Date: 20081230

Dockets: T-371-08
T-372-08
T-373-08

Citation: 2008 FC 537

Toronto, Ontario, December 30, 2008

PRESENT: Kevin R. Aalto, Esquire, Prothonotary

BETWEEN:

File No. T-371-08

ASTRAZENECA CANADA INC. and ASTRAZENECA AKTIEBOLAG

Applicants

and

APOTEX INC. and THE MINISTER OF HEALTH

Respondents

File No. T-372-08

ASTRAZENECA CANADA INC. and ASTRAZENECA AB

Applicants

and

APOTEX INC. and THE MINISTER OF HEALTH

Respondents

File No. T-373-08

ASTRAZENECA CANADA INC. and ASTRAZENECA AB

Applicants

and

APOTEX INC. and THE MINISTER OF HEALTH

Respondents

AMENDED REASONS FOR ORDER AND ORDER

[1] These cases are all Applications commenced under the *Patented Medicine (Notice of Compliance) Regulations*. They deal with various patents and have essentially the same parties except for file T-377-08 in which Takeda Pharmaceutical Company Limited ("Takeda") as patentee, is named as a Respondent in addition to the other Respondents, Apotex and the Minister. All seven Applications are being case managed together and will ultimately be heard together. They all involve drugs known as omeprazole and esomeprazole and there are different patents for these drugs referred to in each of the Applications.

[2] The Notices of Motion seek virtually identical relief. First, an order is sought that the Applications proceed as specially managed proceedings. There was no issue concerning this head of relief, nor could there be, as pursuant to the Practice Direction issued by the Chief Justice on December 7, 2007 all new NOC proceedings are to be continued as specially managed proceedings. Thus, the same case management judge was appointed for all of the Applications by order of the

Chief Justice made April 7, 2008. Second, attached to each motion was a proposed timetable for completing the steps in the Applications. This, too, was not the subject of much debate and the proposed timetables set out in Appendix A to each of the Notices of Motion are approved subject to any changes necessary resulting from this ruling.

[3] The relief requested which was hotly debated was whether the Respondent, Apotex Inc. ("Apotex"), should be required to file its evidence on invalidity before the service of the Applicants' evidence. This requested reversal of filing evidence applies to only three of the seven Applications in which the validity of the patent is raised as an issue by Apotex. Counsel for the Applicants relies in large part on the Practice Direction to support the requested reversal of the evidence.

[4] The Practice Direction provides, in part, as follows:

> A judge or prothonotary will be assigned as case management judge to each newly instituted 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;

[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 in issue in the three applications have not been litigated before while there has been litigation involving the remaining one and as well as, apparently, the four other Applications where the reversal of filing evidence is not sought.

[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.

[12] There are three further matters that arose during argument that require comment. First, the parties advised that they are refining the form of a draft protective order and will forward a draft order to the Court for the Court's approval.

[13] Second, as these seven Applications are being case managed together, except for filings which relate specifically to each case individually, there is no need to duplicate materials seven times. For issues that are common to all of the Applications it is sufficient that a style of cause incorporating all of the styles of cause be used.

[14] Third, prior to the hearing of these motions, an issue arose concerning the form of Notice of Appearance filed by Takeda. In its Notice of Appearance, Takeda altered the form prescribed by the Rules by substituting the word "participate" for the word "oppose". This Court has recently held that such a change to the Notice of Appearance is improper and has stuck it out [see *Schering Plough Canada Inc. et al* v. *Pharmascience Inc et al*, 2008 FC 359]. The *Schering-Plough* decision was issued after Takeda had filed its Notice of Appearance in file T-377-08. In light of this decision, Apotex brought a motion to strike the Notice of Appearance of Takeda. As the *Schering-Plough* decision is now under appeal, I issued a direction that until the appeal is heard and disposed of, Apotex' motion is adjourned *sine die* as is the counter motion brought by Takeda seeking to apply, *inter alia*, the curative provisions of Rules 55, 56 and 59 (b).

