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 REPRESENTATIONS OF THE RESPONDENT: ALEXION'S MOTION RE: CONFLICTS OF INTEREST

(Motion Record Filed 21 August 2015, Returnable 16 September 2015)

Overview

1. Respondent, ALEXION Pharmaceuticals Inc. ("Respondent" or "Alexion"), seeks:

ORDERS:

(a) Quashing the Notice of Hearing and Statement of Allegations of Board Staff based on a conflict of interest involving the Board's Chairperson, Mary Catherine Lindberg, as described below;

(b) Disqualifying Parul Shah, of the PMPRB Legal Services Branch, as a lawyer of record for Board Staff in the proceeding;

(c) Disqualifying David Migicovsky, Christopher Morris, and Perley-Robertson Hill & McDougal LLP as lawyers of record for Board Staff in the proceeding;

(d) Disqualifying Isabel Jaen Raasch from participating in the proceeding or in any way assisting or collaborating with Board Staff in the proceeding;

(e) Directing Board Staff and Isabel Jaen Raasch to destroy any work product generated by Isabel Jaen Raasch in respect of the proceeding; and

(f) requiring Isabel Jaen Raasch to be subject to an ethical screen preventing her from receiving or sharing any information with Board Staff concerning, or having any further involvement with, the proceeding.

2. Members of the public and regulated entities must have confidence in the impartial administration of justice in proceedings before the Board. Proceedings must be commenced and conducted without any conflict of interest or apprehension of bias.

3. The facts, as outlined below, demonstrate that the Chairperson, Mary Catherine Lindberg, had a significant conflict of interest when she made the determination that this case should be prosecuted. At the time, she was a Director of Green Shield, an entity with a direct pecuniary interest in the outcome of the proceeding. That conflict, inherent from the beginning, became manifest when Canadian Life and Health Insurance Association ("CLHIA") joined the litigation as an intervener.

4. Green Shield is a CLHIA member. CLHIA has argued that all its members have an interest in this litigation because they bear the cost burden of the price of Soliris. CLHIA in fact asserts that the panel should issue an Order that somehow compensates its members.

5. Ms. Lindberg, the very person who made the determination to commence the prosecution, is a current Director of Green Shield, a company with a direct pecuniary interest in the outcome of the hearing. Being a Director of Green Shield while having direct supervisory responsibility for this proceeding as Chairperson, Ms. Lindberg has, and at all material times had, an interest directly contrary to Alexion's interests. Due to her conflict, Ms. Lindberg ought to have recused herself and assigned another Board member to determine whether this prosecution ought to have been commenced and continued.

6. Moreover, Board Staff have appointed as Director, Legal Services, Isabel Jaen Raasch, a lawyer who was, until recently, a partner at Gowling Lafleur Henderson ("Gowlings"), the law firm that has been counsel to Alexion since the prosecution was launched. In particular, Ms. Raasch was a Gowlings partner during the first four months of this prosecution. Despite Alexion's protests and requests that Ms. Raasch recuse herself, Board Staff have permitted Ms. Raasch to remain directly involved in the prosecution, and to directly assist current Board Staff counsel. Ms. Raasch's involvement is contrary to her duty of loyalty to Alexion arising from her status as a former Gowlings partner.

7. Natural justice demands: (a) that the Board be free from any reasonable apprehension of bias when launching a prosecution for excessive pricing under the *Patent Act*; and (b) that Board Staff be free of the taint of conflict of interest when conducting a prosecution. Given that Ms. Lindberg made the initial determination to pursue the prosecution and was a director of an organization with a direct pecuniary interest in the outcome of the proceeding, any objective observer with knowledge of the facts would conclude that a reasonable apprehension of bias existed. Furthermore, if Board Staff prosecuting the case recruit a lawyer from the firm representing the respondent to join the prosecution team, a disabling conflict of interest is created. In these circumstances, the proper remedies are: (a) to quash the prosecution and refer the matter back to a Board member who can act without a conflict, and; (b) to disqualify Board Staff's current lawyers as counsel and order Ms. Raasch to be made subject to an ethical screening process that will prevent her involvement in any future prosecution of Alexion.

Conflict Relating to Mary Catherine Lindbergh

8. The right to an unbiased hearing is an essential aspect of procedural fairness and natural justice. As the Supreme Court has noted:

> Both independence and impartiality are fundamental, not only to the capacity to do justice in a particular case, but also to individual and public confidence in the administration of justice. Without that confidence the system cannot command the respect and acceptance that are essential to its effective operation. It is therefore important that a tribunal should be perceived as independent as well as impartial, and that the test for independence should include that perception.[1]

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

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

11. On 6 August 2015, a corporate search of Green Shield Canada ("Green Shield") revealed that Ms. Lindberg is currently a member of the Green Shield Board of Directors. On 7 August 2015, a search of CLHIA's website indicated that Green Shield was a CLHIA member.

