



October 27, 2008

Decision: PMPRB-08-D1-APOTEX
- Preliminary Motions

**IN THE MATTER OF the *Patent Act* R.S.C. 1985, c. P-4,
as amended**

AND IN THE MATTER OF Apotex Inc. (the "Respondent")

1. In this Application, Board Staff have sought various orders requiring Apotex Inc. ("Apotex") to report information to the Board pursuant to the reporting requirements in the *Patent Act* and the *Patented Medicines Regulations*.
2. Each of Board Staff and Apotex brought preliminary motions before the panel of the Board that will hear the Application (the "Panel"). The motions were argued on October 6, 2008. These are the reasons of the Panel on the preliminary motions.

A. Motion of Board Staff

Objections to questions on the cross-examination of Mr. Fahner

3. In support of its position in response to the Application, Apotex filed the affidavit of Gordon Fahner, sworn June 13, 2008. Mr. Fahner was cross-examined on this affidavit by counsel for Board Staff on September 5, 2008. During that cross-examination, counsel for Apotex raised a number of objections to questions.
4. The Panel has considered the written and oral arguments of the parties concerning the objections. The Panel has concluded that Mr. Fahner should, by November 12, 2008, answer the questions described in paragraph 6, below. At this stage of the proceeding, the Panel is satisfied that the answers to these questions could be relevant to the issues in the proceeding. In the event that Board Staff have further questions that arise out of the answers provided by Mr. Fahner pursuant to this decision, Mr. Fahner shall be made available for such further questions within 21 days of a request to that effect by Board Staff. At the argument of the Application, it will be open to counsel to make submissions on the relevance of the answers and the weight that the Panel should place on the answers when assessing the evidence.
5. The Panel notes that Apotex has agreed to complete its undertakings and answer all questions taken under advisement. The Panel will expect these answers and undertaking responses to be delivered by November 21, 2008.

6. The questions to be answered are each of those to which objection was made with the exception of (as they are numbered on the document "Summary of Objections/Refusals by Apotex", exhibit 1, circulated at the argument of the motions) the following, regarding which the Panel sustains the objection of Apotex:
 - a. objection 9
 - b. objection 12, except as regards the companies referred to as Apotex Pharmachem Inc. ("Pharmachem") and Apotex Technologies Inc. ("Technologies"); and
 - c. objection 15, except to the extent to which the affidavit of Ms. Folkins deals exclusively with matters of fact. Mr. Fahner may be questioned as to any disagreement he might have with those factual assertions, to the extent that his expertise permits him to answer.

Additional Parties

7. Board Staff moved to amend its Notice of Application to add Pharmachem, Technologies and Apotex Fermentation Inc. ("Fermentation") as respondents. In the course of the motion the Respondent advised that Fermentation, while having two patents in the laid-open stage, is not yet a patentee. On this basis, Board Staff revised its request and now seeks leave to add only Pharmachem and Technologies as respondents.
8. Pharmachem and Technologies appear to be functionally related companies of Apotex. The rationale advanced by Board Staff for adding them as respondents is that Apotex along with these two companies appear to act in concert with respect to the research, patents and sales of certain patented medicines. The manner in which they act in concert is not yet fully established, given the objections by Apotex to a number of questions on that topic.
9. Board Staff may argue that Apotex is a patentee by virtue of these inter-company arrangements, or that Pharmachem and/or Technologies are patentees that are obliged to report to the Board in respect of sales by Apotex. Though the Panel appreciates that Apotex denies that either scenario is legally compelling, the Panel considers it appropriate to allow Board Staff to present evidence and argument to the effect that, if the Board has jurisdiction in relation to medicines sold by Apotex, it should be Pharmachem and/or Technologies that are the patentees that should be required to report to the Board concerning those sales.
10. Accordingly, Pharmachem and Technologies are proper respondents to the Application. The Panel grants Board Staff leave to amend the Application to add

them as respondents and to add allegations related to these entities to the grounds on which the Application is brought.

