

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.
and the medicine “Soliris”**

**NOTICE OF MOTION and
WRITTEN REPRESENTATIONS OF
THE RESPONDENT ALEXION PHARMACEUTICALS INC.**

RESPONDENT, ALEXION Pharmaceuticals Inc. (“Alexion”) submits this motion to the Hearing Panel (“Panel”) for determination before recommencement of the Hearing on 23 January 2017 in Ottawa.

THE MOTION IS FOR:

1. An Order under Rule 24 of the Board’s *Rules of Practice and Procedure* requiring production of further documents from Board Staff, including:
 - (a) all documents or calculations in Board Staff’s possession, control, or power concerning the price of Soliris during the year 2016 and calculation of the N-NEAP for that year, any alleged excess revenues for 2016, and any requested reduction in the price of Soliris for 2016 or 2017;
 - (b) detailed summaries articulating the amounts Board Staff is claiming as “excessive revenues” in total to date, and exactly what Board Staff claims these totals are based on;

- (c) all relevant details concerning operation of the Board Staff's automated system for calculating drug prices;
 - (d) all documents, electronic or otherwise, relevant to considerations and conclusions surrounding Board Staff's decision to advance claims outside the ambit of the *Guidelines*;
 - (e) final copies of all contract documents (including without limitation the contract identified with Reference Number 15NL029, described as "0362 Data and Database Access Services", Vendor Name IMS AG, and any other relevant contract documents) through which Board Staff obtained the IMS MIDAS Data the Board proposes to rely on at the hearing, and any permissions for or consents to the use of the data in this hearing from any entity pursuant to the relevant contract or contracts;
 - (f) documents relevant to the topics described above in the files of Richard Lemay, Ginette Tognet, Kyle Matte, Jeff Gaul, or any member of Board Staff who has a file in relation to the issues;
 - (g) a requirement that a member of Board Staff deliver, together with the requested documents, an affidavit in the form used in the Federal Court Rules¹, swearing or affirming that the documents are all such documents within their possession, power, and control.
2. An Order adjourning this hearing until such time as the above orders have been complied with and all documents delivered.

¹ Rule 223 of the *Federal Court Rules*.

THE GROUNDS FOR THE MOTION ARE:

Board Staff's Strategy to Date

3. Board Staff have repeatedly been asked by Alexion to produce particulars and documents outlining the basis of Board Staff's case. Such requests and Orders from this Panel to this effect have been repeatedly disregarded by Board Staff. To date, Board Staff has yet to even quantify the total forfeiture amounts it is claiming, or to state any basis for pursuing claims that run directly contrary to the existing legislation and Guidelines. For example, Board Staff have refused to produce figures concerning their analysis of the price of Soliris for 2016 either pursuant to the Guidelines or using the IMS Midas data, even though the Panel has ordered production of this material and it has been revealed during the cross-examination of Mr. Lemay that such information already exists.

4. During even the limited cross-examination of Mr. Lemay conducted so far, it is clear that Mr. Lemay has limited knowledge based on limited involvement in the case apart from reviewing material prepared by others. In contrast, other Board Staff members, like Ginette Tognet, Kyle Matte, and Jeff Gaul have direct knowledge. Board Staff's decision to rely on Mr. Lemay, who has virtually no first-hand knowledge, is an attempt by Board Staff to thwart Alexion from mounting an effective defence by shielding from cross-examination a witness who has knowledge of the case.

5. Mr. Lemay has already admitted on cross-examination that there are other documents that have not been produced, including figures that could be generated from an automated system.

6. On page 381 of the Transcript the following exchange took place:

Mr. Ruby: Okay. So when you were told you would be a witness, you were given copies of this material?

Mr. Lemay: Yes.

Mr. Ruby: Okay. And by "this material", I'm referring to the books in front of you.

Mr. Lemay: Yes.

Mr. Ruby: Did you review anything else in preparation for giving your testimony?

