

**Date: 20081125**

**Docket: T-371-08**

**Citation: 2008 FC 1316**

**Ottawa, Ontario, November 25, 2008**

**PRESENT: The Honourable Mr. Justice O'Keefe**

**BETWEEN:**

**ASTRAZENECA CANADA INC. and  
ASTRAZENECA AKTIEBOLAG**

**Applicants**

**and**

**APOTEX INC. and  
THE MINISTER OF HEALTH**

**Respondents**

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ASTRAZENECA AB**

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**REASONS FOR ORDER AND ORDER**

[1] This is an appeal by which the applicants wish to have set aside the portion of paragraph 2 of the order of Prothonotary Aalto dated April 24, 2008 which removed from the timetables (attached as Schedule A to the motions before Prothonotary Aalto) the reference to Apotex Inc. (“Apotex”) serving evidence first on the issue of invalidity.

[2] At the time of Prothonotary Aalto’s decision, there were seven files involved in this case, three of which were the subject of appeal, but only two are now the subject of this appeal.

[3] The applicants claim that the Prothonotary’s decision fails to give effect to the recent practice direction of the Chief Justice on proceedings under the *Patented Medicines (Notice of Compliance) Regulations* (the “Regulations”) which included a provision for the reversal of the order of evidence in these proceedings.

[4] The applications were commenced in response to notices of allegation from Apotex pursuant to the Regulations.

[5] The applicants submitted that the allegation in one file is 58 pages long with 5 schedules. Schedule E contains 60 references. The applicants claim that Apotex relies on the entirety of each document.

[6] Similar statements are made about the other two files concerning their length and the number of references.

[7] Of the seven files, Apotex has alleged invalidity in only three files (T-371-08, T-372-08 and T-374-08 which is now discontinued).

[8] The applicants stated in paragraphs 4 and 5 of their written representations:

4. Prothonotary Aalto erred in failing to find that the proposed schedule will lead to the just, most expeditious and least expensive determination of these proceedings and dismissing the Applicants' motion as it relates to the order of evidence on alleged patent invalidity. As further detailed below, Prothonotary Aalto proceeded on a wrong principle by basing his decision on numerous irrelevant or incorrect considerations, including:

- (i) how the reversal of order of evidence might impact upon other pending proceedings involving Apotex's esomeprazole magnesium tablets;
- (ii) the possibility of confusion over onus resulting from the reversal of the order of evidence;
- (iii) the purported sufficiency of the allegations; and
- (iv) prior litigation involving different drugs and different patents.

5. Prothonotary Aalto's decision, as explicitly contemplated in his Reasons, has the effect of increasing interlocutory motions and is contrary to the principle of managing proceedings under the *Regulations* in the just, most expeditious and least expensive manner as required by the Practice Direction. Indeed, on this record, the Prothonotary clearly made a reviewable error in concluding that the Applicants had not satisfied his stated test ("... there must be a reasonable prospect that there will be a savings in time and expense ...")

[9] **Issue**

Did the Prothonotary make an error by not allowing for a reversal of the filing of some of the evidence in respect of the three proceedings in which Apotex has raised arguments of invalidity?

[10] **Analysis and Decision**

Standard of Review

The Federal Court of Appeal in *Merck & Co. v. Apotex Inc.* (2003), 30 C.P.R. (4th) 40 at paragraphs 17 to 19 stated:

17. This Court, in *Canada v. Aqua-Gem Investment Ltd.*, [1993] 2 F.C. 425 (F.C.A.), set out the standard of review to be applied to discretionary orders of prothonotaries in the following terms:

[...] Following in particular Lord Wright in *Evans v. Bartlam*, [1937] A.C. 473 (H.L.) at page 484, and Lacourcière J.A. in *Stoicovski v. Casement* (1983), 43 O.R. (2d) 436 (Div. Ct.), discretionary orders of prothonotaries ought not to be disturbed on appeal to a judge unless:

(a) they are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts, or

(b) they raise questions vital to the final issue of the case.

