

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”**

**NOTICE OF MOTION
(CONFLICTS OF INTEREST)**

RESPONDENT, ALEXION Pharmaceuticals Inc. (“Respondent” or “Alexion”), will present a motion before the Panel at the Hearing currently scheduled for 16 September 2015 at the Board’s offices in Ottawa:

THE MOTION REQUESTS ORDERS THAT:

1. The Notice of Hearing and Statement of Allegations of Board Staff be quashed based on a conflict of interest involving the Board’s Chairperson, Mary Catherine Lindberg, as described below;
2. Parul Shah, of the PMPRB Legal Services Branch, be disqualified as a lawyer of record for Board Staff in the proceeding;
3. David Migicovsky, Christopher Morris, and Perley-Robertson Hill & McDougal LLP be disqualified as lawyers of record for Board Staff in the proceeding;
4. Isabel Jaen Raasch: (a) be disqualified from participating in the proceeding or in any way assisting or collaborating with Board Staff in the proceeding; and (b) be subject to an

ethical screen preventing her from receiving or sharing any information concerning the proceeding with Board Staff; and

5. Such other relief as the Board deems just and appropriate to grant.

GROUND FOR THE MOTION ARE:

Conflict Relating to Mary Catherine Lindbergh

6. Members of the public and regulated entities must have confidence in the impartial administration of justice before the Board. Proceedings must be commenced and conducted without any apprehension of bias or conflict of interest. Justice must not only be done but be seen to be done.

7. Mary Catherine Lindbergh has been Chairperson of the Board since March 2011. Under the PMPRB Guidelines (s. A.3.6), Ms. Lindbergh decides whether it is in the public interest for a hearing be held pursuant to subsection 83 (6) of the *Patent Act*.

8. Before issuing a Notice of Hearing, Ms. Lindbergh, in her capacity as Chief Executive Officer of the Board, is informed of the results of Board Staff's review into an instance of possible excessive pricing "solely for the purpose of determining whether a hearing is in the public interest." (Guidelines, s. A.3.7) Ms. Lindbergh not only issues the Notice of Hearing but appoints the Hearing Panel.

9. On 6 August 2015, a corporate search of Green Shield Canada ("Green Shield") revealed that Ms. Lindbergh is currently a member of the Green Shield Board of Directors. On 7 August 2015, a search of the website of the Intervener, Canadian Life and Health Insurance Association Inc. ("CLHIA"), indicated that Green Shield was a CLHIA member.

10. As a Director of Green Shield, Ms. Lindberg has fiduciary duties that would include keeping Green Shield's costs under control. This would include costs relating to patented medicines, including Soliris, purchased by, or on behalf of, Green Shield's insured members.

11. Ms. Lindberg's duty to Green Shield, a member of the intervener CLHIA, places her in an irreconcilable conflict of interest as Chair of the Board. Her duties to Green Shield could reasonably be apprehended to have influenced her decision whether it was in the public interest to issue a Notice of Hearing pursuant to subsection 83 (6) of the *Patent Act*. Green Shield, through its membership in CLHIA has an obvious interest in the outcome of the proceeding and this raises a reasonable apprehension of bias regarding Ms. Lindberg's direction to commence this proceeding.

12. As a CLHIA member, Green Shield will be affected by the Panel's decision. Indeed, in its submissions before this Panel CLHIA has stated:

... the CLHIA is an organization which represents persons who will "in one manner or another" bear the cost burden of the price of Soliris....in 2013 the CLHIA estimates that private payers reimbursed more than \$29 million for Soliris claims, which was up from 2012, when private payers paid approximately \$21.6 million for Soliris claims. The fact that these payments are made pursuant to insured policies, group plans or group policies does not take away from the fact that CLHIA member companies are, together with plan sponsors, individual insureds and group plan members (through co-payments or by exceeding plan maximums), paying a substantial portion of the direct costs for Soliris in Canada.

13. Green Shield also has a direct interest in the remedy being proposed by CLHIA, who have stated in this proceeding:

The CLHIA merely proposes that the remedy imposed, should the board find Alexion charged excessive prices for the period in question, be applied in a way that to some extent compensate those who have borne any excessive pricing.

14. Ms. Lindberg's obligations to Green Shield, which include seeking "compensation" for those who have "borne any excessive pricing", conflict with her obligation to ensure that proceedings before the Board are initiated and conducted impartially.

15. Ms. Lindberg's conflict presents a serious and important issue that must be dealt with to protect the integrity of the administration of justice in this proceeding, and in any other present or future proceedings before the Board. The real or apprehended conflict of interest created by Ms. Lindberg's Green Shield directorship taints the entire prosecution before the Panel. The Notice of Hearing must be quashed. The decision whether a new or fresh proceeding should be commenced must be left to a Board Member other than Ms. Lindberg.

Conflict relating to Isabel Raasch

16. On 7 July 2015, the Board announced the appointment of Isabel Raasch as Director, Legal Services and General counsel.

