

PATENTED MEDICINE PRICES REVIEW BOARD

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

**AND IN THE MATTER OF
Alexion Pharmaceuticals Inc. (the "Respondent")
and the medicine "Soliris"**

WRITTEN REPRESENTATIONS OF BOARD STAFF

(Alexion's Motion Re: Disclosure of Documents)

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PART I – OVERVIEW

1. Alexion seeks an order requiring Board Staff to disclose all documents that they will be adducing or relying upon at the hearing. This is the second time that Alexion has sought an order for disclosure in the context of this proceeding.
2. At the present time the pleadings are not closed. There are outstanding motions relating to the pleadings. (Board Staff has brought a motion to strike paragraphs in the Amended Response filed by Alexion. Alexion has brought a motion to strike paragraphs in the Amended Reply filed by Board Staff.)
3. The purpose of the pleadings in any litigation (including this one) is to define the facts and issues in dispute. Once the pleadings are complete, the parties are able to determine what documents they intend to rely upon at the hearing. The rules of nature justice and fairness require that the parties then exchange documents so that no one is caught by surprise at the hearing.
4. Board Staff has not refused to disclose the documents that it will be relying on at the hearing. Board Staff has consistently advised Alexion that both parties should exchange the documents that they intend to rely on within a reasonable amount of time after the close of pleadings. It would be premature for the Panel to order disclosure now since the pleadings in this matter are not closed.

PART II – STATEMENT OF FACTS

5. On February 12, 2015, counsel for Alexion wrote to counsel for Board Staff and requested particulars and disclosure. On February 21, 2015, counsel for Board Staff wrote to counsel for Alexion and indicated that Alexion's request for disclosure was premature. Counsel for Board Staff also indicated that Board Staff would deliver its documents after the parties exchanged pleadings.
6. On April 27, 2015, Board Staff wrote to the Secretary of the Board and submitted that the parties should exchange electronic and hard copies of the documents they intended to rely upon at the hearing.
7. Notwithstanding the above, on May 15, 2015 Alexion brought its first motion for disclosure and particulars.
8. On June 22, 2015, the parties made oral submissions to the Panel with respect to Alexion's first motion for disclosure and particulars. At the hearing, counsel for Alexion described the relief that Alexion was seeking as follows:

Members of the Panel, if you look at our motion, it says "Motion for Particulars", but in many respects it's also a request for disclosure of the documents that Board Staff apparently acknowledge that we are entitled to in this process. But whether it is ordered in the form of particularization of the allegations or production of the documents, we say it's pretty much the same thing. [emphasis added]

9. On June 23, 2015, the Panel rendered a decision on Alexion's motion for disclosure and particulars. The Panel ordered Board Staff to provide some particulars. The Panel did not order Board Staff to make disclosure at that time. The relevant excerpts from the Panel's reasons are set out below.

1. Board Staff is ordered to provide particulars under paragraphs 1(a), 1(d) and 1(e) as set out in the respondent's Notice of Motion for Particulars.

2. While Board Staff have provided the respondent with much material through earlier exchanges of correspondence, the Panel is of the view that these heads of particulars are necessary to enable the respondent to respond to the Statement of Allegations." (As read)

I now turn to the balance of the Request for Particulars. With respect to paragraph 1(b) of the Motion for Particulars, the Board is of the view that the respondent will receive these documents as part of the document discovery process in advance of the hearing. Indeed, Board Staff Counsel stated that these documents will be provided. Accordingly, the Panel has decided that this request is not properly the subject matter of a Motion for Particulars. [emphasis added]

10. On July 3, 2015, Board Staff complied with the Panel's order regarding particulars and provided additional documents to Alexion.
11. On July 31, 2015, Board Staff brought a motion to strike paragraphs in Alexion's Amended Response to Board Staff's Statement of Allegations.

12. On September 9, 2015 Alexion brought a motion to strike paragraphs in the Amended Reply of Board Staff.
13. On August 28, 2015, counsel for Board Staff wrote to the Panel and proposed a schedule wherein the parties would disclose all documents that they intend to rely on after all of the outstanding motions regarding the pleadings were concluded.
14. At the Case Management Conference on October 13, 2015 the Panel already directed Board Staff and Alexion to disclose the information that they intend to rely upon at the present time, (It is recognized, however, that such disclosure will not be complete. Additional documentation may be forthcoming at the close of pleadings and subsequent to the exchange of expert reports.
15. Notwithstanding the repeated assurances by Board Staff that disclosure should take place after the pleadings were complete, on August 21, 2015 Alexion brought a second motion for disclosure.

