



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"

REASONS FOR DECISION (*Motion to Reconstitute Panel*) Heard on January 17, 2017

1. On January 17, 2017, the panel (the "**Panel**" or "**Hearing Panel**") of the Patented Medicine Prices Review Board (the "**PMPRB**" or the "**Board**") seized with this proceeding heard a motion brought by Alexion Pharmaceuticals Inc. ("**Alexion**" or the "**Respondent**") for an Order requiring that the Panel be reconstituted to restore a third member for the purposes of hearing the case. The Panel dismissed Alexion's motion, with reasons to follow. These are the reasons.

Background

2. Soliris (eculizumab) 10mg/mL ("**Soliris**") is indicated for the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH), a rare and life-threatening blood disorder that is characterized by complement-mediated hemolysis (the destruction of red blood cells).

3. Soliris is also approved as a treatment for patients with atypical hemolytic uremic syndrome (aHUS), a rare and life-threatening genetic disorder characterized by "complement-mediated thrombotic microangiopathy" or TMA (blood clots in small vessels).

4. Soliris is sold in Canada by the Respondent. Board Staff alleges that the Respondent is selling Soliris at a price that is excessive and seeks an Order under sections 83 and 85 of the *Patent Act* requiring Alexion to, *inter alia*, discontinue the sale of Soliris at a price that is alleged to be excessive and to offset the allegedly excess revenues that Alexion has generated from prior sales of Soliris.

Relevant Facts to this Motion

5. On January 22, 2015, the Board issued a Notice of Hearing to require a public hearing with respect to Board Staff's allegations of excessive pricing of Soliris. The Notice of Hearing is silent as to the composition of the Hearing Panel.

6. The purpose of the hearing is to determine whether, under sections 83 and 85 of the *Patent Act*, the Respondent is selling or has sold Soliris in any market in Canada at a price that, in the Board's opinion, is or was excessive, and if so, what order, if any, should be made.

7. At the first case management conference held on April 29, 2015, the parties were advised by Ms. Carolyn Kobernick that she, as well as Board Members, Dr. Mitchell Levine and Mr. Normand Tremblay, were participating in this matter.¹

8. Following several interlocutory motions and adjournments, the hearing for this matter commenced on January 16, 2017, with Panel Members Carolyn Kobernick and Dr. Mitchell Levine. At the commencement of the hearing, before opening arguments and the introduction of any evidence, Dr. Levine advised the parties that:

"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*."²

¹ Case Management Conference of April 29, 2015, Transcript, page 2.

² Hearing Transcript, Volume 1, pg. 1.

9. Alexion filed a Notice of Motion on January 16, 2017 for an Order requiring that the Panel be reconstituted to restore a third member for the purposes of the hearing. No evidence was filed in support of the motion, other than portions of the transcript from the first day of the hearing and copies of the biographies of Board members, filed on the Board's website. The Panel heard oral submissions on the motion on January 17, 2017, and delivered its decision dismissing the motion with reasons to follow that same day.

Submissions of the Parties

10. Alexion submits that "[c]ontinuing 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... 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."³ Alexion further submits that 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."⁴

11. Alexion also submits that there was no notice of the change in composition of the panel, which is a reviewable error, and cites *Moyer v. New Brunswick (Workplace Health, Safety and Compensation Commission)* in support of its submission ("**Moyer**").⁵

12. Alexion further submits that it had a "legitimate expectation that the hearing will be before the three panel members originally appointed" and 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."⁶

³ Notice of Motion, para. 8.

⁴ Notice of Motion, para. 9.

⁵ [2008] N.B.J. No. 191 (NBCA), at para. 12.

⁶ Notice of Motion, paras. 12 – 14.

13. Alexion argues that the change in the Panel results in an imbalance, which results in unfairness for Alexion. Specifically, 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".⁷ In particular, Alexion submits that "shifting now from three to two creates a rather unfortunate impression, appearance that [Alexion is] not going to get the kind of reception of [its] arguments that [it] had hoped for".⁸ "Moreover, a reduction from three to two panel members creates additional prejudice to Alexion, in that it removes the potential for a dissenting view."⁹

14. Alexion does not contest the importance of the medical and legal expertise of the remaining Panel members but submits that the inclusion of Mr. Tremblay, or someone with private sector and pharmaceutical industry experience, is important for balance, and that the Panel should be reconstituted to include a member with such expertise. In this regard, Alexion submits that "if we were back in a guidelines, a pure guidelines approach to the case and were talking \$4 or \$5 million and it's purely guidelines-based liability, it may be one thing, but when the case expands, as it has, to become a substantial piece of commercial litigation... we definitely need a balanced Panel".¹⁰

15. Given the truncated timing of the motion, Board Staff did not file written submissions and presented its arguments by way of oral submissions. Board Staff submits that the amount of potential exposure to the Respondent is irrelevant to the determination of this motion, and that the pertinent question is whether this Panel, as currently constituted with two members, has jurisdiction to hear this case. Board Staff asserts that this Panel has jurisdiction.