17. Ms. Raasch was, until her appointment to the Board, an Ottawa partner of Gowling Lafleur Henderson LLP ("Gowlings"). Gowlings is currently counsel to Alexion in these proceedings and was acted on Alexion's behalf in relation to the proceeding while Ms. Raasch was still a Gowlings partner. Ms Raasch, like any other Gowlings partner, owed a duty of loyalty to Alexion. Alexion had a reasonable basis for believing that a Gowlings lawyer would observe that duty by not, in effect, becoming engaged in the prosecution of a case against Alexion after she left the firm and joined the Board.

18. The Supreme Court of Canada has emphasized that "the duty of loyalty to current clients includes a much broader principle of avoidance of conflicts of interest, in which confidential information may or may not play a role." The duty of loyalty includes a "duty not to act against the interest of the client."

19. After Ms. Raasch left Gowlings and joined the Board, she was required to observe her duty of loyalty to Alexion by playing no role in the prosecution of these proceedings against Alexion. Furthermore, it was incumbent upon the Board to erect an appropriate ethical screen and procedure to ensure that Ms. Raasch did not become involved in the proceeding.

20. On 13 July 2015, Alexion learned that Ms. Raasch was in fact participating in the prosecution of Board Staff's case against Alexion. In particular, it is apparent that Ms. Raasch made a request on behalf of Board Staff to the Office of Regulatory Affairs of Health Canada's Biologics & Genetics Therapeutic Directorate for manufacturing information relating to Soliris. Ms. Raasch's request to BGTD came directly to the attention of Alexion. Ms. Raasch was clearly involved soon after her appointment to the Board in evidence gathering to assist in the prosecution of Alexion before the Board.

21. On 17 July 2015, Gowlings wrote to the board Chairperson, asking that Ms. Raasch recuse herself and cease any further involvement in the proceeding. Gowlings also filed an Amended Response containing the following allegations;

On July 13, 2015, Alexion learned that Isabel Raasch, a former Gowlings partner in Ottawa recently hired as PMPRB General Counsel, had become involved in the prosecution against Alexion. As a former Gowlings' partner, Gowlings' knowledge of Alexion based upon the lawyer client relationship between Gowlings and Alexion is imputed to Ms. Raasch. Alexion was entitled to assume that normal ethical principles would be observed and that an ethical screen would be implemented to ensure Ms. Raasch did not become involved in any proceeding against Alexion. Instead, Board Staff have deliberately violated that principle by permitting her to become involved in the prosecution.

22. On 23 July 2015, Elaine McGillivray, Executive Assistant to Ms. Lindberg responded to the 17 July 2015 letter indicating that "the Chair is away on holidays right now and will get back to you next week." Gowlings responded to Ms. McGillivray by stressing the urgency of the

matter and requesting an assurance that "Ms. Raasch's involvement in the dispute between Board Staff and Alexion has ended."

23. Gowlings never received a response from Ms. Lindberg to the formal request that Ms. Raasch not continue her involvement in the prosecution of Alexion. Instead, in the early evening of Monday, 27 July 2015, Mr. Migicovsky, adopting a defiant tone, wrote Gowlings on behalf of Board Staff denying the existence of any conflict and asserting that Ms. Raasch would have "continued involvement in this matter." Ms. Raasch was, herself, copied on the correspondence.

24. The duty of loyalty owed by a lawyer to his or her client "is essential to the integrity of the administration of justice and it is of high public importance that public confidence in that integrity be maintained." "Unless a litigant is assured of the undivided loyalty of the lawyer, neither the public nor the litigant will have confidence that the legal system...is a reliable and trustworthy means of resolving...disputes and controversies." (See: *R v. Neil*)

25. Alexion had a reasonable expectation that no Gowlings lawyer would become involved in the prosecution against Alexion. The integrity of the administration of justice is undermined by Board Staff's decision to: (a) employ Isabel Raasch in the prosecution of this case rather than immediately erecting an ethical screen that would prevent her involvement; (b) continue to involve Isabel Raasch in the prosecution after Alexion had sought an assurance that she would not be involved; and (c) requiring Alexion to bring a motion before this panel for her removal.

26. Ms. Raasch's involvement taints the Board Staff lawyers with whom she has worked on the prosecution against Alexion. The fruits of and labours performed by Ms. Raasch in furtherance of the prosecution are inevitably shared with Board Staff's current lawyers, Parul Shah, David Migicovsky, Christopher Morris, and Perley-Robertson Hill & McDougal LLP. Board Staff's current lawyers have thereby become tainted through their involvement with Ms. Raasch

and any information, suggestions, directions, or advice she has shared with them in violation of her continuing duty of loyalty to Alexion.

27. The most appropriate remedy is to disqualify all Board Staff's current lawyers and order that Ms. Raasch be immediately subjected to an ethical screening process that will prevent her from any future involvement in the prosecution against Alexion, including involvement with future counsel retained by the Board to deal with this matter.

THE FOLLOWING DOCUMENTARY EVIDENCE will be used at the hearing of this motion:

28. The Affidavit of Anna Di Domenico, sworn 21 August 2015;

Dated: 21 August 2015



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