PART III – STATEMENT OF LAW AND ARGUMENT

16. In *Ciba-Geigy Canada Ltd. v. Patented Medicine Prices Review Board*, the Federal Court considered an order of the Patented Medicine Prices Review Board which dismissed a Patentee's request for disclosure of documents from Board Staff. The Federal Court considered whether the Patentee was only entitled to the documents which Board Staff intended to rely on at the hearing or

whether Board Staff was required to produce all documents relating to any matter at issue. The Federal Court held that the duty of fairness did not require Board Staff to disclose all documents that were relevant to the allegations made in the proceeding. The Federal Court upheld the Board's decision and Board Staff was only required to disclose the documents that it intended to rely on at the hearing.¹

17. Board Staff has repeatedly indicated that it will disclose all of the documents that it intends to rely on at the hearing.
18. In the context of civil proceedings, Courts have consistently held that ordinarily, production and disclosure of documents should not take place until after the pleadings have been completed. (While Courts have the discretion to order production at any time, typically this discretion is only exercised at the pleadings stage where the documents are essential to enable a party to plead. Alexion is not arguing that the documents are necessary for it to plead.) The Courts have noted that the proper scope of disclosure and production is best assessed after pleadings have been completed and the issues are "suitably defined".²
19. In this proceeding, the parties are still at the pleadings stage as there are outstanding motions by Alexion and Board Staff to strike the pleadings. In addition, the Panel has already determined that Alexion does not require any more particulars or disclosure in order to plead. There is therefore no reason for the Panel to order the disclosure of documents prior to the close of pleadings.

¹ *Ciba-Geigy Canada Ltd., Re*, 1994 CarswellNat 859

² *Hedley v. Air Canada*, 1994 CarswellOnt 491 at para. 50 and 53; *Durling v. Sunrise Propane Energy Group Inc.*, 2008 CarswellOnt 7495 at paras. 24 and 25

20. Alexion wrongly implies that Board Staff should have all of its evidence marshalled prior to the commencement of a proceeding against a patentee. This is based upon Alexion wrongly conflating the purpose of an investigation into excessive pricing with the purpose of an excessive price proceeding before the Board. During an investigation Board Staff considers whether there has been compliance with the *Guidelines*. The hearing, however, is not intended to constitute a review of the investigation. The hearing is a fresh opportunity for the Board to determine whether the price of a medicine is excessive under s. 85 of the *Patent Act*.
21. It would be inefficient to require the parties to produce documents prior to the close of pleadings. As stated earlier, Board Staff and Alexion have outstanding motions to strike portions of the pleadings. The Panel's decision regarding the parties' outstanding motions to strike will impact the disclosure that will be required. For example, if the Panel determines that the allegations relating to alleged conflicts of interest in Alexion's Amended Response should be struck, then Board Staff will not be required to disclose documents related to that particular issue and that issue will not need to be addressed by the Panel at the hearing.
22. The Board's *Rules of Practice and Procedure* do not set time limits as to when parties are required to disclose the documents which they will be relying on at the hearing. It is helpful, however, to have regard to the *Federal Courts Rules* and the Ontario *Rules of Civil Procedure* which require parties to disclose documents

within 30 to 60 days after the close of pleadings.³ These rules require disclosure to occur after the close of pleadings in order to ensure that parties are only required to disclose documents which relate to the issues that will actually be dealt with at the hearing (or trial) on the merits. It is also important to note that Rule 22(f) requires that all parties disclose the relevant documents prior to the hearing.

23. Board Staff submits that disclosure should take place within 30 days after the close of pleadings. The pleadings define the issues that will be determined by the Panel at the hearing. Once the pleadings are closed the parties will be able to determine which documents they will be relying on at the hearing. Both parties will then be in a position to exchange the documents they intend to rely on.

24. Board Staff submits that Alexion's motion should be dismissed. The Panel should order the parties to exchange all of the documents that they intend to rely on at the hearing within 30 days after the close of pleadings. In the event, however, that subsequent to the exchange of expert reports, either of the parties determines that there are additional documents that they intend to rely upon, then such documents should be disclosed at that time.

³ Rule 223 (1) of the *Federal Courts Rules* and Rule 29.1.03 of the *Rules of Civil Procedure*

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 19th day of October, 2015

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