbott Laboratories et al. v. Minister of Health et al.*, (2003) 29 C.P.R. (4th) 450; 2003, FC 1512, merely confirms that the jurisprudential criteria for the application of Rule 312 of the *Federal Courts Rules* also apply to a motion to strike evidence filed in sur-reply pursuant to an order of the Court. It does not affect the binding and authoritative nature of the Court of Appeal's decision in *Atlantic Engraving Ltd. v. Lapointe Rosenstein*, (2002) 23 C.P.R. (4th) 5; 2002 FCA 503, which adds to the traditional three part test the requirement that the evidence sought to be adduced not have been available or not having been capable of being brought as part of the Applicant's case in chief.

I agree with the Applicant that the issues upon which it seeks to bring reply evidence are critical, and even central, to the issues in this proceeding. That, however, does not in and of itself suffice to satisfy the application criteria of Rule 312. Indeed, the critical nature of the issues underscores the fact that the evidence was available and known to be relevant at the time the Applicant filed its initial affidavits. The proposed reply affidavit merely states the basis upon which Dr. Husain disagrees with the critique leveled by Dr. Moe against his affidavit in chief. It addresses no new issue

raised by Dr. Moe and addresses no issue not already contained in Dr. Husain's initial affidavit. Much of the content of the proposed reply affidavit is argumentative and can likely be brought to light in cross-examination. On the whole, if such were the kind of reply affidavit contemplated by Rule 312 and its judicial interpretation, then one can expect that for every expert affidavit filed in an NOC proceeding containing a critique of the Applicant's experts, there would be a permissible reply affidavit for the purpose of refining the argument and rebutting the critique. Such a result would be contrary to the legislative intent that NOC proceedings should be summary in nature and proceeded with expeditiously.

In conclusion, I am not satisfied that granting leave to the Applicant to file the proposed reply affidavit would be in the interests of justice or would be of assistance to the Court, nor am I satisfied that the evidence thus proposed to be filed was not available or could not have been brought as part of the Applicant's evidence in chief. I should add here that my decision does not rest on any alleged prejudice to Apotex if the evidence were allowed. Indeed, I am satisfied that, had leave to file the evidence been granted, it would not have caused any prejudice to Apotex. I am satisfied that, in notice of application proceedings, there is no inherent prejudice to a Respondent in not being the last party to file evidence on any issue.

III. The Applicant's Submissions

[4] The Applicant Pfizer argues that the Prothonotary's Order is clearly wrong because the Prothonotary erred by importing a fourth requirement into the three-part test for granting leave to file reply evidence. Pfizer argues that there is a three part test for granting leave to file reply evidence in Patented Medicine (Notice of Compliance) ("PM(NOC)") proceedings as established by *Eli Lilly and Co. v. Apotex Inc.* (1997), 76 C.P.R. (3d) 15 at 20-21 (F.C.T.D.) [*"Eli Lilly"*]. The Court has the discretion to grant an Applicant leave to file reply evidence if the Applicant demonstrates that the evidence it wishes to file:

- a. would serve the interests of justice;
- b. would assist the Court in making its final determination;
- c. would not cause substantial or serious prejudice to the respondents.

[5] The Applicant argues that the three part test has been confirmed in *Abbott Laboratories v. Canada (Minister of Health)* (2003), 29 C.P.R. (4th) 450 [“*Abbott Laboratories*”], as well as in *AstraZeneca AB v. Apotex Inc.* (2004), 36 C.P.R. (4th) 48 at para. 25; 2004 FC 1207 [“*AstraZeneca*”], and in *Bayer AG v. Canada (Minister of Health and Welfare)* (1994), 58 C.P.R. (3d) 377 at 380.

