Date: 20081229

Docket: T-118-08

Citation: 2008FC1162

Toronto, Ontario, December 29, 2008

PRESENT: Kevin R. Aalto, Esquire, Prothonotary

BETWEEN:

BIOVAIL CORPORATION and DEPOMED, INC.

Applicants

and

THE MINISTER OF HEALTH and APOTEX INC.

Respondents

AMENDED REASONS FOR ORDER AND ORDER

[1] In what circumstances is it appropriate to require the generic in Patented Medicine *(Notice of Compliance) Regulations (the Regulations)* to deliver its evidence in support of its invalidity allegation first and thereby reversing the order of evidence? This contentious issue is being raised more frequently in proceedings under the *Regulations*. The *Regulations* themselves do not contemplate specifically the reversal of evidence in this way. However, the Court, in some circumstances, has made orders that such a reversal of evidence is appropriate and in its recent

Practice Direction has made the issue a matter for consideration at the outset of any proceeding under the Regulations.

[2] On this motion, the Applicants, Biovail Corporation and Depomed Inc. (collectively "Biovail") seek disclosure pursuant to section 6(7) of the *Regulations* and a schedule for the remaining pre-hearing steps in the proceeding including a reversal in the ordering of evidence. Biovail has commenced this proceeding to prohibit the Minister from issuing a Notice of Compliance to Apotex for its drug Apo-Metformin ER.

I. Reversal of Evidence

[3] Biovail argues that the principal issue raised in the Notice of Allegation filed by Apotex Inc. ("Apotex") is one of validity. Apotex asserts the so-called *Gillette* defence, which Biovail categorizes as an invalidity attack made in the guise of non-infringement allegations. Biovail also seeks information relating to various aspects of the release rate profile of the Apotex product, which is an issue in the proceeding. Because it is invalidity that is an issue, Biovail argues that this proceeding is the "quintessential case" to reverse the order of evidence on invalidity.

[4] In several recent cases, the Court has ordered that evidence on invalidity be reversed and in the Court's Practice Direction dated December 7, 2007, such a reversal of evidence is contemplated.

[5] The Court's approach to ordering a reversal of evidence is to streamline proceedings, narrow issues, and expedite proceedings. All of this within the context that a reversal of evidence

will in all likelihood lead to the least expensive and most expeditious determination of the issues on the merits in a manner that remains just [see *Pharma v. Pharmascience Inc.*, [2007] FCJ 1568].

[6] In the ordinary course of an application, Rule 306 mandates that the Applicant's affidavits and documentary exhibits shall be served and filed within 30 days after issuance of a Notice of Application. Rule 307 stipulates that within 30 days after service of the Applicant's affidavits a Respondent shall serve and file any supporting affidavits and documentary exhibits. These are the usual procedural rights afforded to parties to an application.

[7] However, those rights are merely procedural, and in this new era of case management of proceedings under the Regulations, it is recognized that traditional procedural rights do not always lead to the just, most expeditious and least expensive hearing. Slavishly following the provisions of Rules 306 and 307 can often result in motions seeking the right to adduce reply or even sur-reply evidence. Such motions do not result in the just, most least expensive and most expeditious hearing of the matter. Rather, they frequently delay the proceedings even further and cause additional expense. They also use an inordinate amount of judicial resources which can be more usefully put to the hearing of matters on their merits.

[8] Thus, the interplay of case management, the Practice Direction, and the flexibility incorporated into the *Federal Courts Rules*, permit procedural rights to be varied so as to ensure that not only is a level playing field maintained but that the matter moves forward in the most expeditious and least expensive way. One of the objectives of case management is to provide the

flexibility necessary to respond to the needs of a case without all of the procedural formality that so often delays proceedings.

[9] Whether this is a quintessential case to direct the reversal of evidence need not be determined. What is important is whether or not requiring Apotex to lead its evidence first on invalidity will narrow issues, lead to a more streamlined proceeding, reduce judicial intervention and the use of judicial resources, and result in fairness to the parties.

[10] The Practice Direction which came into force on January 7, 2008 provides as follows:

> **Practice Direction – NOC Proceedings**
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> Pursuant to Rule 384, the Court may order that a proceeding commenced under the provisions of the Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 as amended, (NOC proceeding) shall forthwith continue as a specially managed proceeding.
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> 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:
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> 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**;
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> 2. fixing a schedule for filing evidence, conducting cross-examination and dealing with any other matters such as section 6(5) motions;
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> 3. fixing a date for the filing of a requisition for hearing; and

> 4. any other matters useful to ensure the just, most expeditious and least expensive disposition of the proceeding.

