

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. (the “Respondent”)
and the medicine “Soliris”**

**WRITTEN REPRESENTATIONS OF BOARD STAFF IN RESPONSE TO ALEXION'S
MOTION RE: CONFLICT OF INTEREST RELATING TO MARY CATHERINE
LINDBERG**

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PART I – BOARD STAFF’S POSITION

1. Alexion seeks an order quashing the Notice of Hearing and Statement of Allegations of Board Staff based on an alleged conflict of interest involving the Board’s Chairperson, Mary Catherine Lindberg. Board Staff submits that Alexion’s motion should be dismissed.
2. Alexion has failed to demonstrate that the Chairperson had a “closed mind” when she determined that it was in the public interest for the Board to hold a public hearing to determine whether Alexion has been and is selling Soliris at an excessive price. Furthermore, the Chairperson’s decision does not “predetermine” any issues or prejudice Alexion at the hearing. The Hearing Panel must still determine whether the price of Soliris is excessive.

PART II – STATEMENT OF FACTS

3. Mary Catherine Lindberg is the Chairperson of the Board. Ms. Lindberg is not a member of the Hearing Panel and has not (and will not) make any adjudicative decisions in the context of this Hearing.
4. The Board’s Guidelines provide that if the Chairperson decides that it is in the public interest that a hearing be held, pursuant to s.83(6) of the *Patent Act*, to determine whether a patented medicine is being or has been sold at an

excessive price, the Chairperson will issue a Notice of Hearing and will appoint a panel of Board members to preside at the hearing¹.

5. The Notice of Hearing in this matter was issued on 20 January 2015.

PART III – THE CHAIRPERSON’S DECISION TO ISSUE THE NOTICE OF HEARING IS NON-ADJUDICATIVE

6. The Board carries out its statutory obligations by separating its review functions, performed by Board Staff, and its adjudicative function, performed by Board panel members.² When Board Staff completes a review into an instance of possible excessive pricing, it may attempt to communicate with the patentee to resolve the potential excessive pricing allegation. However, when a resolution is not possible, Board Staff will submit a report to the Chairperson.
7. The Chairperson, in her capacity as Chief Executive Officer of the Board, reviews Board Staff’s report for the sole purpose of determining whether it is in the public interest to hold a public hearing.³
8. To preserve the impartiality of Board members, until a matter is brought before a Hearing Panel at a public hearing, no Board member is informed of the results of Board Staff’s review into an instance of possible excessive pricing, other than, as

¹ A.3.6. of the PMPRB Guidelines

² Guidelines, A.3.4

³ Guidelines, A.3.7

noted above, the Chairperson in her management capacity as the Chief Executive Officer of the Board, pursuant to s.93(2) of the *Patent Act*, for the purpose of determining whether a hearing is in the public interest⁴.

9. In the *Nicoderm Jurisdiction 1* decision,⁵ the Board described the nature of the decision taken by the Chairperson [emphasis added]:

In making this determination [whether it is in the public interest that there be a public hearing], the Chairperson determines, among other things, whether the allegations made by Board Staff, if proven true, would establish a prima facie case of excessive pricing by a patentee under the Board's jurisdiction. The Chairperson's role in this context is as the senior management official of the Board directing its operations and ensuring that public hearings are held (and only held) in appropriate cases; **it is not in any sense adjudicative and the Chairperson undertakes no analysis of whether the facts alleged by Board Staff are, or will be, proven.**

[...]

There is no prejudice to a patentee in the Chairperson's decision to initiate a public hearing, only the requirement that the matters in issue be presented and determined in public instead of internally by the Board alone.

10. In upholding the Board's decision,⁶ the Federal Court reiterated the Board's reasoning in the *Nicoderm Jurisdiction 1* decision [emphasis added]:

⁴ A.3.7. of the PMPRB Guidelines

⁵ PMPRB – 99 – D2 – Nicoderm at Page 2

[87] The Board's policy provides that the Chairperson "may" issue a notice of hearing if he holds the view that the investigation has shown that the price "may" be or has been excessive. This language obviously confers discretion upon the Chairperson to issue a notice of hearing if, after reviewing the Staff report and the VCU, he believes that there may have been excessive pricing. **This does not represent, in any way, a determination concluding that there was excessive pricing by the patentee or former patentee.**

[88] In this regard, I refer to the Board's reasons in its decision on jurisdiction, Part I. The Board noted that in deciding whether to issue a notice of hearing, the Chairperson considers whether the results of the investigation, if proven true, would show a prima facie case of excessive pricing.