12. In Canada, directors are regarded as fiduciaries of the company they serve. A director must ensure the company's interests are paramount and has a fiduciary duty to

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[1] *R. v. Valente,* [1985] 2 S.C.R. 673 at para. 22 (S.C.C.)

act in the best interests of the corporation. If a director fails to meet her or his fiduciary duty, courts will hold the director strictly liable. The fiduciary duty of a director obliges the director to prefer the private interests of the corporation.[2]

13. The director's fiduciary duties to advance and protect the "best interests" of a corporation are typically interpreted to mean maximizing the value of the corporation (although it can also encompass other factors). As the Supreme Court has noted:

> From an economic perspective, the "best interests of the corporation" means the maximization of the value of the corporation ...[3]

14. In the case of an insurer like Green Shield, "maximizing the value of the corporation" includes minimizing the costs of drugs purchased by, or on behalf, of Green Shield's insured members.

15. Ms. Lindberg's private duty to Green Shield, a member of the intervener CLHIA, places her in an irreconcilable conflict of interest as Chairperson of the Board. Her duties to Green Shield can 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* in this case. The exercise of Ms. Lindberg's discretion to prosecute in this case is particularly problematic because the case is novel, raises issues of first impression, and involves an allegation of excessive pricing in circumstances where an introductory price was never increased and was not the subject of an excessive pricing allegation for the first three years it was on the market.

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[2] Green Shield is a corporation incorporated pursuant to the *Canadian Business Corporations Act* (CBCA). Paragraph 122(1)(a) of the CBCA establishes the fiduciary duty of directors.

[3] *Peoples Department Stores Inc. (Trustee of) v. Wise*, [2004] 3 S.C.R. 461 at para. 42 (S.C.C.)

16. Green Shield, through its membership in CLHIA, has an obvious pecuniary interest in the outcome of the proceeding.

17. 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.

18. 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 compensates those who have borne any excessive pricing.

19. Ms. Lindberg's private 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 in the public interest.

20. While the issue of CLHIA's participation in the hearing arose after the hearing began, the conflict existed before the decision to commence the proceeding was made. CLHIA's participation simply provides irrefutable evidence that CLHIA's member companies themselves believe their financial interests are directly affected by the

outcome of the hearing, above and beyond any interest asserted on behalf of Canadians in general. This was the basis of CLHIA's bid to be added as intervening parties.

21. CLHIA member companies also have a direct interest in the outcome of the hearing. Not only are CLHIA members seeking to obtain lower drug prices, but they request a remedy that would have the Board apply the allegedly "excessive" revenues earned by Alexion to "compensate" CLHIA member companies—which includes Green Shield.

22. As noted above, Ms. Lindberg is duty-bound to maximize Green Shield's value as a company. Maximizing Green Shield's value would include minimizing the drug acquisition price of Alexion. This placed Ms. Lindberg in an irreconcilable conflict of interest when making the decision to initiate the current prosecution against Alexion.

23. The test for disqualifying bias does not require that actual bias be proved, and it does not imply any actual wrongdoing on the part of the person against whom an apprehension of bias is alleged. The Supreme Court described the issue as follows:

> In Canadian law, one standard has now emerged as the criterion for disqualification. The criterion as expressed by deGrandpre J. in Committee for Justice and Liberty ... is the reasonable apprehension of bias.
>
> Determining whether the judge brought or would bring prejudice into consideration as a matter of fact is rarely an issue. Of course, where this can be established, it will inevitably lead to the disqualification of the judge. Here, as in many cases, it is conceded by the parties that there was no actual bias on (the judge's) part ... as submitted by the parties, his personal integrity is not in doubt, either in these appeals or in any appeal in which he has sat as a member of this court. Nevertheless, it is said the circumstances of the present case are such as to create a reasonable apprehension of bias on his part.

> The "reasonable apprehension of bias" can be seen as a surrogate for actual bias on the assumption that it may be unwise or unrealistic to require that kind of evidence. It is obviously impossible to determine the precise state of mind of an adjudicator.[4]

24. The actual test for a reasonable apprehension of bias commonly adopted by the courts was that formulated by deGrandpre J. in *Committee for Justice and Liberty*, supra, at paragraph 40:

> 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 ..."

