

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. (“Respondent”)
and the medicine “Soliris”**

WRITTEN REPRESENTATIONS OF THE RESPONDENT

**(REQUEST FOR PARTICULARS, CROSS-EXAMINATION OF ERIC LUN,
and DIRECTIONS RE: MOTION TO STRIKE PASSAGES OF
PROVINCIAL MINISTERS’ AMENDED APPEARANCE)**

PART 1 – Nature of Motions

1. Respondent Alexion has brought motions asking the Panel to: (a) order Board Staff to deliver further particulars of allegations in the Statement of Allegations; (b) grant leave to cross-examine Eric Lun on his affidavit sworn 1 April 2015; (c) schedule a further motion for an order striking out irrelevant portions of the Amended Notice of Appearance filed by the provincial Health Ministers; (d) extend the date for Alexion to formally reply to the Ministers’ Amended Appearance until after Mr. Lun has been cross-examined; and (e) permit Alexion to file a further or amended Response following delivery of particulars delivered by Board Staff.

PART 2 - Overview

2. The Statement of Allegations, delivered 20 January 2015, relies principally on the assertion that the drug Soliris was sold “at the highest international price among the

comparator countries” (or “HIPC” test) listed in the Board’s Guidelines. Requests have been made, but Board Staff have refused, to disclose information and provide particulars of how Alexion has allegedly failed to comply with the HIPC test. Moreover, based on their Reply and other communications with Alexion and Board Staff, it appears Board Staff may be alleging excessive pricing based on factors within s. 85 of the *Patent Act* independent of the HIPC test but have refused to disclose information or provide particulars of those allegations. Board Staff’s refusal to disclose information or provide particulars offends basic notions of fairness and the rules of pleading.

3. The Ministers filed Mr. Lun’s affidavit in support of an Amended Notice of Appearance after Alexion had challenged the relevance of the initial Notice of Appearance and related material. Alexion wishes to challenge Mr. Lun’s evidence by cross-examination before bringing a motion to strike portions of the Ministers’ Amended Notice of Appearance.

4. Once particulars have been provided by Board Staff, the Panel should permit Alexion to file an Amended Response to the Statement of Allegations. Once the cross-examination has taken place, the Panel should hear the motion to strike and then permit Alexion to file a formal written response to what remains of the Ministers’ Amended Notice.

PART 3 – Facts

5. Alexion relies upon the facts as stated in the grounds for the Notice of Motion and the supporting affidavit of Anna Di Domenico.

PART 4 – The Law

Particulars and Disclosure

6. In *Throttle Control Tech Inc. v Precision Drilling Corp.*, 2010 FC 1085 the Federal Court reviewed the case law on particulars in civil proceedings. The court listed a number of purposes served by particulars. Specifically particulars:

- a. Inform the party opposite of the case it has to meet;
- b. Prevent surprise at trial;
- c. Enable the party opposite to know what evidence it will have to gather and present at trial;
- d. Focus the allegations and limit the generality of the pleadings;
- e. Limit the issues for trial and discovery; and
- f. Tie the party pleading to the allegations made in the pleading, thus ensuring that nothing new will be raised at discovery or trial without leave. (at para. 11)

7. From the commencement of this proceeding, Alexion has sought disclosure of information and particulars that are only within Board Staff's knowledge and control. The information and particulars are necessary for precisely the purposes listed in the *Throttle Control* decision. For allegations under the HIPC test, Alexion has sought particulars concerning sources relied upon in calculating international prices and particulars of documents relating to calculations used, made, or considered by Board Staff. Apart from the HIPC test, Alexion has sought basic particulars and disclosure about Board Staff's case theory. On the existing pleadings, Alexion cannot discern how the price of Soliris is excessive, based upon the HIPC test or otherwise.

8. Without knowing the case it has to meet, Alexion cannot know what evidence it will have to gather and present at the hearing. In the absence of particulars and disclosure, Alexion faces unfocused and general allegations of excessive pricing without reference even to the specific factors Board Staff rely upon under s. 85 of the *Patent Act*. Surprise is unavoidable.

9. Apart from mentioning the HIPC test, which itself still requires more particularity and disclosure, it is not clear what other issues will be argued before the Panel at the hearing. It is imperative for Board Staff to be tied down to a case theory Alexion can meet, and the Panel fully appreciate, before the hearing is commenced.