[6] Pfizer contends that the Prothonotary erred by importing a fourth requirement into the test for granting leave to file reply evidence. This fourth requirement, referred to by Pfizer as the “available in chief” requirement, examines whether the evidence sought to be filed in reply was available at an earlier date. Pfizer submits that the Prothonotary erred by importing the “available in chief” requirement from *Atlantic Engraving* into the test to grant leave to file reply evidence in PM(NOC) proceedings. Pfizer notes that the “available in chief” requirement in *Atlantic Engraving* applied when a party sought leave to file reply evidence after cross-examinations had already occurred. In contrast, cross-examinations have not taken place in the present matter. Moreover, *Atlantic Engraving* was a trade-marks appeal, while the present matter is part of a PM(NOC) proceeding. Pfizer argues that PM(NOC) proceedings are unique, and that the issues are often only made clear to the applicant after the respondent has filed its evidence. Pfizer suggests that the Court has therefore adopted a more permissive approach to allowing reply evidence in PM(NOC) proceedings, and cites *Abbott Laboratories* in support of this claim.

[7] Pfizer argues that since the Prothonotary clearly erred in law, the Motions Judge should hear the matter *de novo*: *Canada v. Aqua-Gem Investments Ltd.*, [1993] 2 F.C. 425 at 454 (C.A.) [“*Aqua-Gem*”]; *Merck & Co., Inc. v. Apotex*, [2004] 2 F.C.R. 459 at para. 19, 2003 FCA 488 [“*Merck*”].

Since Apotex did not allege any prejudice at the hearing, Pfizer submits that the only two remaining issues are whether the proposed evidence is in the interests of justice and whether it would assist the Court.

[8] The Applicant argues that Dr. Husain's affidavit will service the interests of justice as granting Pfizer leave to file reply evidence will ensure that both parties have had fair opportunities to adduce affidavit evidence on the issues and to respond to issues raised by the other party. Pfizer also claims that counsel must have the appropriate tools to present their case on behalf of their client. Pfizer suggests that Dr. Husain's reply evidence serves the interest of justice as his reply affidavit will respond to Apotex's evidence on substantive issues.

[9] Pfizer equally maintains that Dr. Husain's reply evidence will assist the Court, as it will assist the Court in making its final determination. The Applicant claims that it should be permitted to explain and respond to Apotex's evidence to ensure that all facts are properly before the Court, and to ensure that the Court has received a complete, balanced view of the evidence.

[10] Finally, while Prothonotary Tabib suggested in her reasons that Pfizer will likely be able to respond to Dr. Moe's affidavit in cross-examination, Pfizer argues that the Court has recognized that cross-examination "is no substitute" for written reply evidence: *AstraZeneca*, above, at paragraph 31. Pfizer therefore submits that on hearing the matter *de novo*, the Motions Judge should grant it leave to file Dr. Husain's reply affidavit.

IV. The Respondent's Submissions

[11] Apotex argues that Prothonotary Tabib was not clearly wrong in deciding to reject the filing of Dr. Husain's affidavit, and did not err in law in reaching her decision. The Respondent claims that reply evidence is not permitted in the ordinary course, and that it constitutes extraordinary relief that can only be obtained through leave of the Court. Apotex submits that a party wishing to file a supplemental affidavit must demonstrate that the material is necessary, that it was not available at an earlier date, that the evidence could not have been included in its initial affidavit, and that its inclusion will not delay the proceeding. It claims that the Court will not grant leave to file a supplemental affidavit where the subject matter of the affidavit has been or could have been included in the Applicant's initial affidavit evidence. In support of this argument, Apotex relies on *Wayzhushk Onigum Nation v. Kakeway* (2000), 182 F.T.R. 100 at 101 (F.C.T.D.); *Deigan v. Canada (A.G.)* (1999), 165 F.T.R. 121 at 123 (F.C.T.D.); and *Wright v. Mission Institution* (1998), 159 F.T.R. 104 at 105-106 (F.C.T.D.). According to Apotex, Applicant needs to satisfy the three criteria of the *Eli Lilly* test once the above criteria have been met.

[12] Apotex submits that *Atlantic Engraving* did not change the three-part test applicable to motions under Rule 312. In its view, the Federal Court of Appeal provided guidance with respect to what factors should be considered when determining whether the material would serve the "interests of justice". Apotex suggests that the Federal Court of Appeal directed lower courts to consider whether the evidence to be filed was available earlier, and cautioned against filing that would allow a party to split its case.