⁷ Notice of Motion, para. 20.

⁸ Hearing Transcript, Volume 2 Public, pgs. 102 – 103.

⁹ Notice of Motion, para. 21.

¹⁰ Hearing Transcript, Volume 2 Public, pgs. 104.

16. Board Staff submits that there is no requirement in the *Patent Act* with respect to the number or composition of the Hearing Panel, with the sole exception that there must be two members to constitute a quorum.¹¹ Board Staff noted the following:

- i. Section 93(2)(a) of the *Patent Act* gives the Chair the absolute right to assign members to a proceeding as the Chair sees fit and there is no requirement regarding the background or number of people on a specific hearing panel;
- ii. Section 96(2) of the *Patent Act* grants the Board the power, with the approval of the Governor in Council, to make general rules, including with respect to the number of members of the Board that constitutes a quorum; and
- iii. Rule 4 of the PMPRB *Rules of Practice and Procedure* (the "**Rules**")¹² sets a quorum at 2 .

17. Board Staff submits that there is a quorum in this case, and as long as there is a quorum, the hearing should proceed. In Board Staff's submission, proceeding with the hearing with two members cannot be contrary to procedural fairness or a breach of legitimate expectations if the statute clearly sets out a quorum of 2.

18. Alexion submits that "[w]hile 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."¹³ In Board Staff's submission, Alexion has misinterpreted Rule 4, as a quorum is defined as the minimum number of members of an assembly or society that must be present at any of its meetings to make the proceedings of that meeting valid. Thus, as long as there are two members, there is compliance with Rule 4.¹⁴ Board Staff directed the Panel to the *Robinson*¹⁵ case, in

¹¹ Hearing Transcript, Volume 2, pgs 107 – 108.

¹² SOR/2012-247.

¹³ Notice of Motion, para. 10.

¹⁴ Hearing Transcript, Volume 2, pg. 111.

¹⁵ *Robinson et al. v Ontario Securities Commission*, Ont SCJ (February 29, 2000), paras. 1 -3.

which the court upheld the decision of the hearing panel to continue with two members after the third member passed away, because the statutory quorum was met. Board Staff notes that in the *Robinson* case, the change in the composition of the Panel occurred in the middle of the hearing after some of the evidence had already been introduced.

19. Furthermore, Board Staff submits that it cannot be Alexion's legitimate expectation that a hearing panel will represent divergent interests, such as the inclusion of a private sector member with pharmaceutical industry experience, because such an intention is not reflected in the statute or the Rules. By contrast, legislation governing other boards or tribunals specifically sets out requirements for membership or appointment (see for example, section 6 of *Public Service Labour Relations and Employment Board Act*,¹⁶ sections 9 and 13 of the *Northwest Territories Surface Rights Board Act*¹⁷; and section 9 of the *Canada Labour Code*¹⁸). In reply, Alexion submits that these statutes actually show a trend towards including divergent viewpoints on hearing panels, and therefore support its position.

20. In Board Staff's submission, it is also irrelevant that Mr. Tremblay was present for the hearing of the numerous interlocutory motions in this case because it is commonplace that judges will hear and decide interlocutory motions even though those judges do not ultimately hear the final case. Board Staff submits that Alexion is alleging that this Hearing Panel, as currently constituted, will not apply the factors under section 85 of the *Patent Act* fairly, but in Board Staff's submission, it is not permissible to engage in speculation regarding the change in the composition of the Hearing Panel and the background of the people that are on the Hearing Panel.¹⁹

21. Board Staff submits that a reasonable person would not find any apprehension of bias in this case. The onus to establish a reasonable apprehension of bias is high and it "is inappropriate for a party to bring a disqualification motion if the essential purpose of

¹⁶ SC 2013, c 40, s 365.

¹⁷ SC 2013, c 14, s 11.

¹⁸ RSC 1985, c L-2.