10. The *Throttle Control* decision articulates the principles behind, and purposes of, particulars in civil proceedings between private litigants. The importance of disclosure and particulars in proceedings prosecuted before public tribunals is even greater than in private proceedings. In *Fischer v. Canada (Attorney General)*, [2012] F.C.J. No. 793 (FTD) the Federal Court affirmed the right of a party to an administrative proceeding to know the case to be met:

[27] In addition, similar failures to disclose central issues relied upon by other tribunals have been found by the Federal Court of Appeal to constitute breaches of procedural fairness (see Danakas, McKenna and Garg). While these other tribunals are distinguishable from a classification grievance committee in that their processes are more adversarial and involve hearings more similar to those before a court, the Court's decisions do not turn on the nature of the process before the tribunal but, rather, on the need to ensure the fundamental right of an individual to know the case to be met and to be afforded an opportunity to respond to central issues. Indeed, in my view, this fundamental right, which is the cornerstone of the *audi alteram partem* rule, must be respected in any case where an important interest of an individual is at stake. Important interests are at stake in classification grievances, as the outcome will affect grievors' remuneration and pensions for as long as they remain in the positions which are the subject of the grievance. [Underlining added.]

11. In *May v. Ferndale Institution*, [2005] 3 S.C.R. 809 (SCC) a majority of the Supreme Court of Canada described the duty of disclosure in administrative proceedings as follows:

92 In the administrative context, the duty of procedural fairness generally requires that the decision-maker discloses the information he or she relied upon. The requirement is that the individual must know the case he or she has to meet. If the decision-maker fails to provide sufficient information, his or her decision is void for lack of jurisdiction. As Arbour J. held in *Ruby*, at para. 40:

As a general rule, a fair hearing must include an opportunity for the parties to know the opposing party's case so that they may address evidence prejudicial to their case and bring evidence to prove their position.... [Underlining added.]

12. The public interest in fairness and transparency of proceedings before administrative tribunals is especially important in proceedings where parties are exposed to penalties. In this case, a finding of excessive pricing leads to confiscation by the Board of revenues earned by Alexion from the lawful sale of government-approved products. Indeed, Board Staff is effectively seeking what amounts to a fine, penalty, or partial forfeiture of revenues linked to the sale of Soliris: particularized allegations and full and complete disclosure of Board Staff's case are paramount.

13. Board Staff, and their counsel, have adopted an indifferent attitude toward particulars and timely disclosure of pertinent information, even in regard to the HIPC test. In effect their counsel say: "it's for Board Staff to know and for Alexion to find out." This adversarial and obstructionist approach is entirely inappropriate in the prosecution proceedings in the public interest where the result is confiscation of property. Acting responsibly, professionally, and in the public interest, Board Staff and their counsel should have voluntarily provided particulars and engaged in timely disclosure of relevant information and documents. Alexion should not have been forced to bring a motion

before the Panel to obtain what could easily have been provided as a matter of course by Board Staff in conformance with their prosecutorial obligations. Board Staff, and their counsel, have instead demonstrated a disposition to deliberately hold back on disclosure and particulars in a manner clearly contrary to the public interest, highly prejudicial to Alexion, and unhelpful to the Panel's timely and full appreciation of the case.

Cross-Examination of Mr. Lun

14. Alexion seeks leave to cross-examine Mr. Lun on his affidavit before an intended motion to strike irrelevant portions of the Ministers' Amended Notice of Appearance.

15. The right to cross-examine an affiant of a sworn affidavit is fundamental. In a recent decision involving an ambassador of a foreign state who resisted cross-examination on his sworn affidavit, *Canadian Planning and Design Consultants, Inc. v. State of Libya et al.* (unreported 13 March 2015) Justice Braid of the Ontario Superior Court wrote:

It is a basic rule of evidence that a voluntary witness who provides an affidavit is required to submit to cross-examination because the right to cross-examine is essential to give any weight to an affidavit.

That basic rule of evidence has been recognized in the Supreme Court of Canada decision in *R. v. Darrach* [2000] 2 SCR 433 and later commented on by the Newfoundland and Labrador Court of Appeal in the case of *Royal Canadian Mounted Police and Rees* (decided March 29, 2005)

16. The decisions relied on by Justice Braid, *R. v. Darrach* [2000] 2 SCR 433 and *Royal Canadian Mounted Police and Rees*, 2005 NLCA 15, emphasize the right of

cross-examination in criminal and civil cases. The principle is equally applicable, it is submitted, before administrative tribunals.

17. Mr. Lun submitted his sworn affidavit in support of the Ministers' Amended Notice of Appearance in circumstances where it was clear Alexion was challenging the initial Notice of Appearance. Alexion has a presumptive right to cross-examine Mr. Lun on his affidavit and to have a transcript of his evidence available when the motion to strike parts of the Amended Notice of Appearance is heard by the Panel.

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