

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 SUBMISSIONS OF THE RESPONDENT:
ALEXION'S MOTION RE: DISCLOSURE OF DOCUMENTS
(Motion Returnable 16 September 2015)**

Overview

1. Respondent, ALEXION Pharmaceuticals Inc. ("Respondent" or "Alexion"), brings a motion for disclosure of:

- (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 to examine their own witnesses in chief and to cross-examine Alexion's witnesses at the hearing;
- (c) Any other evidence, documentary or otherwise, that Board Staff will be adducing or relying upon at the hearing.

2. Alexion is entitled to this disclosure. Natural justice demands that Alexion know the case it has to meet in response to Board Staff's prosecution.

3. Board Staff resists disclosure on the basis that they have no ethical duty to act in accordance with natural justice. In effect, Board Staff argue that they can conduct the litigation like a zealous plaintiff's lawyer seeking to "win" a judgment for Her Majesty confiscating a significant portion of Respondent's revenues from the sale of Soliris.

Board Staff's position is inconsistent with their duty as a regulatory prosecutor to act ethically, in the public interest, and in accordance with fundamental fairness.

Background

4. On 12 February 2015, Alexion's counsel asked Board Staff's counsel to disclose documentation underlying allegations made in the Statement of Allegations ("Allegations") dated 15 January 2015.
5. On 20 February 2015, Board Staff counsel refused to disclose the requested documents, stating that the request for documents was premature and that "Board Staff will deliver its documents within a reasonable time frame after the parties have exchanged pleadings".
6. Alexion delivered its Response to the Allegations on 9 March 2015.
7. Board Staff delivered its Reply to the Alexion Response on 10 April 2015.
8. Despite the exchange of pleadings, Board Staff did not deliver its documents.
9. On 16 April 2015, following delivery of Board Staff's Reply, Alexion informed the Board Secretary that it would seek production of documents relating to the Allegations.
10. On 21 April 2015, the Board Secretary requested that the parties deliver, by 27 April 2015, details concerning: the volume, nature, and method of delivery and format of documents; information on fact witnesses; and, information concerning the use of expert witnesses.

11. On 27 April 2015, Alexion's counsel indicated that an expert witness had been retained to deal with issues raised in relation to the Highest International Price Comparison ("HIPC") test. The Board Secretary was informed by Alexion that, without particulars and disclosure, the company could not provide assistance on delivery of documents or information on fact witnesses. Indeed, Alexion stated in the 27 April 2015 letter that without knowing the case it had to meet it was "not possible...to make written submissions on documentary productions, witnesses, experts, or the expected duration of proceedings."

12. Board Staff responded to the Board Secretary's inquiries on 27 April 2015 stating that: "the parties should exchange electronic and hard copies of the documents which they will rely on at the hearing"; that they intended to call "at least two witnesses at the hearing" and deliver "will-say statements"; and, that they would call "at least one expert prepare a report and testify at the hearing." Board Staff have provided no further detail identifying their witnesses and expert. Nor have they disclosed any documents or other evidence they intend to rely on at the hearing.

13. On 15 May 2015, Alexion brought a motion requesting particulars of the Allegations. Board Staff opposed the motion.

14. On 23 June 2015, the Panel ruled on Alexion's motion for particulars, ordering Board Staff to provide particulars concerning several assertions in the Allegations. In the oral reasons for the Order, Panel member Kobernick observed, in relation to documents sought by Alexion, that Alexion would:

...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. [Underlining added.]

15. Following the June 2015 hearing of Alexion's motion, Alexion's counsel wrote Board Staff counsel asking that Board Staff make their documentary disclosure on the same date, 3 July 2015, as Board Staff were required under the Panel's Order to deliver the particulars ordered by the Panel.

16. On 3 July 2015, Board Staff provided some documents together with the particulars ordered by the Panel.

17. On 6 July 2015, Alexion counsel wrote to Board Staff counsel requesting confirmation that the documents received on 3 July 2015 comprised the documents Board Staff intended to rely on at the Hearing.