[89] The issue of actual excessive pricing is a matter to be resolved at the public hearing, when all interested parties are given the opportunity to lead evidence, cross-examine and make submissions. That being so, I agree with the arguments of the respondent Attorney General of Canada and the intervener that **the issuance of the notice of hearing does not represent the Board's conclusion on the issue, but rather constitutes an allegation that is sufficiently substantiated to justify a hearing on the merits.**

11. The Chairperson's decision does not entail any conclusion as to the merits of the case to be heard at the hearing, but only the Chairperson's conclusion as Chief

⁶ Hoechst Marion Roussel Canada Inc. v. Canada (Attorney General), 2005 FC 1552

Executive Officer of the Board that it is in the public interest that there be a public hearing.⁷

12. In its Written Representations, Alexion repeatedly misconstrues the nature of the Chairperson's decision. Contrary to Alexion's Representations, the Chairperson does not and will not have any involvement in this proceeding. Further, the Chairperson did not determine the merits of Board Staff's allegations regarding excessive pricing when she decided that it was in the public interest to have a public hearing.
13. As the Board and the Federal Court's decision in the *Nicoderm* proceeding make clear, the Chairperson's decision is non-adjudicative. The Chairperson's decision that there is public interest in having a public hearing does not predetermine any issues or prejudice the patentee at the Hearing.

PART IV – THE STANDARD OF IMPARTIALITY FOR NON-ADJUDICATIVE DECISION MAKERS

14. At paragraph 28 of Alexion's Written Representations, Alexion admits that that an administrative decision-maker is not held to the same standards as a judge or adjudicator. However, the case law Alexion refers to in its Written Submissions, and the reasonable apprehension of bias test that Alexion relies on, apply to

⁷ PMPRB – 99 – D2 – Nicoderm at Page 5

judicial decision-makers. They do not apply to administrative decision-makers making non-adjudicative decisions.

15. The Supreme Court has confirmed that while the duty of fairness applies to all administrative bodies, “the extent of that duty will depend upon the nature and the function of the particular tribunal.”⁸ The Court elaborated on the spectrum of standards of bias [emphasis added]:

It can be seen that there is a great diversity of administrative boards. Those that are primarily adjudicative in their functions will be expected to comply with the standard applicable to courts. That is to say that the conduct of the members of the Board should be such that there could be no reasonable apprehension of bias with regard to their decision. At the other end of the scale are boards with popularly elected members such as those dealing with planning and development whose members are municipal councillors. With those boards, the standard will be much more lenient. **In order to disqualify the members a challenging party must establish that there has been a pre-judgment of the matter to such an extent that any representations to the contrary would be futile.**⁹

16. The Supreme Court also explicitly warned against automatically disqualifying an administrative board member merely because she serves as a corporate director:

⁸ *Newfoundland Telephone Co. v. Newfoundland (Board of Commissioners of Public Utilities)*, [1992] 1 SCR 623, 1992 CanLII 84 (SCC) at p. 10.

⁹ *Newfoundland*, p. 11.

Nor should there be undue concern that a board which draws its membership from a wide spectrum will act unfairly. It might be expected that a board member who holds directorships in leading corporations will espouse their viewpoint. Yet I am certain that although the corporate perspective will be put forward, such a member will strive to act fairly. Similarly, a consumer advocate who has spoken out on numerous occasions about practices which he, or she, considers unfair to the consumer will be expected to put forward the consumer point of view. Yet that same person will also strive for fairness and a just result. Boards need not be limited solely to experts or to bureaucrats.¹⁰

17. The Supreme Court has thus established that the reasonable apprehension of bias test is not the standard to which administrative decision-makers should be held. Rather, it is the "closed mind" test, which requires the party alleging bias to demonstrate on a balance of probabilities that the decision-maker's mind was "so closed that any submissions would be futile."¹¹

18. When the Chairperson decided that it was in the public interest to have a public hearing, she made a non-adjudicative decision which is at the very low end of the spectrum for the standard of impartiality. The Chairperson's decision is comparable to the role played by the Federal Human Rights Commission when it decides to refer a matter to the Human Rights Tribunal:

¹⁰ *Newfoundland*, p. 9.