25. The issue is not proof of actual bias, but appearance of bias. The test requires the party seeking to establish disqualification based on a reasonable apprehension of bias to prove the apprehension on a balance of probabilities. Typically, a finding of a disqualifying apprehension of bias will result in a new proceeding.[5]

26. Obviously, where a judge or other decision-maker has a direct financial interest in the outcome of a case, he or she cannot be permitted to exercise discretion relating to that case. That principle extends as well to situations in which the decision-maker is the *director of a company* with a direct interest in the case. The leading case on point is *R. v. Bow Street Metropolitan Stipendiary Magistrate and others, ex parte Pinochet Ugarte*, [1999] 1 All E.R. 577 ("*Pinochet*") where Lord Browne-Wilkinson stated as follows:

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[4] *Weywakum Indian Band v. Canada*, [2003] 2 S.C.R. 259 at para. 60 (S.C.C.) referring to *Committee for Justice and Liberty v. Canada (National Energy Board)* [1978] 1 S.C.R. 369 at 394 (S.C.C.).
[5] See *Hazelton Lanes Inc. v. 1707590 Ontario Ltd.*, [2014] O.J. No. 5365 at paras. 64-65 (Ont. C.A.).

> If the absolute impartiality of the judiciary is to be maintained, there must be a rule which automatically disqualifies a judge who is involved, whether personally or as a director of a company, in promoting the same causes in the same organization as is a party to the suit. There is no room for fine distinctions if Lord Hewart CJ's famous dictum is to be observed: it is "of fundamental importance that justice should not only be done, but should manifestly and undoubtedly be seen to be done" (see R. v. Sussex Justices, Ex p. McCarthy [1924] 1 K.B. 256 at 259, [1923] All E.R. Rep 233 at 234). [Emphasis added]

27. This reasoning has been adopted with approval in Canada.[6] As the Court of Appeal for Ontario described *Pinochet*, it is remarkably similar in its essential facts as this case in that the judge with an alleged conflict was a director of a charity closely allied to the intervener:

> In the result, Lord Browne-Wilkinson was of the opinion that Lord Hoffmann's association with AI was such that he had a sufficient interest in the appeal to require his automatic disqualification. He found the critical facts to be that AI was a party to the appeal, that AI was joined as an intervener to the appeal in order to argue for a particular result, that the result was achieved and that Lord Hoffmann was the director of a charity closely allied to AI and sharing, in this respect, AI's objects.[7]

28. In this case, Ms. Lindberg ought to be subject to the same rule of automatic disqualification from exercising discretionary authority over the decision whether or not to prosecute a case against Alexion. While it is acknowledged that an administrative decision-maker is not held to the same standards as a judge or adjudicator, an administrative decision-maker cannot make a decision in a manner that creates a reasonable apprehension of bias based on her duties to an entity with a pecuniary interest in the outcome.

29. The apprehended bias created by Ms. Lindberg's Green Shield directorship taints the entire prosecution before the Panel. The Notice of Hearing should be quashed to

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[6] See *Benedict v. Ontario*, [2000] O.J. No. 3760 at para. 17 (Ont. C.A.)
[7] Supra, para. 18.

preserve and protect public confidence in the Board. The decision whether a new or fresh proceeding should be commenced can be left to the independent decision of a Board Member other than Ms. Lindberg.

Conflict Relating to Isabel Raasch

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

31. Ms. Raasch was, until her appointment to the Board, an Ottawa partner of Gowlings. Gowlings is currently counsel to Alexion in these proceedings and 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 becoming engaged in prosecution of a case against Alexion after she left the firm and joined the Board.

32. The "duty of loyalty" has been described as follows by the Court of Appeal for Ontario:

> [the] broader duty of loyalty to former clients is based on the need to protect and promote public confidence in the legal profession and the administration of justice. What is of concern is the spectre of a lawyer attacking or undermining in a subsequent retainer the legal work which the lawyer did for the former client or of a lawyer effectively changing sides by taking an adversarial position against a former client with respect to a matter that was central to the previous retainer.[8] [Emphasis added by Court]

[8] *Consulate Ventures Inc v Amico Contracting & Engineering*, [2010] ONCA 788 at para 31 (Ont. C.A), citing *Brookville Carriers Flatbed GP Inc v Blackjack Transport Ltd*, [2008] NSCA 22 at para 51 (NSCA).