Mr. Lemay: Yes.

Mr. Ruby: What did you review?

Mr. Lemay: Materials that relate to Soliris.

Alexion's Cross-Motion for Disclosure

7. The relief requested by Alexion is reasonable and is based on information revealed during the course of the hearing itself. Alexion only discovered the limitations on Mr. Lemay's knowledge through the cross-examination of Mr. Lemay. Alexion has also discovered the existence of other evidence, including that the automated system could easily be used to generate a report of the final 2016 N-NEAP and alleged excess revenues based on the Guidelines and other case theories Board Staff are advancing. It is outrageous that Alexion does not know the forfeiture exposure, price reductions, or other liabilities it faces at this stage of the proceedings. In defiance of directions from the Panel itself, Board Staff have failed to deliver information for the 2016 price of Soliris, even though Alexion has filed its Form 2 and the calculations are available from the Board's automated system as described in the cross-examination of Mr. Lemay.

8. Moreover, as noted above and in Board Staff's own Notice of Motion, evidence is "relevant" where it "concerns the key facts on which the decision will turn". It is now obvious that Board Staff has not produced all relevant evidence it possesses, despite repeated requests from Alexion and directions from the Panel.

9. Board Staff are under an obligation, as part of the duty of fairness and natural justice, to provide adequate disclosure of the case Alexion must meet, particularly where they are seeking confiscation and forfeiture of significant revenues from Alexion. They have a clear duty to disclose the documents and evidence they will be relying upon at the hearing but, for strategic reasons, are withholding disclosure with the apparent objective of surprising Alexion or gaining some other tactical advantage.

10. The duty of procedural fairness requires Board Staff to disclose all facts, documents, testimony, and other evidence they will rely on for purposes of the hearing. Board Staff have consistently refused to disclose the documents and evidence they rely on in support of the Allegations. There is ample authority for the proposition that Board Staff, as a regulatory prosecutor, has a duty to comply with basic rules of procedural fairness. This means that Board Staff must act fairly and judiciously to ensure that Alexion has an opportunity to know the case it has to meet. This is all the more important in this case because Board Staff now seek to confiscate over \$100 million in Alexion's lawfully earned revenues.

11. In *CIBA-Geigy Canada Ltd. v. Canada (Patented Medicine Prices Review Board)*, (“*CIBA-Geigy*”)² the Federal Court considered whether the criminal law disclosure principles articulated in *R. v. Stinchcombe* applied to a hearing before the Board. The Court found that although *R. v. Stinchcombe* did not apply, the doctrines of fairness and natural justice applied to regulatory prosecutions before the Board and required Board Staff to make disclosure of the allegations and the documents they intended to rely on in making a case for excessive pricing:

In summary, when the statutory scheme of the Board is looked at, the Board is a regulatory board or tribunal. There is no point in the legislature creating a regulatory tribunal if the tribunal is treated as a criminal court. The obligations concerning disclosure imposed by the doctrine of fairness and natural justice are met if the subject of the inquiry is advised of the case it has to meet and is provided with all the documents that will be relied upon.³ [Emphasis added.]

12. Importantly, the Federal Court states that “the subject of the inquiry” (i.e., Alexion) has the right to disclosure of documents the Board Staff intend to rely upon, in order to know the case it must meet. Board Staff’s documentary disclosure is required by the doctrine of fairness in the context of a regulatory prosecution. Board Staff’s obligation to disclose is *not* equivalent to the reciprocal disclosure obligations of plaintiff and defendant in civil litigation.

13. The Federal Court of Appeal upheld the Federal Court’s decision in *CIBA-Geigy*, noting that “[t]here are admittedly extremely serious economic consequences for an unsuccessful patentee at a s. 83 hearing, and a possible effect on a corporation’s

² *CIBA-Geigy Canada Ltd. v. Canada (Patented Medicine Prices Review Board)*, [1994] 3 F.C. 425, [1994] F.C.J. No. 626 (QL) (T.D), aff’d at [1994] F.C.J. No. 884 (QL) (F.C.A.).