[11] In the developing line of cases dealing with the reversal of evidence, the principles noted above have been applied. The cases included *Lundbeck Canada Inc. v. Ratiopharm Inc*., 2008 FC 579; *Astrazeneca Canada Inc. v. Apotex Inc*., 2008 FC 537, [2008] F.C.J. No. 681 (QL); *Abbot Laboratories v. Canada (Minister of Health)*, 2007 FC 1291, [2007] F.C.J. No. 1660 (QL); *Pharma v. Pharmascience Inc*., 2007 FC 1196, [2007] F.C.J. No. 1568 (QL)). In *Pharma*, Madam Prothonotary Tabib made the following observations:

> 7. I am satisfied that the Court has, in the context of case management, discretion to vary the order in which evidence of the parties on an application is to be served and filed if it is satisfied that it is necessary for the just, most expeditious and least expensive determination of the proceedings on its merits. That discretion is contemplated in Rule 385(1)(a). Additional support for this proposition, if needed, can be found in Rule 55, which allows the Court to vary a rule or dispense with compliance in special circumstances. An analogy may also be drawn with Rule 274, which sets out the order in which evidence is to be led at a trial, but specifically provides that the Court may direct otherwise.
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> 19. I recognize that there is an undeniable tactical advantage accruing to the party, whoever it might be, who files its evidence second. That party not only gets to file its evidence in substantially the way it had anticipated to present and shape it, but has the added advantage of having the opportunity to adapt it so that it best opposes its opponent's; in the absence of any independent evidence of its own, that party also has the opportunity of weakening and attacking directly its opponent's evidence and mining its credibility. These are tactical advantages, which although legitimate, are neither substantive nor procedural. Such tactical advantages, it is hoped at least, should not in the end determine the outcome of the proceedings.

> 20. For better or for worse, the procedure contemplated by the Rules for dealing with applications under the Regulations results in the respondent having this tactical advantage and it seems to me that in order to deprive it of this advantage without its consent, substantial savings in time, expense and resources, both of the Court and of the parties would have to be expected.
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> 21. As mentioned above, this matter involves issues of infringement, lack of sound prediction and inutility for which evidence should be adduced in the normal order; reversal would therefore apply to only part of the evidence, a procedure which is, as yet, unfamiliar to the Court and the parties and might for that reason and absent exemplary cooperation between the parties, require more interlocutory interventions by the Court.

[12] Madam Prothonotary Tabib refused to exercise her discretion in favour of reversing the ordering of evidence. The overriding factor in the exercise of that discretion appears to be the fact that reversal would apply to only one part of the evidence and given that there were many issues in play, it did not make sense in that context to order the reversal of evidence.

[13] That case is distinguishable from the current case, as it appears that there are not only fewer issues but the case is focused on the implication of the *Gillette* defence.

[14] In *Lundbeck,* Madam Prothonotary Aronovitch exercised her discretion in directing the reversal of evidence. In that case, the Applicants sought to have the Respondents deliver their evidence on issues of invalidity before the Applicants. There was agreement among the parties that the Applicant should file their evidence first on infringement. The parties were divided over whether the evidence on the allegations of invalidity should result in the Respondent leading its evidence first. At issue, was a consideration of whether there should be partial reversal on invalidity

or full reversal on invalidity issues. In coming to the conclusion the partial reversal would not provide any economies in the action and potentially create a greater complexity and procedural wrangling, Madam Prothonotary Aronovitch observed as follows:

> 27. Having considered these factors, I am not persuaded that a partial reversal will provide any economies in the circumstances. As Prothonotary Tabib observed a partial reversal is a procedure which is as yet unfamiliar to the Court and requires great cooperation. More compelling is that in this instance, neither counsel advocates this method of proceeding or has any enthusiasm for it. I agree with counsel who are *ad idem* that a partial reversal, in this instance, offers no efficiencies over the status quo.
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> 28. I would add that the dissection of the grounds of invalidity in the manner discussed above presupposes that it is possible to identify and separate out the evidence and argument on sound prediction, overbreadth and section 53, of the *Patent Act* from the evidence and argument in respect of the other allegations raised in Ratiopharm's NOA. In practice, there is likely considerable overlap both of evidence and argument among the different allegations of invalidity. Requiring each party's experts to address only certain issues in their initial affidavits and other related issues in reply, may create unnecessary duplication and complexity, as it is foreseeable that parties may bring additional motions for clarification requiring time consuming intervention by the Court in the management of the proceeding.
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> 29. Full inversion on invalidity is also not without complexity. Where, as is the case, the grounds of invalidity include sound prediction, overbreadth, and bad faith, and where the applicant may wish to file factual and expert evidence thereon that is new, it will likely require the adjudication of motions to file reply evidence thereby adding a layer of complexity. However these proceedings in the ordinary course, are rarely immune from motions to adduce reply evidence and in this case, there are obvious and substantial benefits to be gained by having the respondent put in all of its evidence on invalidity issues first that outweigh any complexity engendered by the possibility of having to provide some reply to new facts that may be in the applicants' possession.

> 30. The substantial narrowing of the issues on invalidity that are in play, along with the likely commensurate limits on the number of experts cannot but offer substantial economies including in respect of the likelihood of the need for reply evidence. I am satisfied that full reversal on issues of invalidity, in the circumstances of this case, is fair, and will result in a trimmer and more expeditious proceeding.