33. While Alexion is unaware of any evidence that Ms. Raasch held actual confidential information pertaining to Alexion, the principles of the duty of loyalty extend to cases in which lawyers have taken adversarial positions against former clients in the absence of any concern over confidential information. As the Ontario Superior Court has noted:

> As most rules of professional conduct suggest, a former client has a legitimate claim to expect counsel's loyalty to persist with respect to the subject matter of the retainer, even after the client-lawyer relationship has ended and even if there is little or no possibility that confidential information can be misused (footnote omitted). In such circumstances, courts are quite prepared to find that a reasonable member of the public would hold the integrity of the justice system in considerably less esteem if, despite the protests of the former client, the original lawyer was permitted to launch an all out attack (footnote omitted).[9]

34. As the Supreme Court of Canada has written, the duty of loyalty extends beyond confidential information:

> While the Court is most often preoccupied with uses and abuses of confidential information in cases where it is sought to disqualify a lawyer from further acting in a matter, as in *MacDonald Estate, supra*, 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 ...[10]

35. After Ms. Raasch left Gowlings and joined the Board, she was required to maintain her duty of loyalty to Alexion by playing no role in the prosecution of these proceedings against Alexion. Furthermore, the Board had an obligation to establish an appropriate ethical screen to ensure that Ms. Raasch did not become involved.

36. On 13 July 2015, Alexion learned that Ms. Raasch was in fact participating in the prosecution of Board Staff's case against Alexion. Specifically, Ms. Raasch made a

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[9] *R. v. A. (I.)*, [2015] O.J. No. 1325 at para. 34 (Ont. S.C.),Citing with approval Michel Proulx and David Layton, Ethics and Canadian Criminal Law, (Toronto: Irwin Law Inc., 2001) at p. 306.
[10] *R. v. Neil*, [2002] 3 S.C.R. 631 at para. 18 (S.C.C.)

request on behalf of Board Staff to the Office of Regulatory Affairs of Health Canada's Biologics & Genetics Therapeutic Directorate (BGTD) 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.

37. 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.

38. 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."

39. 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 indicating

that Ms. Raasch would have "continued involvement in this matter." Ms. Raasch was copied on the 27 July 2015 correspondence and on subsequent communications from Mr. Migicovsky to the Board, including correspondence dating 1 September 2015, all of which shows her "continued involvement in the matter."

40. Alexion had a reasonable expectation that no Gowlings lawyer would become involved in the prosecution of Alexion in this case. 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 establishing an ethical screen that would prevent her involvement; (b) continue involving Isabel Raasch in the prosecution after Alexion sought an assurance that she would not be involved; and (c) requiring Alexion to bring a motion for her disqualification.

41. Ms. Raasch's involvement taints the Board Staff lawyers with whom she has worked on the prosecution against Alexion. The efforts performed by Ms. Raasch in furtherance of the prosecution, and the fruits of those efforts, 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 Ms. Raasch's continuing duty of loyalty to Alexion.

42. In this case, the Board was promptly informed of Alexion's objection to Ms. Raasch's involvement soon after it was learned that she was conducting investigative work to assist the "prosecution team." It was incumbent upon Ms. Raasch to ensure that

she had no involvement with any proceeding involving a former client. Prompt implementation of an ethical screen would have protected the existing prosecution team in their continued representation of Board Staff. Instead, Board Staff counsel denied the conflict and responded defiantly by continuing to involve her in the prosecution, even copying Ms. Raasch on correspondence exchanges after Board Staff were informed of Alexion's objection. This response has tainted all existing Board Staff counsel in their continued role as prosecutors in the matter as well as any work product generated by Ms. Raasch.

43. The most appropriate remedy is to disqualify all Board Staff's current lawyers, order the destruction of Ms. Raasch's work product, and require the Board to immediately create an ethical screening process preventing Ms. Raasch from any future involvement in the prosecution against Alexion in contravention of the duty of loyalty. This should include preventing Ms. Raasch from having any involvement with future counsel retained by Board Staff to prosecute the matter.

Order Requested

44. Alexion respectfully requests that the Panel grant orders:

(a) Quashing the Notice of Hearing and Statement of Allegations based on the conflict of interest involving the Board's Chairperson, Mary Catherine Lindberg;

(b) Disqualifying Parul Shah, of the PMPRB Legal Services Branch, as a lawyer of record for Board Staff in the proceeding;

(c) Disqualifying David Migicovsky, Christopher Morris, and Perley-Robertson Hill & McDougal LLP as lawyers of record for Board Staff in the proceeding;

(d) Disqualifying Isabel Jaen Raasch from participating in the proceeding or in any way assisting or collaborating with Board Staff in the proceeding;

(e) Directing the destruction of any notes or work product generated by Isabel Jaen Raasch in relation to this proceeding; and

(f) Requiring Isabel Jaen Raasch to be subject to an ethical screen preventing her from receiving or sharing any information with Board Staff, or their counsel, concerning any proceeding against Alexion.

Dated: 2 September 2015

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