B. Apotex Motion

Consolidation of the Application and the Apo-Salvent pricing hearing

11. In response to the Application, Apotex denies that the Board has jurisdiction to require Apotex to report to the Board concerning the matters described in the Application. However, Apotex acknowledges being a patentee with respect to the medicine Apo-Salvent, and while it denies the Board's jurisdiction to make orders pertaining to sales by Apotex of Apo-Salvent, Apotex does report to the Board regarding its sales of that medicine. In a separate proceeding, the Board has issued a Notice of Hearing concerning allegations by Board Staff that Apo-Salvent is and has been sold at excessive prices.
12. On this motion, Apotex has sought an order consolidating the two proceedings. Apotex notes, among other things, that there is some commonality of issues and that some evidence and argument will be common to both proceedings. Apotex placed emphasis on the fact that, in both proceedings, Apotex argues that the provisions of the *Patent Act* that establish the Board, at least insofar as they might be found to entitle the Panel to make the orders sought by Board Staff, are not constitutional, in that the orders sought by Board Staff would have the *Patent Act* apply in an area of exclusively provincial jurisdiction. The basis for the constitutional challenge is somewhat different in the two proceedings, given the different orders sought by Board Staff.
13. On this motion, Apotex argues that it will be unnecessarily burdensome on the parties and the Board to have to hear evidence and argument twice, particularly concerning the business of Apotex and the constitutional question.
14. The Board does attempt to avoid duplication of evidence or argument in its proceedings. However, the Panel does not believe that consolidation of the two proceedings involving Apotex is practically or legally sound. Despite the potential for some overlap, the two proceedings involve different topics, have different procedures and are on separate (and different) timelines. Based on the constitutional law positions outlined by Apotex in its pleadings in the two proceedings, it would appear that even the evidence and argument on the constitutional question will be different in the two proceedings. Finally, a pricing hearing can take a considerable length of time to complete, and the Apo-Salvent matter could substantially delay the hearing of this Application. Accordingly, the Panel will not order consolidation of the two proceedings.

15. Nonetheless, some avoidance of duplication may be possible. This Panel will be hearing the Apo-Salvent matter. In that proceeding, the Panel could incorporate the record of evidence and argument, insofar as it is relevant to that proceeding, from this Application. The record on this question in the Apo-Salvent matter can then be supplemented in a manner that addresses the particular context of that proceeding. This was the approach taken recently by a panel of the Board that heard two pricing hearings concerning very similar medicines.

The affidavit of Patricia Folkins

16. Board Staff filed the affidavit of Ginette Tognet in support of the Application. Apotex then filed the Fahner affidavit, discussed above, in response. Board Staff then filed the "Reply Affidavit of Patricia Folkins." Ms. Folkins is a patent agent and her evidence was said by Board Staff to be in reply to the Fahner affidavit. The Folkins affidavit is proffered as expert evidence on the topic of whether certain patents pertain to certain medicines.
17. Apotex moves to strike the Folkins affidavit on two grounds. First, that it is not proper reply evidence; second, that it is not proper expert evidence, in that it provides opinions on questions of law.
18. On the first ground, the Panel is satisfied that the Folkins affidavit is properly filed in reply to certain allegations in the Fahner affidavit. Until the Fahner affidavit was filed, there was little more than a bald allegation by Apotex, in its Response, on the topic addressed in the Folkins affidavit.
19. The Panel observes that the Folkins affidavit provides some evidence on matters that were not specifically addressed by the Fahner affidavit. However, this appears to have been done in an effort to provide a similar section of evidence for each of the nineteen patents in issue, and the Panel considers this reasonable.
20. On the second ground, the Panel agrees with Apotex that the Folkins affidavit contains opinions on pure questions of law. To the extent it does so, it is not proper expert evidence.
21. The *Patent Act* gives the Board jurisdiction in relation to patents of inventions that "pertain to a medicine". An inquiry in this regard involves (i) an examination of the relationship between the patent and the medicine in question; and (ii) a legal conclusion as to whether or not, as a result of that relationship, the patent is for an invention that "pertains to a medicine" within the meaning of that phrase in the *Patent Act*.

22. The Folkins affidavit begins with a discussion of the law by which it is determined whether a patent pertains to a medicine. Ms. Folkins then states that the purpose of her affidavit is to provide her opinion:

...as to whether the nineteen patents are “patents which pertain to medicines” identified by Board Staff as being sold by Apotex Inc. I have done so by applying the test as set out in *ICN Pharmaceuticals*.

23. Generally speaking, the Folkins affidavit contains a series of assertions about the inventions described in each of the nineteen patents – typically processes for producing certain molecules. After each description, the role of the molecule in a medicine sold by Apotex is described and Ms. Folkins concludes that, therefore, the patent pertains to the medicine.
24. There are assertions of fact in the Folkins affidavit: those concerning the inventions described in the patents and their use in the medicines in question. The Panel considers this to be proper expert evidence. As for the conclusions that the patents pertain to the medicines in question, the Panel considers these to be legal conclusions and will not ascribe any weight to them, or to any of the discussion of law in the affidavit.

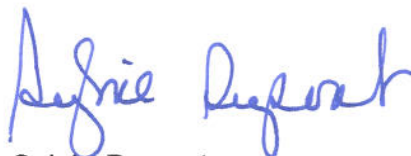
Board Members: Dr. Brien G. Benoit
Anne Warner La Forest

Board Counsel: Gordon Cameron

Appearances

For Board Staff: Guy Pratte, Counsel
Nadia Effendi, Counsel

For the Respondent:
Katherine Kay, Counsel
Daniel Murdoch, Counsel



Sylvie Dupont
Secretary of the Board