Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

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
(Various Motions Related to Procedural Matters Heard on October 28, 2015)

1. On October 28, 2015, the panel (the "**Panel**") of the Patented Medicine Prices Review Board (the "**Board**") seized with this proceeding heard five motions related to this matter. Four of the motions were brought by the Respondent, Alexion Pharmaceuticals Inc. ("**Alexion**" or the "**Respondent**"). The remaining motion was brought by Board Staff.

2. Alexion seeks the following relief:

(a) An Order striking out paragraphs 1 and 3, and Appendix A of the Further Amended Notice of Appearance of the Minister of Health for British Columbia dated June 26, 2015;

(b) An Order striking out paragraph 7 and the amended portion of paragraph 9 of Board Staff's Amended Reply dated September 1, 2015 (the "**Amended Reply**");

(c) An Order requiring Board Staff to provide disclosure of various documents and evidence; and

(d) An Order designating certain attachments to the Affidavit of Danielle Marshall sworn on June 5, 2015 filed by Alexion as confidential, and an

Order designating as confidential future evidence of a similar nature that may be disclosed in this proceeding.

3. Board Staff seeks an Order striking out paragraph 37 and the second sentence of paragraph 38 of Alexion's Amended Response dated July 17, 2015 (the "**Amended Response**").

4. The Panel will deal with each motion separately below. Based on the reasons that follow, the Panel makes the following Orders:

(a) Alexion's motion to strike portions of the Further Amended Notice of Appearance of the Minister of Health for British Columbia is dismissed;

(b) Alexion's motion to strike paragraph 7 and the amended portion of paragraph 9 of the Amended Reply is dismissed. However, Alexion is granted leave to file a Surreply within 10 days of this Order if Alexion wishes to respond to the allegations related to subsection 85(2) of the *Patent Act* (the "***Patent Act***")[1] found in the Amended Reply;

(c) With respect to Alexion's motion requiring Board Staff to provide disclosure of various documents and evidence, the parties have exchanged a number of documents upon which they may rely at the hearing. The Panel orders that Board Staff and Alexion shall exchange documents on which they intend to rely upon at the hearing, to the extent identified, within 30 days of the date of this Order;

(d) Alexion's request to designate as confidential certain attachments to the Affidavit of Danielle Marshall is granted. A protocol is attached at Appendix "A" to these reasons outlining the procedure to be followed with respect to claims of confidentiality for records to be filed in this proceeding; and

(e) Board Staff's motion to strike out paragraph 37 and the second sentence of paragraph 38 of the Amended Response is granted.

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[1] R.S.C. 1985, c. P-4.

Background

5. 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).

6. 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).

7. Soliris is sold in Canada by the Respondent, Alexion. Board Staff has determined that the Respondent is selling Soliris at a price that is excessive and seeks an Order under section 83 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.

8. 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.

9. 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.

10. In a motion heard on September 16, 2015, Alexion raised allegations of conflicts of interest and reasonable apprehensions of bias on the part of a number of the individual counsel involved in this proceeding and the Chairperson of the Board. The Panel dismissed this motion in a decision dated October 5, 2015.[2]

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[2] Board Decision – *Respondent's Motion Relating to Conflicts of Interest* (October 5, 2015): http://pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/MotionRelatingtoConflictsofInterest-October5thdecision-Final.pdf.

11. At a pre-hearing conference held on October 28, 2015, the Panel heard five motions relating to procedural issues in respect of this proceeding. The Panel's reasons with respect to each motion are set out in the separate sections that follow.

Motion to Strike Further Amended Notice of Appearance of Minister of Health

12. Alexion seeks an Order striking out paragraphs 1 and 3, and Appendix A of the Further Amended Notice of Appearance of the Minister of Health for British Columbia (the "**Minister**") dated June 26, 2015.

(a) Relevant Facts

13. As outlined below, the facts relevant to this motion are somewhat complex as a result of earlier objections and other procedural issues that have occurred in respect of the filing of the Notice of Appearance by the Minister.