18. On 7 July 2015, Board Staff counsel sent an email to Alexion counsel indicating that the documents provided on 3 July 2015 "were not intended to constitute the disclosure of Board Staff." For a second time, Board Staff counsel stated that it "would be premature to have documentary disclosure at the present time."

19. Since 7 July 2015, Board Staff have not provided documentary disclosure.

Alexion Entitled to Disclosure as a Matter of Procedural Fairness

20. On 28 August 2015, counsel for the Board Staff wrote to the Secretary of the Board to propose that the Board Staff and Alexion disclose all documents they intended to rely on by the same date, 20 October 2015.

21. Board Staff's position fails to reflect that Alexion, as a regulated entity, was required to file its pricing information under *Patent Act* and *Patented Medicines Regulations* and that Board Staff had access to this information in advance of commencing the prosecution. In other words, Alexion had already made disclosure of relevant documents, as compelled by statute and regulation, *well before* Board Staff initiated the prosecution. It is now up to the Board Staff to provide any documents they intend to rely upon in prosecuting Alexion, at which point, Alexion may, if relevant, disclose further documents in response to what Board Staff discloses.

22. Indeed, for purposes of the hearing at this time, Alexion will only be relying upon its periodic filings with the Board, the particulars and related disclosures of Board Staff made in response to the Panel's Order dated 23 June 2015, and the report of one expert relating to foreign exchange rates. It is only if Board Staff's disclosures raise new issues that Alexion may rely on other material. When Board Staff's disclosure is made, Alexion will have a better idea of the case being prosecuted and be in a position to identify additional relevant documents it intends to rely upon.

23. Board Staff's suggestion that disclosure of documents should be made by both parties at the same time fails to acknowledge Board Staff's obligations in bringing a prosecution against Alexion relating to allegedly excessive prices. Board Staff's obligation to disclose documents is not a reciprocal obligation dependent on Alexion's disclosure that would arise, for example, if this were a civil proceeding. Rather, disclosure is an obligation placed upon the Board Staff as prosecutor as is a matter of procedural fairness and natural justice because Alexion, as the regulated entity facing a significant fine or penalty, has the right to know the case it has to meet. In previous

written and oral submissions before the Panel dealing with delivery of particulars, Board Staff assured Alexion and the Panel that disclosure would be made and did not suggest the disclosure obligations would depend of on simultaneous disclosure by Alexion. See: *Written Representations of Board Staff* dated 5 June 2015, at paragraph 41; *Transcript Of Proceedings*, 22 June 2015, at pages 60 – 61.

24. Board Staff have failed to act in conformance with their obligations as prosecutors acting in the public interest. Board Staff, and their counsel, have been overly adversarial in the prosecution of this case. 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.

25. The duty of procedural fairness, including the opportunity to be heard, 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. Their filings in this proceeding demonstrate Board Staff have misapprehended their role as prosecutors acting in the public interest. Instead of seeing themselves as regulatory prosecutors having duties of fairness and candour, they see their role as that of zealous plaintiffs' lawyers hoping to "win" a judgment confiscating Alexion's assets by any means necessary including for reasons that they have still failed to articulate.

26. 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.

27. In *CIBA-Geigy Canada Ltd. v. Canada (Patented Medicine Prices Review Board)*, (“CIBA-Geigy”) ¹ the Federal Court considered whether the criminal law disclosure principles articulated in *R. v. Stinchcombe* applied to 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.² [Emphasis added.]

28. 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.

¹ *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.).

² *Ibid.*, at para. 32.

29. 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 reputation in the market place."³ 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.

30. At this point, Alexion has no documents to disclose beyond its regulatory filings, which Board Staff already possess. Alexion will not know whether it will rely on additional documents until after it has received disclosure from the Board Staff. At that point, Alexion will have a better idea of the case it has to meet. If Alexion identifies any additional documents it will rely upon after receiving Board Staff's disclosure, the documents will be disclosed within an agreed-upon time.