¹¹ *Newfoundland*, p. 17

The Commission is not an adjudicative body; that is the role of a tribunal appointed under the Act. When deciding whether a complaint should proceed to be inquired into by a tribunal, the Commission fulfills a screening analysis somewhat analogous to that of a judge at a preliminary inquiry. It is not the job of the Commission to determine if the complaint is made out. Rather its duty is to decide if, under the provisions of the Act, an inquiry is warranted having regard to all the facts.¹²

19. In *Zundel v. Canada (Attorney General)*, the Federal Court considered an allegation of bias against a member of the Human Rights Commission who referred a matter to the Human Rights Tribunal. The Federal Court described the standard of impartiality in that context as follows [emphasis added]:

In order to succeed in his challenge in this case the **applicant must show that Ms. Falardeau-Ramsay had a closed mind when she participated in the Commission's decision to refer the complaint against Mr. Zundel to a Tribunal.**

[...]

As a non-adjudicative body the Commission owes to complainants and respondents a duty of fairness with a much lower content than that owed by a Tribunal to which a complaint is referred for adjudication.

[...]

The test, therefore, is not whether bias can reasonably be apprehended, but whether, as a matter of fact, the standard of open-mindedness has been

¹² *Cooper v. Canada (Human Rights Commission)*, [1996] 3 SCR 854, 1996 CanLII 152 (SCC) at para. 53.

lost to a point where it can reasonably be said that the issue before the investigative body has been predetermined.¹³

20. The Federal Court of Appeal upheld this decision:

The case law demonstrates that legal assumptions made by the Commission in deciding to request the formation of a Tribunal do not amount to decisions as to the state of the law or its impact on those concerned. [The Commission] decides none of the issues which underlie its decision to proceed to the next stage; these are left to the Tribunal.

[...]

The motions judge applied the proper standard of review when he concluded at paragraph 49 of his reasons that his intervention would only be justified:

if I am satisfied that there is no rational basis in law or on the evidence to support the Commission's decision that an inquiry by a Tribunal is warranted in all the circumstances of the complaints.¹⁴

21. The reasonable apprehension of bias test does not apply given that the Chairperson is an administrative decision-maker who, in this case, made a non-adjudicative decision. The applicable test is whether the Chairperson had a closed mind to the point where it can be said that the issues now before the Hearing Panel have been predetermined. As noted above, there has been no

¹³ *Zundel v. Canada (Attorney General)*, [1999] 4 FCR 289 at paras. 19-21.

¹⁴ *Zundel v. Canada (Attorney General)*, 2000 CanLII 16731 at para. 4.

pre-determination of the Board Staff's allegations in this proceeding and no prejudice to Alexion.

22. There is no evidence that the Chairperson had any direct or indirect pecuniary interest in this matter when she decided that a hearing would be in the public interest. Further, there is no evidence that would demonstrate that the Chairperson had a closed mind to the point where it can be said the issues now before the Hearing Panel have been pre-determined. None of the issues Board Staff has raised in these proceedings has been pre-determined. The Hearing Panel must still determine whether Alexion has sold or is selling Soliris at an excessive price. As stated above, the Chairperson has not and will not be involved in any adjudicative decisions related to this proceeding.
23. Alexion has failed to discharge its burden to demonstrate on a balance of probabilities that the Chairperson had a closed mind when she decided that a public hearing should be held. Furthermore, there is no evidence or any rational basis upon which it could be concluded that any of the issues in this proceeding have been pre-determined by the Chairperson.
24. Board Staff submits that Alexion's motion should be dismissed.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 11th day of September, 2015

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