14. On March 9, 2015, the Minister filed a Notice of Appearance in this proceeding (the "**Initial Notice of Appearance**"). In the Initial Notice of Appearance, the Minister, on his own behalf and on behalf of the Minister of Health for the Province of Manitoba (collectively, the "**Ministers of Health**"), provided notice of their intention to make representations supporting the proposed orders of the Board on the basis set out by Board Staff in the Statement of Allegations.

15. The Initial Notice of Appearance also indicated that the Ministers of Health intended to rely upon the material facts set out in the Statement of Allegations and upon the documents noted in the List of Attachments to the Statement of Allegations filed by Board Staff. In addition, the Ministers of Health stated in the Initial Notice of Appearance that they also intended to rely on affidavit evidence to be filed at a later date.

16. On March 13, 2015, the Secretary of the Board wrote to the Ministers of Health advising that the Ministers of Health failed to meet the requirements of Rule 21(2) of the *Patented Medicine Prices Review Board Rules of Practice and Procedure* (the "**PMPRB Rules**")[3] as the Initial Notice of Appearance filed by the Ministers of Health failed to

[3] SOR/2012-247.

adequately specify the representations or material upon which the Ministers of Health intended to rely at the hearing. The letter from the Secretary of the Board indicated that if the Ministers of Health did not submit an amended Notice of Appearance, they may not be permitted to file evidence at the hearing beyond that which is listed in the Initial Notice of Appearance.

17. On March 17, 2015, the Ministers of Health requested the right to amend the Initial Notice of Appearance to provide further particulars of the material facts upon which the Ministers of Health intend to rely and to permit the Minister to also make representations on behalf of the Ministers of Health for Ontario and for Newfoundland and Labrador (hereafter, included in the "**Ministers of Health**").

18. The Respondent objected to the filing of an amended Notice of Appearance by the Ministers of Health. Board Staff did not oppose such an amendment. On March 26, 2015, the Board issued an order extending the time to allow the Ministers of Health to file an Amended Notice of Appearance (the "**Amended Notice of Appearance**").

19. On April 2, 2015, the Ministers of Health filed the Amended Notice of Appearance. The Ministers of Health also filed an affidavit sworn by Eric Lun, Executive Director of the Drug Intelligence and Optimization Branch, Medical Beneficiary and Pharmaceutical Services Division of the Ministry of Health of British Columbia, on which the Minsters of Health intended to rely.

20. In a letter dated April 16, 2015, Alexion objected to the filing of the Amended Notice of Appearance and sought leave to cross-examine Mr. Lun on his affidavit. The letter from Alexion's counsel states as follows, in pertinent part:

> "While we acknowledge that the provincial Ministers may attend the hearing and make representations under subsection 86(2) of the *Patent Act*, the representations must be 'with respect to the matter being heard'. The *Patent Act* does not confer a right to make submissions on irrelevant issues, much less the right to request an alternative remedy that goes beyond the *Act* and Guidelines."

21. In response, the Ministers of Health sought leave from the Panel to withdraw the affidavit from the record. At the hearing of the motion of the Respondent on June 23, 2015, the Ministers of Health were permitted to withdraw the affidavit.

22. On June 26, 2015, the Ministers of Health filed a Further Amended Notice of Appearance. In the Further Amended Notice of Appearance, the Ministers of Health set out their intention to make additional representations as outlined in paragraphs 1 and 3 of the Further Amended Notice of Appearance. In paragraph 1 of the Further Amended Notice of Appearance, the Ministers of Health state that they intend to make representations supporting the orders sought by Board Staff, but also make representations to request that the Panel issue the following relief pursuant to section 83 of the *Patent Act*:

> "(a) the Respondent reduce the price of Soliris to a price that does not exceed the lowest price for Soliris among all comparator countries; and
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> (b) the Respondent offset cumulative excess revenues that it has received by paying to the federal government an amount equal to the excess revenues the Board estimates that the Respondent has generated from the sale of Soliris at an excessive price, with the Board to use the lowest price for Soliris among all comparator countries as the basis for the calculation."