[15] In *Abbott Laboratories*, Justice Phelan was faced with a motion by the Applicants seeking an ordering requiring the Respondent to serve its evidence prior to that of the Applicant. This was a second proceeding under the Regulations respecting the same patent and was effectively the re-litigation of the infringement issue. In his decision, Justice Phelan determined that notwithstanding the argument of the Respondent that the Court had no jurisdiction to make an Order reversing the evidence, that indeed there was such jurisdiction which arose "in special circumstances" and under the auspices of "case management". He framed the issue as "whether this is an appropriate case or are there special circumstances to make an order reversing the order of filing evidence in the making of submissions".

[16] Justice Phelan denied the motion in so far as it sought a reversal of evidence. It is to be noted however, that Justice Phelan's decision pre-dated the Courts Practice Direction of December 7, 2007, which came into force on January 8, 2008 and in his decision directed that the case be specially managed.

[17] Finally, in the *Astrazeneca* cases, the unique circumstances of that series of cases militated against the reversal of evidence. As was observed in that case:

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.

[18] In that case the fact that were some seven cases proceeding together. It was not the most expeditious and least expensive approach to have a reversal of evidence in three of them as it could lead to confusion and delays.

[19] Here, there is only one proceeding and contrary to the argument of Apotex invalidity is clearly the main issue. Apotex alleges six grounds of invalidity including insufficiency, improper selection and overbreadth. Apotex argues that the *Gillette* defence is both an invalidity attack *and* an invalidity attack. It is not necessary to determine this point. Suffice it to say that invalidity is a dominant focus of Apotex' attack on the patent in issue. Thus, if the reversal of evidence will lead to a more streamlined proceeding and result in a more expeditious and less expensive proceeding then the reversal of evidence should be ordered. In my view, this case will benefit from a reversal of evidence. Biovail will know the case it has to meet on validity. It will avoid splitting of the case. If there are issues which Apotex may need to respond to they will be more sharply defined. It will define more specifically exactly what Apotex is alleging as its six grounds of invalidity and perhaps Apotex may decide that only a few of those grounds will be pursued. It will avoid the filing of evidence by Biovail in a vacuum and filing evidence on every possible point of alleged invalidity. Thus, the purpose of the reversal of evidence will be met.

[20] There is no comprehensive list of factors to consider for ordering a reversal of evidence, nor can there be, as cases vary from one to another. It may be that the complexity of the NOC, the level of detail provided in the grounds in the Notice of Application or whether the allegation of invalidity in the NOC is the primary allegation are factors which may come into play. However, the dominant consideration for the reversal of evidence will be whether it will result in the streamlining of the

proceeding or result in delay and increased expense by further motions seeking to file reply evidence.

[21] In this case the reversal of evidence should result in the streamlining of the proceedings and meet the objectives noted above.

II. Section 6 (7) Disclosure

[22] Biovail also seeks disclosure pursuant to section 6 (7) of the Regulations which provides as follows:

> 6 (7) On the motion of a first person, the court may, at any time during a proceeding,
>
> (a) order a second person to produce any portion of the submission or supplement filed by the second person for a notice of compliance that is relevant to the disposition of the issues in the proceeding and may order that any change made to the portion during the proceeding be produced by the second person as it is made;

[23] In *Biovail Corp.* v. *Canada* (*Minister of National Health and Welfare)*, [2002] F.C.J. No. 1539, the Court set out a three part test for disclosure pursuant to this section summarized as follows:

1. that request for disclosure is timely;
2. that the information already provided is insufficient; and
3. that the disclosure of the sought after information is necessary and relevant to the disposition of the issues in the proceeding.

[24] Apotex has already provided substantial disclosure including dissolution data, release rate profiles and swell-ability information. Indeed, the sought after information does not exist, i.e. section 2.7.1 of Apotex's ANDS. Biovail's evidence states that the evidence should exist. It is, however, not part of the ANDS. Apotex has already provided extensive disclosure which, based on the material before me, should be more than sufficient for Biovail to respond to the issues at stake. Thus, Biovail's request does not meet all the tests required for a section 6 (7) order to be made in this case.

ORDER

THIS COURT ORDERS that:

1. That the present application shall proceed according to the following schedule:

   a) Apotex' evidence shall be served within 90 days from the date of this Order;

   b) The Applicants' evidence shall be served within 90 days after the service of Apotex's evidence;

   c) Cross-examinations thereon shall be completed within 90 days after the service of the Applicants' evidence;

   d) A requisition for hearing may be served and filed as soon as cross-examinations have been completed, and, in any event, shall be served and filed within 20 days after cross-examinations have been completed;

   e) The Applicants' Application Record shall be served and filed within 45 days after cross-examinations have been completed; and

   f) Apotex's Responding Record shall be served and filed within 45 days after the Applicants' Application Record has been served and filed.

2. In the event any of the parties require a variation to the timetable herein, they may seek the variation by writing to the Court if on consent. If the variation is not on consent the party seeking the variation shall arrange a case conference with the Court.

3. No party shall bring any motions without first arranging a case conference with the Court to review the proposed issue(s) on the motion.

4. The motion is otherwise dismissed.

5. As success has been divided, there are no costs of this motion.

"Kevin R. Aalto"
Prothonotary

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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