[13] Apotex argues that Pfizer has failed to distinguish *Atlantic Engraving*. The Respondent argues that there is nothing in *Atlantic Engraving* suggesting that it should not apply when considering whether to allow the filing of reply evidence in PM(NOC) proceedings. Although cross-examinations have not started in the present matter, Apotex argues that the Prothonotary still found that the evidence was available to Pfizer at an earlier time, and that the interests of justice would not be served by allowing the evidence to be filed at this stage. According to Apotex, the Prothonotary did not err by importing a fourth factor into the three-part test for reply evidence. Rather, she considered the test in light of the Federal Court of Appeal's decision in *Atlantic Engraving*.

[14] Apotex submits that the Motions Judge does not need to hear the matter *de novo*. It also argues that Pfizer has failed to support its bald assertions that it has met the three-part test for reply evidence.

V. Standard of Review

[15] It is trite law that discretionary Orders of a Prothonotary cannot be disturbed by a motions judge unless:

- a. the question(s) raised in the motion are vital to the final issue of the case;
- b. the orders are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or a misapprehension of the facts (*Aqua-Gem*, above; *Merck*, above).

[16] The Applicant did not argue that the order under appeal addresses questions that are vital to the final issue of the case. Although the Prothonotary stated that certain issues raised in the proposed affidavit of Dr. Husain raise issues that are critical to the proceedings, it has not been argued that the Applicant's ability to raise the issues by way of a reply affidavit is vital to the final issue of the case. The onus therefore remains on the Applicant to establish that the Prothonotary's Order was clearly wrong.

VI. Analysis

[17] Pfizer asserts that the Prothonotary's decision is clearly wrong since the Prothonotary erroneously imported and applied a fourth component into the test for determining whether to grant leave to file reply evidence. The Federal Court appears to be somewhat divided on the question of whether there is a fourth "availability" component to the test for leave to file reply evidence. In the case of *Abbott Laboratories*, above, which Prothonotary Tabib attempts to distinguish in the reasons of her impugned Order, Justice Heneghan suggests that the test for leave to file reply evidence is made up of three factors, as identified by *Eli Lilly*, above. In contrast, Justice Beaudry recently held that when the four factors found in *Atlantic Engraving* are met, the Court may allow the filing of additional evidence: *Purdue Pharma v. Novopharm* [2006] F.C.J. No. 497, 2006 FC 385 at para. 13 [*"Purdue"*]. Prothonotary Tabib has similarly stated in the reasons for her Order presently under appeal that *Atlantic Engraving* adds a requirement to consider "availability" in addition to the traditional three part test articulated in *Eli Lilly*. In the recent decision in *Pfizer Canada Inc. v. Canada (Minister of Health)* 2006 FC 790, Justice Lemieux upheld a Prothonotary's decision to grant an applicant leave to serve and file a reply affidavit, and referred to both *Eli Lilly* and *Atlantic Engraving*. However, Justice Lemieux decided to uphold a Prothonotary's Order to grant leave to

file reply evidence on the basis of the difference between reply affidavits and supplementary affidavits, and did not conclusively determine whether there are three or four parts to the test to grant leave to file reply evidence.

[18] The confusion as to the test to grant leave to file reply evidence arises out of attempts to determine the reach of paragraphs 8 and 9 of the Federal Court of Appeal's *Atlantic Engraving* decision. I reproduce the paragraphs below:

¶ 8 Pursuant to rule 306 of the Federal Court Rules, 1998, an applicant has thirty days from the filing of its notice of application to file its supporting affidavits and exhibits (appeals under section 56 of the Trade-marks Act fall within Part 5 of the Rules entitled "Applications" (rules 300 to 334) and therefore must be commenced by way of a notice of application). By exception, rule 312 allows a party, with leave of the Court, to file additional affidavits. Under that rule, the Court may allow the filing of additional affidavits if the following requirements are met:

- i) The evidence to be adduced will serve the interests of justice;
- ii) The evidence will assist the Court;
- iii) The evidence will not cause substantial or serious prejudice to the other side (see *Eli Lilly and Co. v. Apotex Inc.* (1997), 76 C.P.R. (3d) 15 (T.D.); *Robert Mondavi Winery v. Spagnol's Wine & Beer Making Supplies Ltd.* (2001), 10 C.P.R. (4th) 331 (T.D.)).