¹⁹ Hearing Transcript, Volume 2, pgs. 127 – 128.

that step is a form of reverse 'judge shopping' because of subjective dissatisfaction with the arbitrator. A reviewing Court should be vigilant in examining the motive for bringing a motion to ensure that it is not brought for a purely tactical advantage": *Ontario Provincial Police Commissioner v. MacDonald* ("**OPPC**").²⁰

22. Finally, with respect to Alexion's submission that the change in the composition of the Hearing Panel removes the potential for a dissenting view, Board Staff submits that, even if correct, this is a neutral factor since the dissenting view could be towards Board Staff, and, in any event, section 97(2)(b) of the *Patent Act* sets out that in the case of disagreement, the view of the panel member presiding over the hearing is the determinative one. Accordingly, the statute confirms the potential for a dissenting view and mandates how it is to be resolved.

23. Ultimately, in Board Staff's submission, there is no imbalance, unfairness or an apprehension of bias, and the hearing should proceed with the Hearing Panel as presently constituted.

Analysis

i. The statutory quorum is satisfied.

24. Rule 2 of the Rules states: "For the purposes of these Rules, the members assigned by the Chairperson under subsection 93(2) of the Act to deal with a matter constitute the Board." Rule 4 of the Rules states: "In any proceeding, a quorum of the Board consists of two members."

25. *The Dictionary of Canadian Law*²¹ defines quorum as the "minimum number of members who must be present for that body to exercise its powers validly".

26. There is no dispute that the statutory quorum is met in this case, as there are two Board members on the Hearing Panel. The original appointment of three members to

²⁰ 2009 CarswellOnt 1242, paras. 24 – 26.

²¹ Carsewell, 4th Edition.

the Hearing Panel at the discretion of the Chair does not in any way override or change the statutory quorum.

27. There is clear authority that a hearing should continue if a Panel member resigns so long as the statutory quorum is met. For example, the Manitoba Court of Appeal held as follows in *Ballard v Arkin* at paragraph 10:²²

In our view common sense supplies the answer. There must be countless administrative bodies whose ranks are depleted by a death or resignation of a member. Is the effect of such an event to paralyse the body and rob it of the capacity to function until the vacancy has been filled? Surely such a view of the law would result in great inconvenience and disorder. The better and more practical view is that a vacancy does not denude a body of its legal status or place it in a state of suspended animation until its numbers are again brought to full strength. That is surely one of the reasons why such bodies commonly have a provision for a quorum. The remaining members of the body can continue to act for it, provided that their numbers are at all times sufficient to satisfy the requirements of the applicable quorum. (emphasis added)

28. The decision of the Ontario Divisional Court in the *Robinson* case is directly on point. In that case, the Divisional Court upheld the decision of a hearing panel of the Ontario Securities Commission to continue with two members after the third member passed away, because the statutory quorum was met, and even though (in contrast to this proceeding), the hearing had already started and evidence had been introduced.

29. The *Moyer* case, relied on by Alexion is clearly distinguishable. That case involved the swapping of 2 members on a 3 member panel for 2 new members in the middle of the hearing on the merits of the case and without notice to the Respondent. This resulted in a breach of the duty of fairness since the members who heard the case were effectively no longer the members who would decide the case, and no notice was provided to Mr. Moyer regarding the change in the Panel and his right to start the hearing anew in front of the new Panel. This is not the case here as the hearing had not even started when the change in the composition of the Hearing Panel occurred, there is no swapping of members and those Panel members who are hearing the case

²² 1973 CarswellMan 24 (CA), para. 10.

are also the decision-makers. As in the *Robinson* case, the Hearing Panel has lost a member, but the statutory quorum is still met, and the two remaining Panel members have the jurisdiction to proceed.

30. There is also no prejudice to Alexion arising from the fact that Mr. Tremblay participated in the previous interlocutory motions but will not be participating in the hearing on the merits. There is no statutory provision or rule of natural justice that requires Panel members who participate in interlocutory matters to also participate in the hearing on the merits. In this regard, the Panel notes that it is common in Canadian courts and tribunals for judges or adjudicators who hear interlocutory motions to ultimately not preside over the hearing on the merits.

ii. There is no reasonable apprehension of bias or lack of impartiality.

31. Alexion alleges a reasonable apprehension of bias on the part of this Hearing Panel as currently constituted.

32. The test set out by the Supreme Court of Canada for reasonable apprehension of bias is that "the apprehension of bias must be a reasonable one, held by reasonable and right minded persons, applying themselves to the question... 'what would an informed person, viewing the matter realistically and practically – and having thought the matter through – conclude. Would he think that it is more likely than not that [the decision-maker], whether consciously or unconsciously, would not decide fairly."²³

33. Alexion submits that 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."²⁴ Alexion did not file any evidence in support of this submission.