Board Staff Required to Act Fairly and in Public Interest as Prosecutors

31. Board Staff takes the position that they are entitled to adopt tactics that a plaintiff's lawyer might use in civil litigation. Board Staff's Motion to Strike portions of Alexion's Amended Response adopts the position that Board Staff are duty-bound to "'fearlessly raise every issue' to help the client's case and to function as advocate in a 'necessarily partisan' fashion."⁴ Board Staff expressly denies that their role is one of regulatory prosecutor bound to act fairly and in furtherance of the public interest.

³ *CIBA-Geigy Canada Ltd. v. Canada (Patented Medicine Prices Review Board)*, [1994] F.C.J. No. 884 (QL) (F.C.A.) at para. 9.

⁴ Written Representations of Board Staff (Board Staff's Motion to Strike), dated 31 July 2015, at para. 36.

32. Numerous authorities have noted that the Board Staff function as “prosecutors”⁵. Indeed, Board Staff refer to themselves as prosecutors. Unlike a private litigant seeking to obtain financial advantages for their client, Board Staff have a clear duty to act fairly and in the public interest by bringing prosecutions in a balanced and forthright manner, and only when a prosecution is in the public interest.

33. Several commentators have observed that government lawyers engaged in prosecution have ethical duties different from lawyers in private practice and, in particular, must act in favour of the public interest, not merely just to win cases. According to Professor Allan Hutchinson, a lawyer like Board Staff’s counsel in this case are charged with ensuring the public interest is protected, and should not be concerned with “winning” a case for their government client:

The significant difference between private lawyers and government lawyers is that the latter have a much greater obligation to consider the public interest in their decisions and dealings with others than the former. This is particularly so in the case of the criminal prosecutor. Because prosecutors fulfill a "public function," it must be carried out "fairly and dispassionately."

[...]

While they do not fulfill exactly the same roles or assume exactly the same obligations, government lawyers and prosecution lawyers both share a common duty to advance the public interest as a direct and explicit undertaking. [...] The development of constitutional and administrative law has been marked by the approved imperative to hold public actors to different standards of conduct and accountability than their private counterparts. Informed by a distinctly democratic sensibility and commitment to the public interest, courts have required public bodies to look to a broader set of interests than their own parochial and partisan

⁵ See e.g. *Hoechst Marion Roussel Canada Inc. v. Canada (A.G.)*, 2001 FCT 795, [2001] F.C.J. No. 1151, at paras. 16, 19, 42, 47; *Hoechst Marion Roussel Canada Inc. v. Canada (A.G.)*, 2005 FC 1552, [2005] F.C.J. No. 1928 (QL) at para. 82; Roger T. Hughes and Dino P. Clarizio, *Halsbury's Laws of Canada – Patents, Trade Secrets and Industrial Design (2012 Reissue)*, HPT-154 Powers and obligations of the Board.

concerns in determining the most appropriate and reasonable course of action to be followed. In short, like the bodies that they serve and represent, government lawyers are different in that they are expected to have a more expansive and more public appreciation of their roles and responsibilities than their private counterparts.

[...]

Government lawyers clearly have an obligation to pursue the public interest, not simply the private interests of their government client. Although the precise scope of that obligation might well be contentious, its existence and good sense is surely not.⁶ [Emphasis added.]

34. In other words, even though a proceeding before the Board is not a *criminal* prosecution, it is a regulatory prosecution where lawyers acting for the government should, at all times, treat their prosecution of a regulated party as a “public function” that is to be undertaken in a “fair and dispassionate” manner.