Where such discretionary orders are clearly wrong in that the prothonotary has fallen into error of law (a concept in which I include a discretion based upon a wrong principle or upon a misapprehension of the facts), or where they raise questions vital to the final issue of the case, a judge ought to exercise his own discretion *de novo*.

18. MacGuigan J.A. went on, at pp. 464-465, to explain that whether a question was vital to the final issue of the case was to be

determined without regard to the actual answer given by the prothonotary:

[...] It seems to me that a decision which can thus be either interlocutory or final depending on how it is decided, even if interlocutory because of the result, must nevertheless be considered vital to the final resolution of the case. Another way of putting the matter would be to say that for the test as to relevance to the final issue of the case, the issue to be decided should be looked to before the question is answered by the prothonotary, whereas that as to whether it is interlocutory or final (which is purely a pro forma matter) should be put after the prothonotary's decision. Any other approach, it seems to me, would reduce the more substantial question of "vital to the issue of the case" to the merely procedural issue of interlocutory or final, and preserve all interlocutory rulings from attack (except in relation to errors of law).

This is why, I suspect, he uses the words "they (being the orders) raise questions vital to the final issue of the case", rather than "they (being the orders) are vital to the final issue of the case". The emphasis is put on the subject of the orders, not on their effect. In a case such as the present one, the question to be asked is whether the proposed amendments are vital in themselves, whether they be allowed or not. If they are vital, the judge must exercise his or her discretion *de novo*.

19. To avoid the confusion which we have seen from time to time arising from the wording used by MacGuigan J.A., I think it is appropriate to slightly reformulate the test for the standard of review. I will use the occasion to reverse the sequence of the propositions as originally set out, for the practical reason that a judge should logically determine first whether the questions are vital to the final issue: it is only when they are not that the judge effectively needs to engage in the process of determining whether the orders are clearly wrong. The test would now read:

Discretionary orders of prothonotaries ought not be disturbed on appeal to a judge unless:

a) the questions raised in the motion are vital to the final issue of the case, or

b) the orders are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts.

[11] I am of the view that the question raised in this case is not vital to the final issue of the case. Accordingly, I must determine whether the order is clearly wrong “in the sense that the exercise of discretion by the Prothonotary was based upon a wrong principle or upon a misapprehension of the facts.”

[12] The Practice Direction issued by the Chief Justice reads in part as follows:

A judge or prothonotary will be assigned as case management judge to each newly institute NOC proceeding. The case management judge or prothonotary will convene a conference with counsel for the parties shortly after all parties have appeared in the proceeding or the time for appearance has expired. At that conference, counsel for the parties will be expected to address:

1. whether it is appropriate to reverse the order in which some or all of evidence is submitted, that is, the respondent (generic) would file some or all of its evidence first and the applicant (brand) file some or all its evidence in response.

[13] The Prothonotary noted in paragraphs 5 and 6 of his reasons for order and order:

[5] It is to be noted that one fundamental aspect of the Practice Direction is to incorporate the general principle of both Rules 3 and 385 of the *Federal Courts Rules* into the case management of NOC proceedings. That principle is that NOC proceedings are to be case managed “to ensure the just, most expeditious and least expensive disposition of the proceeding”.

[6] Thus, in the specific circumstances of these seven applications, the issue is whether it is “appropriate” that Apotex file its evidence first on the issue of validity in three of the seven Applications. It should be noted that Counsel for the Applicants argues that two of the three patents . . .

[14] From these remarks, it is apparent that the Prothonotary considered the reason for the Chief Justice’s Practice Directive.

[15] Prothonotary Aalto’s decision is stated in part in paragraphs 7, 8, 9, 10 and 11:

[7] While the Practice Direction launches a new era of case management for NOC proceedings to ensure they move to a hearing in a just and timely manner, it is my view that reversing the filing of evidence in this series of Applications will not achieve that result. Thus, the ordinary approach should be followed and the Applicants will file their evidence first in accordance with the schedule the parties have agreed to.