[15] In the circumstances, to ensure these applications all move forward in a timely way, the parties in T-377-08 will follow the timeline in Schedule A to the Notice of Motion in file T-377-08 in which Takeda is named as Respondent/Patentee. One of the purposes of the Practice Direction is to provide the flexibility to ensure that NOC proceedings move fairly and efficiently to a hearing within the strict timeline of two years contained in the *PM(NOC) Regulations.* Case management provides the opportunity for the Court to react quickly to issues as they arise and to provide the necessary directions to carry out the purposes of the Practice Direction. As I noted in a prior Direction issued in these files:

> Within the case management regime there is much flexibility in responding to the specific needs of a case or group of cases that may be outside the traditional jurisprudence or practice of the Court. Thus, counsel should not necessarily feel constrained by the jurisprudence or past practices in dealing with procedural issues. Counsel are encouraged to look for innovative and common sense

> approaches to solving issues without unduly dwelling on procedural precedent.

[16] Thus, until the issue of the form of the Notice of Appearance is dealt with by the Federal Court of Appeal, these matters will continue together in accordance with the timelines proposed. The Court will provide the appropriate directions concerning the status of Takeda in response to the decision of the Federal Court of Appeal and any directions the Federal Court of Appeal may give concerning the status of a patentee named as a respondent in an application where it will not be opposing the applicant.

ORDER

THIS COURT ORDERS that

1. The timetables attached as Schedule "A" to the Notices of Motion in files T-373-08, T-376-08, and T-378-08 are hereby approved.

2. The timetables attached as Schedule "A" to the Notices of Motion in files T-371-08, T-372-08 and T-374-08 are hereby approved subject to an amendment to remove the reference to Apotex filing first on the issue of invalidity so that these timetables track the same timetables as the Applications referred to in paragraph 1 of this Order.

3. The timetable attached as Schedule "A" to the Notice of Motion in file T-377-08 is hereby approved subject to further review of the status of Takeda Pharmaceutical Company Limited as a Respondent/Patentee following the Federal Court of Appeal's disposition of the appeal in *Schering-Plough et al* v. *Pharmascience Inc*. et al.

4. In the event that any of the times stipulated in the timetables require amendment, such amendment shall be sought by the party by arranging a case conference with the Court which will issue the appropriate directions without a party being required to bring a motion.

5. The motion brought by Apotex Inc. to strike the Notice of Appearance of Takeda Pharmaceutical Company Limited and the motion brought by Takeda Pharmaceutical Company Limited granting leave to vary the form of their Notice of Appearance as filed are

both adjourned *sine die* pending the decision of the Federal Court of Appeal in *Schering-Plough et al.* v. *Pharmascience Inc. et al*.

6. Counsel for the Applicant(s) shall arrange a case conference with the Court following the filing of the Respondent's evidence in order to review the status of the Applications.

7. No party shall serve any motion in any of these Applications unless and until a case conference has been convened to review the issue(s) which will be the subject of the proposed motion.

8. Any party may, at any time, request a case conference with the Court to review any issue that arises in the conduct of these Applications.

"Kevin R. Aalto"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	**T-371-08** **T-372-08** **T-373-08**
STYLE OF CAUSE:	**ASTRAZENECA CANADA INC. and ASTRAZENECA AKTIEBOLAG** **and** **ASTRAZENECA CANADA INC. and ASTRAZENECA AB** **and** **ASTRAZENECA CANADA INC., ASTRAZENECA AB** **v.** **APOTEX INC. and THE MINISTER OF HEALTH** **and** **APOTEX INC. and THE MINISTER OF HEALTH** **and** **APOTEX INC. and THE MINISTER OF HEALTH**
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	APRIL 14, 2008
REASONS FOR ORDER AND ORDER BY:	AALTO P.
DATED:	APRIL 24, 2008

APPEARANCES:

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MR. ANDREW BRODKIN	FOR THE RESPONDENT (APOTEX INC.)
MR. VIK TENEKJIAN	FOR THE RESPONDENT/PATENTEE (TAKEDA PHARMACEUTICAL COMPANY LIMITED)

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