35. In arguing that government lawyers have different ethical obligations than private lawyers, Professor Adam Dodek notes that because government lawyers exercise public power, their ethical obligations should be greater than those of a private practice lawyer:

Normatively, government lawyers should be held to higher ethical standards than other lawyers because they are exercising public power. This is what it means to be lawyers for the Crown because the Crown is the concept that personifies the exercise of state power. As discussed below, government lawyers are not just passive vessels implementing the instructions of their political masters. Government lawyers interpret, advise and advocate on the powers and duties of the Crown. In so doing, government lawyers exercise public power. This exercise of public power

⁶ Allan C. Hutchinson, “In the Public Interest’: The Responsibilities and Rights of Government Lawyers” (2008) 46 *Osgoode Hall L.J.* 105-129 (QL), at paras. 12-13, 29.

is therefore the key distinction between government lawyers and all other lawyers.⁷

36. The public interest expressed in the price regulation sections of the *Patent Act* includes, *inter alia*, the deterrence of excessive ex-factory prices. As part of this regulatory scheme, the *Patent Act* permits the confiscation of a patentee's property and the imposition of financial penalties. A finding of excessive prices does not result in damages for an aggrieved plaintiff but, rather, in a confiscation of the excess revenues by Her Majesty, together with potential penalties of up to twice the excess revenues under s. 83(4) if the patentee engaged in a policy of selling at an excessive price.

37. Board Staff's characterization of counsel's role, as zealous advocates devoted to winning judgment, is at odds with their duties as regulatory prosecutors. In particular, the confiscatory and punitive aspects of price regulations in the *Patent Act* demonstrate why a prosecution must be brought only when it is in the public interest, and only in a manner consistent with fundamental fairness. That means, among other things, that:

- (a) Board Staff must have formed their case against a regulated party *before* bringing a prosecution;
- (b) the case must give rise to a prosecution that, viewed dispassionately, has merit; and
- (c) Board Staff must be forthright and prompt in disclosing the allegations and the documents relied upon so that a regulated party knows the case to meet *before* the regulated party is required to respond to allegations and produce its own documents.

38. It would appear Board Staff did not have relevant evidence when the case was commenced. They are presently attempting to obtain evidence and information to make

⁷ Adam M. Dodek, "Lawyering at the Intersection of Public Law and Legal Ethics: Government Lawyers as Custodians of the Rule of Law" (2010) 33 Dalhousie L.J. 1 (QL), at p. 10.

the case Board Staff commenced several months ago. On 14 July 2015, Alexion received an email indicating Board Staff was using Isabel Raasch, a former Gowlings partner who had only recently left the firm, to make inquiries of Health Canada to obtain evidence in support of the prosecution. Quite apart from ethical concerns about Ms. Raasch's conduct, her efforts in July 2015 show that Board Staff did not have the evidence necessary to prove their case at the time the Allegations were delivered in January 2015.

39. Board Staff's tactical approach is particularly egregious and detrimental to Alexion. The Board's process lacks even civil discovery rights, including documentary and oral discovery, designed to protect Alexion from surprise. The standard for disclosure by Board Staff is that it must produce only documents *it intends to rely upon*, not the civil standard requiring disclosure of all relevant documents in the Board's possession.⁸ In essence, Board Staff counsel advocate that Alexion should be deprived of the disclosure rights of a civil litigant, yet they characterize their own ethical obligations as the same as those of a plaintiff's lawyer in a civil case. The Panel should reject this hypocrisy.

40. Board Staff's tactical litigation strategy is unfair and prejudicial. Disclosure of the case Alexion has to meet, which is vital to Alexion's ability to respond, should take place early in the process and continue before the hearing. Withholding disclosure harms the process, is prejudicial to Alexion, and undermines public confidence in the Board's integrity.

⁸ *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), at para. 32.

Order Requested

41. Respondent Alexion requests that the Board grant its Motion for Disclosure and order Board Staff to disclose forthwith:

- (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 witness and to cross-examine Alexion's witnesses at the hearing;
- (c) Any other evidence, documentary or otherwise, that Board Staff will be adducing or relying upon at the hearing.

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