[8] In reaching this conclusion, I have carefully considered the submissions of counsel for the Applicants and the objectives of the Practice Direction. Counsel for the Applicants argues that reversing the evidence will meet the policy objectives of the Practice Direction by not only refining the issues but also reducing the volume of evidence thus ensuring the “just, most expeditious and least expensive” determination of these Applications. In particular, counsel points to the fact that there are 60 items of prior art cited by Apotex in Schedule E to the Notices of Allegation (“NOA”). Counsel argues that the Applicants are compelled to deal with all of them as there is no indication whether all or any of these will be the subject of Apotex’ evidence. Thus, it is argued, it makes good sense to reverse the evidence as this will result in cost saving and be more expeditious. However, if it were only three cases and not seven this argument would be more persuasive. Here, the NOA’s are very detailed and outline with great specificity exactly what the issues are and what evidence supports Apotex’ invalidity argument. It can hardly be said that given the history of litigation and the detailed information contained in the NOA’s that the Applicants do not know nor have reasonably detailed insight into the position of Apotex on

invalidity. Further, in reviewing Schedule E it is apparent that many of the references to monographs and texts is limited to but a few pages of each reference. Thus, while the 60 items, at first blush, may seem like a large number of items to respond to, the actual pages referred to do not appear to be that significant especially where there has been a prior litigation history involving these drugs although perhaps not specifically to two of the patents.

[9] The NOC proceeding is a flawed procedure in that a party with the onus on a particular issue does not have to file their evidence first. This approach to some extent encourages parties to engage in a “cat and mouse” game of what precise grounds and evidence they rely upon in support of their respective positions until the hearing. The process does little to narrow the issues.

[10] One approach to clarifying the positions at an early stage is to provide for the reversing of the filing of evidence on validity issues. This approach meets the objective of moving the matter forward in a more cost effective and expeditious way. It is being ordered more frequently notwithstanding that it removes a “tactical advantage” from the generic that is advancing the position of invalidity of the patent. However, to do so there must be a reasonable prospect that there will be a savings in time and expense [see, for example, *Purdue Pharma v. Pharmascience Inc.*, 2007 FC 1196]. In my view of this specific series of cases, no such savings in time and expense will be achieved by requiring Apotex to lead its evidence first on validity. Indeed, as these cases will be heard by the same Judge, there is a real possibility of confusion developing during the course of the hearing over who has the onus on certain issues. This group of NOC proceedings is complex enough without adding further complications and possible confusion over the reversal of evidence in three of them.

[11] If the Applicants are prejudiced by virtue of having to lead their evidence first and do not, for example, lead evidence on an unexpected point that is raised by Apotex, there is ample flexibility within the case management regime as contemplated by the Practice Direction, to counteract such prejudice by, for example, allowing the filing of reply evidence. Thus, the objectives of “just, least expensive, most expeditious” can be easily met within the case management regime. In the circumstances, the motion will be dismissed insofar as it relates to the reversal of the filing of evidence.



[16] In *Sawridge Band v. Canada* (2001), 283 N.R. 107 (F.C.A.) at paragraph 11, Mr. Justice Rothstein stated for the Court:

11 We would take this opportunity to state the position of this Court on appeals from orders of case management judges. Case management judges must be given latitude to manage cases. This Court will interfere only in the clearest case of a misuse of judicial discretion. This approach was well stated by the Alberta Court of Appeal in *Korte v. Deloitte, Haskins and Sells* (1995), 36 Alta. L.R. (3d) 56, at 58, and is applicable in these appeals. We adopt these words as our own.

[...] This is a very complicated lawsuit. It is the subject of case management and has been since 1993. The orders made here are discretionary. We have said before, and we repeat, that case management judges in those complex matters must be given some "elbow room" to resolve endless interlocutory matters and to move these cases on to trial. In some cases, the case management judge will have to be innovative to avoid having the case bog down in a morass of technical matters. Only in the clearest cases of misuse of judicial discretion will we interfere. In this case, the carefully crafted orders made by the case management judge display sound knowledge of the rules and the related case law. In particular, the order contains a provision that the parties are free to return to the case management judge for relief from the imposition of any intolerable burden imposed by the order. No clear error has been shown and we decline to interfere. While there may be some inconvenience to some of the parties, this does not translate into reversible error. We are not here to fine tune orders made in interlocutory proceedings, particularly in a case such as this one.

