

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 OF THE RESPONDENT,
Alexion Pharmaceuticals Inc.**

RESPONDENT, ALEXION Pharmaceuticals Inc. (“Alexion”) will make a motion before the Hearing Panel (“Panel”) at the recommencement of the Hearing on 17 January 2016 in Ottawa.

THE MOTION IS FOR:

1. An Order requiring that the Panel be reconstituted to restore a third member for the purposes of hearing this case.

THE GROUNDS FOR THE MOTION ARE:

Introduction

2. The hearing involves substantial asset forfeiture allegations and important issues relating to pricing of drugs used to treat rare (orphan) diseases. The hearing was commenced before a hearing panel composed of three members appointed by Ms. Mary-Catherine Lindberg, the former Chair of the Board.

3. The panel members appointed were Dr. Mitchell Levine, Ms. Carolyn Kobernick, and Mr. Normand Tremblay. All three members have been involved at each stage, including the hearing of an extensive number of preliminary motions.

4. At the commencement of the evidentiary phase of the hearing on 16 January 2017, Alexion learned for the first time that Mr. Tremblay would not be part of the Panel, which would be limited to only Dr. Levine and Ms. Kobernick. Dr. Levine stated:

Monsieur Normand Tremblay has had to resign from the Panel for personal reasons and we will be proceeding with the two of us, which is a quorum under Rule 4 of the Board's *Rules of Practice and Procedure*.

5. The Panel as constituted by the former Chair represented a balance of relevant viewpoints and experience: legal, medical, and business. Mr. Tremblay, the only Panel member with business and pharmaceutical industry experience, is described on the Board's website as follows:

Mr. Tremblay is President and Chief Executive Officer of an innovative company (diaMentis inc.) which is currently developing a mental health diagnostic tool, and teaches at the Université du Québec in the area of management, project management and innovation. He brings to the Board a vast experience and expertise in strategic and operational planning and organizational development. For over 20 years, Mr. Tremblay has been active in various areas of the business field, both nationally and internationally. He has also sat on investment committees and a number of administrative boards, including the National Research Council of Canada (NRCS) from 2007 to 2010.

6. It was reasonable and understandable that the former Chair of the Board would include Mr. Tremblay on the Panel given his extensive private sector business experience.

7. As the only panel member with private sector business experience, Mr. Tremblay's presence on the Panel, together with Ms. Kobernick (legal and public sector) and Dr. Levine (medical and pharmacology) created a reasonable expectation, and appearance, of balanced and impartial viewpoints in the Panel's adjudicative process.

8. Continuing the hearing before a panel of only two members, neither with private sector business experience, raises significant concerns about procedural fairness and natural justice, particularly given the issues of confiscation and forfeiture of business assets at issue in this proceeding and Alexion's reasonable expectations of how the Panel would be constituted so as to include a member with private sector and industry experience and knowledge.

9. The change in constitution of the Panel has substantial implications for the fairness of the hearing. The original appointment of three panel members ensured that diverse views and experience would be represented on the Panel. Mr. Tremblay has extensive experience in the pharmaceutical industry itself. Alexion believed Mr. Tremblay's views, would inform the views of the other Panel members, and were intended to serve as a balance against the expertise of panel members Dr. Levine (medicine and academia) and Ms. Kobernick (law and public service). A reasonable person, viewing the changed composition of the Panel, would conclude that the new panel is less likely to appear impartial towards a manufacturer like Alexion.

10. The *Patented Medicine Prices Review Board Rules of Practice and Procedure* (the "Rules") state, in section 2, that "the members assigned by the Chairperson under subsection 93(2) of the Act to deal with a matter constitute the Board". While section 4 of the Rules contains an express power to create a quorum of the Board consisting of two members, a two-member panel was deliberately not the approach taken in this case. For purposes of this case, the "Board" was a three-member panel "assigned" "to deal with the matter." The former Chair had reasons to appoint a three-member panel and there has been no change in circumstances to warrant a diminished or reduced

panel. Indeed, the significance and complexity of issues has increased as the case has evolved. Moreover, there was no notice of the change in composition of the panel, reviewable error in and of itself: *Moyer v. New Brunswick (Workplace Health, Safety and Compensation Commission)*, [2008] N.B.J. No. 191 (NBCA), at paragraph 12.