³ *Ibid.*, at para. 32.

reputation in the market place.”⁴ While criminal procedure rights did not apply, both the Federal Court and the Federal Court of Appeal found that, in light of the serious economic and reputational impact of a successful prosecution, basic fairness required a respondent to have sufficient disclosure to know the case it had to meet.

14. In order to obtain all relevant evidence from Board Staff so as to allow Alexion to know the case it has to meet, and Board Staff’s previous conduct, it is now necessary to adopt a more stringent procedure than has been followed to date. Alexion therefore requests that the above-noted witnesses, who have actual knowledge of the matters at issue, be ordered to produce their files, to include the documents described above. A Board Staff member should also be required to swear an affidavit of documents in the form provided in the Federal Court Rules confirming that all document production has taken place.

15. While this procedure is more exacting than the procedures originally contemplated by the Panel, it is the only just process in the circumstances, given the following:

- (a) Repeated attempts by Alexion to obtain meaningful particulars and disclosure from Board Staff have proven futile;
- (b) Board Staff have increased the potential forfeiture liability of Alexion to over \$100 million;
- (c) Board Staff have produced a fact witness with virtually no first-hand knowledge of the case; and

⁴ *CIBA-Geigy Canada Ltd. v. Canada (Patented Medicine Prices Review Board)*, [1994] F.C.J. No. 884 (QL) (F.C.A.) at para. 9.

- (d) Board Staff is evidently continuing the pattern it has adopted throughout this process of making sudden last-minute changes to their demands deliberately timed to interfere with Alexion's ability to understand the case it has to meet and prepare a meaningful response.

Alexion's Motion for an Adjournment

16. An adjournment of the hearing is now an unfortunate necessity. There is no point to continuing with a process in which full disclosure has not been made by Board Staff. Alexion would suffer irreparable prejudice if the adjournment is not granted.

17. Alexion obviously cannot continue with the examination of Board Staff's fact witness where the fact witness proffered lacks basic knowledge of the case, and all relevant documents, including the total forfeiture amount, have not been produced.

18. Board Staff have proffered two expert witnesses: (1) Mr. Schwindt, who has opined that the Guidelines are a fair application of the statutory criteria found in the *Patent Act*; and (2) Mr. Addanki, who has opined that a radical departure from the Guidelines is justified on economic grounds in the circumstances of this case.

19. To properly cross-examine the experts on their respective opinions, the factual basis for Board Staff's case must first be disclosed and established. The expert's evidence must be tested against all relevant foundational facts established through the Board's fact evidence.

20. Critical to the establishment of that factual matrix are certain key facts, including the total forfeiture amounts Alexion is exposed to in terms of alleged "excessive

revenues” to date, and just as significantly, which of the statutory criteria found in Section 85 of the *Patent Act* Board Staff are relying on as a basis for that liability.

21. Until the actual and complete factual basis of the case is established, cross-examination of the experts will of necessity be partial only. It is pointless to examine, in the abstract, whether Board Staff’s experts believe the Guidelines are “fair” or alternatively whether a departure from the Guidelines is required, without first establishing the facts as to what aspects of the statutory criteria Board Staff are claiming to be relying upon and the rationale for why the Board is departing so dramatically from the Guidelines in this case.

22. In the alternative, should Board Staff see fit to allow Board Staff’s motion and/or to deny Alexion’s motion, Alexion requires time to respond with appropriate measures. Allowing Board Staff to proceed by way of surprise tactics during the hearing itself, without allowing Alexion time to respond, is a fundamental breach of the duty of procedural fairness.

THE FOLLOWING DOCUMENTARY EVIDENCE is being relied upon by Alexion for the purpose of this motion:

23. The pleadings and proceedings herein and such material as counsel may adduce and the Panel admit.

Dated: 21 January 2017

Original signature redacted

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