[17] I will now address the applicants' remaining arguments.

[18] Prothonotary Aalto correctly noted that the request for a reversal of filing of evidence applied to only three files: T-371-08, T-372-08 and T-374-08. The Prothonotary clearly stated in paragraph 7 of his reasons that he was not going to order a reversal in the filing of evidence in these applications as such a reversal would not “ensure they move to a hearing in a just and timely manner”.

[19] In paragraph 8 of his reasons, he again addresses the submissions of the applicants and the objectives of the Practice Direction. In particular, he addresses the applicants’ submission that Apotex has cited 60 items of prior art in Schedule E of the Notices of Allegation. For ease of reference, I will repeat what Prothonotary Aalto stated in paragraph 8 of his reasons:

In particular, counsel points to the fact that there are 60 items of prior art cited by Apotex in Schedule E to the Notices of Allegation (“NOA”). Counsel argues that the Applicants are compelled to deal with all of them as there is no indication whether all or any of these will be the subject of Apotex’ evidence. Thus, it is argued, it makes good sense to reverse the evidence as this will result in cost saving and be more expeditious. However, if it were only three cases and not seven this argument would be more persuasive. Here, the NOA’s are very detailed and outline with great specificity exactly what the issues are and what evidence supports Apotex’ invalidity argument. It can hardly be said that given the history of litigation and the detailed information contained in the NOA’s that the Applicants do not know nor have reasonably detailed insight into the position of Apotex on invalidity. Further, in reviewing Schedule E it is apparent that many of the references to monographs and texts is limited to but a few pages of each reference. Thus, while the 60 items, at first blush, may seem like a large number of items to respond to, the actual pages referred to do not appear to be that significant especially where there has been a prior litigation history involving these drugs although perhaps not specifically to two of the patents.

[20] The applicants contend that the Prothonotary should not have made reference to the “series of applications”. I do not agree with this submission as all the applications are being case managed together by the same Prothonotary. Even if the Prothonotary was in error on this point, the Prothonotary gave other correct reasons for refusing to reverse the order of the production of evidence in the applications that were in issue before him.

[21] In paragraph 16 of his reasons, Prothonotary Aalto dealt with the issue of the removal of a tactical advantage from the respondent, Apotex if the order of evidence was reversed. I am of the view the Prothonotary was correct in his analysis.

[22] With respect to the applicants being able to lead reply evidence if the need arises, I cannot see where the Prothonotary made any error in this respect.

[23] The applicants submitted that Prothonotary Aalto proceeded on a wrong principle because his decision appears to be based upon his concern that the judge hearing the matter would be confused over who has the onus on certain matters if the order of producing evidence is reversed in the three files. I agree with the respondents that this is an obiter remark by the Prothonotary and even if in error, does not give grounds to set aside the Prothonotary’s decision.

[24] In summary, I am not of the opinion that the portion of Prothonotary Aalto’s order that is under appeal was clearly wrong “in the sense that the exercise of discretion by the Prothonotary was

based upon a wrong principle or upon a misapprehension of the facts". Consequently, the motion (appeal) by the applicants is dismissed with costs to the respondent, Apotex.

[25] I have not dealt with Court File No. T-374-08 as a notice of discontinuance was filed on that file.

**ORDER**

[26] **IT IS ORDERED that** the motion (appeal) of the applicants is dismissed with costs to the respondent, Apotex.

“John A. O’Keefe”

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Judge

**FEDERAL COURT**  
**SOLICITORS OF RECORD**

**DOCKET:** T-371-08 and T-372-08

**STYLE OF CAUSE:** ASTRAZENECA CANADA INC. et al

- and -

APOTEX INC. and  
THE MINISTER OF HEALTH

**PLACE OF HEARING:** Toronto, Ontario

**DATE OF HEARING:** May 26, 2008

**REASONS FOR ORDER  
AND ORDER OF:** O'KEEFE J.

**DATED:** November 25, 2008

**APPEARANCES:**

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