²³ *R v S (RD)*, [1997] 3 SCR 484.

²⁴ Notice of Motion, para. 19.

34. Allegations of reasonable apprehension of bias are considered on a case by case basis with regard to the facts of each particular case. The Panel finds that the reasonable apprehension of bias alleged by Alexion is speculative, not based on any specific act by the Hearing Panel, and not supported by any evidence. It is based on an unsubstantiated presumption that the current members of the Hearing Panel, due to their alleged lack of private sector experience, will not be fair to Alexion. The courts have made it clear that allegations of reasonable apprehension of bias must be proved with evidence, not mere speculation.²⁵ Simply because certain board members have a certain background does not mean that there is a reasonable apprehension of bias.²⁶

35. Furthermore, it appears that Alexion is asserting that Mr. Tremblay should be included on the Hearing Panel because Mr. Tremblay may be inclined in favour of Alexion's position. This appears to the Panel to be an attempt by Alexion to engage in "reverse judge shopping", which is inappropriate and to be discouraged, as noted in the *OPPC* case.

36. The threshold for proving allegations of reasonable apprehension of bias is high. Alexion has not satisfied this threshold, for the reasons given above.

iii. The Respondent has no legitimate expectation that the Hearing Panel will comprise three Members, or that it will include a member with private sector and pharmaceutical industry experience.

37. Rule 4 is clear that a quorum of the Board consists of two members. Alexion is asserting that it has a legitimate expectation to have a Hearing Panel that includes a member with Mr. Tremblay's experience (or effectively a quorum of three members). Alexion noted that it is not suggesting that the medical experience of Dr. Levine or the legal and public sector experience of Ms. Kobernick are not important in the process,

²⁵ *Adams v Workers' Compensation Board* (1989), 42 BCLR (2d) 228 (CA).

²⁶ *Canadian Pacific Ltd v Matsqui Indian Band*, 1995 CarswellNat 264 (SCC).

but that it had a legitimate expectation to have an additional member with private sector experience.²⁷

38. These alleged legitimate expectations are not grounded in the law. The *Patent Act* and the Rules authorizes the *ad hoc* appointment of Board members and does not prescribe any requirements for their appointment either as Board members or as members of a hearing panel. Section 92(1) of the *Patent Act* states that the "Minister may establish an advisory panel to advise the Minister on the appointment of persons to the Board, which panel shall include representatives of the provincial ministers of the Crown responsible for health, representatives of consumer groups, representatives of the pharmaceutical industry and such other persons as the Minister considers appropriate to appoint." The establishment of an advisory panel is not a requirement, as reflected by the word "may", and in any event, only applies to appointment of members to the Board, and not to the appointment of any Board members to a hearing panel in any specific proceeding. There is no basis for any expectation that a member with particular experience will be assigned to any particular proceeding.

39. Furthermore, legitimate expectations can only arise and provide a broader scope of procedural protections where the positive practice or conduct giving rise to the reasonable expectation is clear, unambiguous and unqualified.²⁸ The Board has not made any such clear or unqualified representation to Alexion that the composition of the Hearing Panel would be three members, or that it would include a member with private sector experience. Such a practice is not outlined in any of the Board's publications or Rules and, in fact, the Board has proceeded in the past with two-member hearing panels: see for example, *Adderall XR*,²⁹ *ratiopharm*³⁰ and *Galderma*.³¹

²⁷ Hearing Transcript, Volume 2, pg. 102.

²⁸ *Agraira v Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36.

²⁹ PMPRB-06-D3-ADDERALL XR – Merits (10 April 2008).

³⁰ PMPRB-08-D3-ratiopharm – Merits (30 June 2011).

³¹ Board Order on the Merits (19 December 2016): http://pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Galderma_Decision_December_19_2016.pdf.

40. The only legitimate expectation that Alexion can have is for a hearing before two duly appointed members of the Board (whoever they may be), and that legitimate expectation is fully satisfied in this case.

Conclusion and Order

41. Based on the foregoing reasons, Alexion's motion was dismissed.

Dated at Ottawa, this 1st day of February, 2017.

Original signed by

Signed on behalf of the Panel by
Dr. Mitchell Levine

Panel Members:

Dr. Mitchell Levine
Ms. Carolyn Kobernick