

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”**

ALEXION’S REPLY ARGUMENT (RE: DISCLOSURE)

OVERVIEW and FACTS

1. Since early in the proceeding, Alexion has sought documentary disclosure from Board Staff. Disclosure was requested so that Alexion could fully inform itself of the case it must meet consistent with the doctrines of fairness and natural justice. Alexion has also required disclosure to brief expert witnesses involved in the preparation of reports for use at the hearing.
2. Rather than accommodating disclosure requests in a responsive and timely manner, including through partial disclosure while pleading issues were resolved, Board Staff counsel have persistently resisted disclosure relating to excessive pricing allegations in the Statement of Allegations.
3. Board Staff’s failure to provide disclosure (and particulars) have been a source of tension, frustration, delay, and even acrimony throughout these proceedings. These consequences could have been avoided through cooperative, timely, and fair

disclosure, even if disclosure was incremental pending clarification of pleading issues by the Panel. For example, there has never been any question that international pricing information, and application of the Highest International Price Comparison Test, would be a central feature of the hearing. There was no valid excuse for delaying disclosure of that material.

4. On 13 October 2015, almost 10 months after the Statement of Allegations was first issued, the Panel directed Board Staff to deliver a list of documents. Board Staff provided the list on 20 October 2015 and have since helpfully provided electronic copies of listed documents that Alexion was able to forward immediately to experts to facilitate preparation of their reports.

5. Alexion submits that that the Panel should order Board Staff to disclose immediately all other documents in their possession or control that could be relied on for purposes of any other issues raised in the current pleadings. Furthermore, any future disclosure should take place within 10 days of finalization of pleadings.

6. Finally, the suggestion in Board Staff's submissions that "additional documentation may be forthcoming...subsequent to the exchange of expert reports" is procedurally abusive. In effect, Board Staff suggest that they are entitled to deliberately withhold documents they will rely on until after delivery of Alexion's expert reports. No system of discovery, in criminal or civil cases, permits this approach. The request offends basic rules of fairness and natural justice.

LAW and SUBMISSIONS

Minimum Disclosure Requirements in *CIBA-Geigy*

7. In *CIBA-Geigy Canada Ltd. v. Patented Medicine Prices Review Board*, the Federal Court of Appeal dealt specifically with the extent of documentary disclosure required by Board Staff to a patentee in a hearing before the Board. The decision took into account the “admittedly extremely serious economic consequences” for a patentee at a hearing as well as the “possible effect on a Corporation’s reputation in the marketplace.” The court also observed that disclosure should contemplate the “valid objective” of proceeding “as informally and expeditiously as the circumstances of fairness permit.”

8. While the patentee, *CIBA-Geigy*, did not obtain all disclosure sought, the Federal Court of Appeal approved of a trial court decision, and a decision of a Board Panel, acknowledging significant disclosure obligations “imposed by the doctrine of fairness and natural justice.” In *CIBA-Geigy*, that meant being “provided with all the documents that will be relied on” in conformance with requirements of fairness and natural justice.

9. Alexion respectfully requests that this Panel to order Board Staff to meet the same “comprehensive prior disclosure” provided in *CIBA-Geigy*. The following documents should be disclosed:

- (a) all evidence and documents underlying factual allegations and expert opinions board staff will be relying on at the hearing;
- (b) all documents board staff will use in chief to examine its own witnesses and to cross-examine Alexion’s witnesses at the hearing; and

- (c) all other evidence, documentary or otherwise, that Board Staff will be adducing or relying upon at the hearing.

Board Staff's Delays

10. Board Staff's 10-month delay in providing documents relevant to international pricing and the HIPC was inexcusable and inconsistent with the statutory mandate to proceed as expeditiously as possible consistent with fairness principles. These documents were always part of the case alleged in the Statement of Allegations and countered in the Response. Late delivery of the documents was prejudicial and delayed Alexion's ability to instruct experts fully.

11. The recent disclosure provided by Board Staff in response to the Panel's 13 October 2015 direction relates only to international pricing under s. 85(1)(c) of the *Patent Act*. None of the disclosures relate to any excessive pricing factor other than under s. 85(1)(c), whether provided in relation to the original Statement of Allegations or otherwise. Alexion therefore assumes there is no documentary evidence to support any allegation of excessive pricing other than found within s. 85(1)(c). If such documents exist, they could and should have been produced months ago to enable review by Alexion and any appropriate expert.

12. In the event that the recent disclosure is incomplete, the Panel should order Board Staff to immediately disclose all other documents, if any, that they intend to rely upon for purposes of the allegations contained in the original Statement of Allegations. There is no valid reason to further delay production of these documents in contravention of the statutory mandate to proceed expeditiously.

13. To the extent that there are still issues about the scope of the pleadings, Alexion is prepared to accept additional disclosure in increments provided documents are delivered within 10 days of the Panel's decision on the final pleadings.

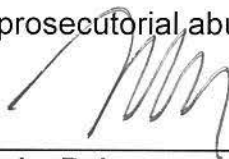
14. Alexion maintains its position that any properly prepared counsel acting in the public interest in a prosecution under s. 85 of the *Patent Act* should know, by the time the Statement of Allegations is delivered, the documentary evidence they will be relying on for purposes of the hearing. Indeed, apart from statutory filings for late 2014 or 2015, the extensive material produced by Board Staff in response to the Panel's recent order all pre-dates issuance of the Statement of Allegations on 15 January 2015. The position advanced by Board Staff reveals either a deliberate policy of withholding production (in violation of the rules of fairness and natural justice) or a state of disorganization and ill-preparedness unworthy of counsel prosecuting a hearing before the Board in the public interest.

15. In civil proceedings, significant documentary and oral discovery regularly takes place before substantial pleading amendments. Indeed, civil rules permit pleading amendments even at trial. Board Staff cannot use current pleading issues to deliberately withhold production of documents that relate to issues in the Statement of Allegations, initial Response, and initial Reply that have been clearly known for several months. Waiting until finalization of current motions was a poor excuse for delaying disclosure. The recent disclosure ordered by the Panel illustrates that disclosure can properly be made while there are disputes over pleadings.

16. Alexion's documentary disclosure obligations are completely independent of Board Staff, who, as prosecutors of these administrative proceedings, have the burden of proving excessive prices. Alexion is nonetheless prepared to indicate to Board Staff whether there are any documents in its possession that it will be relying upon at the hearing that differ from Board Staff's disclosures. Finally, Alexion will also agree to a Joint Exhibit Book for purposes of the hearing to facilitate an efficient and expeditious hearing process.

17. The suggestion that further disclosure should take place subsequent to exchange of expert reports is as incomprehensible as it is outrageous. Expert reports are based upon existing disclosure and not an invitation to further document production. Such a procedure will only invite further delay and lead to supplementary expert reports. That the suggestion is even made reveals that Board Staff either still have no evidence to prove their case or intend deliberately to withhold documents they intend to rely on. The Panel should not tolerate or encourage such prosecutorial abuses.

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