11. For the reasons described below, it is also not the appropriate approach in this case. Proceeding with only two members as a substitute for a balanced and representative group of three would be procedurally unfair and raises a reasonable apprehension of bias.

Procedural Fairness

12. Alexion has a legitimate expectation that the hearing will be before the three panel members originally appointed, or before a similarly balanced reconstituted panel.

13. The doctrine of legitimate expectations was described as follows in *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817 (SCC):

26 Fourth, the legitimate expectations of the person challenging the decision may also determine what procedures the duty of fairness requires in given circumstances. Our Court has held that, in Canada, this doctrine is part of the doctrine of fairness or natural justice, and that it does not create substantive rights: ... As applied in Canada, if a legitimate expectation is found to exist, this will affect the content of the duty of fairness owed to the individual or individuals affected by the decision. If the claimant has a legitimate expectation that a certain procedure will be followed, this procedure will be required by the duty of fairness ... [Citations omitted]

14. Alexion requests that it be afforded the procedural benefit specifically provided for by the former Chair: a hearing before a three-member panel including a member

who has private sector and pharmaceutical industry experience as originally contemplated in the former Chair's original direction.

Impartiality

15. A panel of two members under these circumstances does not meet the basic test for impartiality.

16. That test was stated as follows in the leading case of *R. v. Lippé*, [1991] 2 S.C.R. 114 (S.C.C.) at para. 57:

If the Canadian Charter does not guarantee "ideal" institutional impartiality, what is the test for determining when there is an infringement? The parties agree that the test for both "independence" and "impartiality" should be that set out by de Grandpré J. in *Committee for Justice and Liberty v. National Energy Board*, [1978] 1 S.C.R. 369, at p. 394, a test adopted in *Valente*, supra, as applicable to both the issue of independence and impartiality (at p. 684, citing de Grandpré J. and at p. 689):

... the apprehension of bias must be a reasonable one, held by reasonable and right-minded persons, applying themselves to the question and obtaining thereon the required information. In the words of the Court of Appeal, that test is "what would an informed person, viewing the matter realistically and practically -- and having thought the matter through -- conclude".

...

This is also the test that is to apply to institutional impartiality.

17. The Supreme Court went on to describe a "two step" process for determining whether a tribunal meets the test, in para.

60 Step One: Having regard for a number of factors including, but not limited to, the nature of the occupation and the parties who appear before this type of

judge, will there be a reasonable apprehension of bias in the mind of a fully informed person in a substantial number of cases?

61 Step Two: If the answer to that question is no, allegations of an apprehension of bias cannot be brought on an institutional level, but must be dealt with on a case-by-case basis.

18. This test has been consistently applied to administrative tribunals performing court-like functions, as well as to courts: see *Bell Canada v. Canadian Telephone Employees Assn.*, [2003] S.C.J. No. 36 (S.C.C.) at paras. 24 and 25.

19. In this case, the currently constituted Panel without Mr. Tremblay or someone like him with business and pharmaceutical industry experience leaves the Panel bereft of a vital and relevant viewpoint. Courts often defer to expert tribunals because they possess this very type of expertise. A reasonable person would conclude that a panel consisting of only two members without industry experience would appear to be less balanced and impartial than a panel, like the original panel in this case, comprised of three members, including a member with substantial private sector and industry experience.

Prejudice to Alexion

20. The diminution in the appearance of impartiality of the Panel created by Mr. Tremblay's resignation raises a reasonable apprehension of bias and is procedurally unfair given the established practice in this case of having a Panel of three, including a member with extensive industry experience.

21. Moreover, a reduction from three to two panel members creates additional prejudice to Alexion, in that it removes the potential for a dissenting view.

22. A diminution in the range of expertise of the Panel, combined with procedural prejudice, requires the current Panel to adjourn the hearing and re-commence with a properly constituted panel.

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

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

Dated: 16 January 2017

Original signature redacted

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