¶ 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 (see *Salton Appliances (1985) Corp. v. Salton Inc.* (2000), 181 F.T.R. 146, 4 C.P.R. (4th) 491 (T.D.); *Inverhuron & District Ratepayers Assn. v. Canada (Min. of Environment)* (2000), 180 F.T.R. 314 (T.D.)).

[19] Pfizer suggests that the Federal Court of Appeal's comments in paragraph 9 of *Atlantic Engraving* do not apply to PM(NOC) proceedings. There is nothing on the face of the Federal Court of Appeal's decision suggesting that its reasons should not apply with equal force to the PM(NOC)

proceedings. Although *Atlantic Engraving* was a trade-marks case, in my view the Federal Court of Appeal's comments with respect to the rules governing the filing of additional affidavit apply to all motions brought under Rule 312.

[20] Pfizer also attempts to limit the reach of *Atlantic Engraving* by suggesting that it only applies to situations where cross-examination has already taken place. Although cross-examinations already occurred in *Atlantic Engraving*, the Federal Court of Appeal's reasoning in paragraph 9 of its decision suggests that a party must put its best case forward at the first opportunity and must not be able to split its case. While this meant that in *Atlantic Engraving* a party had to demonstrate that the evidence it sought to adduce was not available prior to the cross-examination stage, in other cases, a party seeking to adduce evidence may need to show that its evidence was not available at some other earlier date (such as at the time of filing its first affidavit evidence), in order to satisfy the Court that it is not attempting to split its case or is otherwise failing to put its best case forward at the first opportunity. I do not read the Federal Court of Appeal's reasoning as being limited to cases where cross-examination has already taken place. Rather, I extract from *Atlantic Engraving* the general concern that Rule 312 should not be used to allow a party to split its case or to delay putting its best case forward.

[21] In sum, I believe that the Federal Court of Appeal's decision of *Atlantic Engraving* dictates that the availability of evidence is an additional factor that must be considered as part of the test for granting leave to file additional affidavit material. While Pfizer submits that such a factor does not apply to PM(NOC) proceedings, in my view the availability of evidence plays an important role in

safeguarding the legislative intent, which Prothonotary Tabib accurately described as being “that NOC proceedings should be summary in nature and proceeded with expeditiously”.

[22] I therefore agree with Justice Beaudry in *Purdue*, above, that there are four factors to consider before leave to file additional material can be granted pursuant to Rule 312:

[12] Rule 312 of the *Federal Courts Rules*, SOR/98-106 gives the Court a discretionary power to allow parties to file supplementary evidence. In *Mazhero v. Canada (Industrial Relations Board)*, 2002 FCA 295, [2002] F.C.J. No. 1112 (F.C.A.) (QL), Justice John M. Evans wrote that applications for judicial review were summary proceedings that should be determined without undue delay, and that the discretion of the Court to permit the filing of additional material should be exercised with great circumspection.

[13] In *Atlantic Engraving Ltd. v. Lapointe Rosenstein*, 2002 FCA 503, [2002] F.C.J. No 1782 (F.C.A.) (QL), Justice Marc Nadon stated that the Court may allow the filing of additional evidence if the following requirements are met:

- a) the evidence to be adduced will serve the interests of justice;
- b) the evidence will assist the Court;
- c) the evidence will not cause substantial or serious prejudice to the other side;
- d) the evidence was not available at an earlier date.

[emphasis removed]

[23] It follows that the Prothonotary correctly described the test for granting leave to file reply evidence, and her Order was therefore not clearly wrong on this basis.

[24] In short, in my view the Prothonotary did not misconstrue the test for granting leave to file additional evidence pursuant to Rule 312 of the *Federal Courts Rules*, nor did she err in her application of the test.

ORDER

THIS COURT ORDERS that the motion is denied with costs.

“Max M. Teitelbaum”

Judge

FEDERAL COURT
SOLICITORS OF RECORD

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