23. The intended submissions of the Ministers of Health with respect to the appropriate relief to be granted by the Panel differ somewhat from the relief sought by Board Staff. More specifically, the Ministers of Health intend to make representations in support of an order to reduce the price of Soliris to a price that does not exceed the "lowest price" among comparator countries, whereas Board Staff has sought an order to reduce the price of Soliris to a price that does not exceed the "international median" among the comparator countries.

24. A statement of the representations that the Ministers of Health intend to make and the material facts on which the Ministers of Health are relying are referenced in paragraph 3 and set out in detail in Appendix A of the Further Amended Notice of Appearance.

(b) Submissions of the parties

25. The Ministers of Health submit that subsection 86(2) of the *Patent Act* provides explicit recognition of the unique position of the Ministers of Health in each province by providing them with a right to intervene in proceedings under section 83 of the *Patent Act*, as well as a broad discretion to make submissions that go beyond those expressly identified in the Statement of Allegations of Board Staff.

26. The Ministers of Health submit that they are not in the same position as interveners in the proceeding. In this regard, the Ministers of Health rely on subsection 86(2) of the *Patent Act* which provides the Ministers of Health with a right to appear and make representations in the proceeding. The Ministers of Health contrast this right with the procedure applicable to interveners and in particular, Rule 20 of the PMPRB Rules, which requires individuals who claim an interest in the subject matter of a proceeding to bring a motion to the Board for leave to intervene. The Ministers of Health are not required to make any such motion, but have a right to appear and make representations before the Board.

27. Further, pursuant to Rule 20(5) of the PMPRB Rules, the Board may grant or deny a motion for intervener status, and the Board may impose any conditions or restrictions on the intervention that it determines to be appropriate after considering relevant factors. The Ministers of Health submit that Rule 21 of the PMPRB Rules, which entitles provincial ministers of health to file a Notice of Appearance, does not provide the Board with an analogous authority to impose conditions or restrictions on the contents of the Notice of Appearance or on the representations that the Ministers of Health may make to the Board.

28. The Ministers of Health submit that there is a clear distinction between the statutory entitlement of Ministers of Health to appear and make representations in a matter before the Board and the ability of an interested party to seek status as an intervener. The Ministers of Health submit that they are entitled to bring to the Board the unique perspective of the Ministers of Health on the matters at issue in this proceeding.

29. Alexion submits that the Ministers of Health have advanced a new or different case, and sought different relief, than Board Staff. Alexion submits that subsection 86(2) of the *Patent Act* limits the representations of the Ministers of Health to "the matter being heard" and the Ministers of Health are not able to seek alternative relief or make submissions on issues other than those set out in the Statement of Allegations as filed by Board Staff.

30. Alexion further submits that the Ministers of Health intend to rely upon facts that are beyond the scope of the proceeding, namely the following:

(i) recommendations made by the Common Drug Review (CDR) in relation to reimbursement of Soliris by public drug plans;

(ii) the process by which public drug plans review medicines such as Soliris for potential reimbursement;

(iii) the cost of Soliris in comparison to other publicly-funded medicines; and

(iv) the importance of the public list price of a medicine in relation to negotiations and other reimbursement policies.

31. The Respondent alleges that the factual and legal issues raised in the Further Amended Notice of Appearance will complicate the proceeding and defeat the purpose of ensuring the fair and expeditious resolution of this matter. Alexion alleges that the allegations of the Ministers of Health are unfocussed general complaints about the price of Soliris and have the potential to convert the hearing into a broad inquiry into the procurement of patented medicines by public entities across Canada.

32. In addition, Alexion submits that the remedy sought in the Further Amended Notice of Appearance goes beyond the remedial approaches articulated in the *Patented Medicine Prices Review Board Guidelines* and the Board's jurisprudence.

33. Board Staff generally adopted the submissions of the Ministers of Health. In addition, Board Staff disagreed with Alexion's submission that the position of the Ministers of Health is inconsistent with that of Board Staff. Board Staff further submits that the pleadings of the Ministers of Health relate to the same cause of action to be

heard by the Panel, namely, whether the price of Soliris is excessive under section 85 of the *Patent Act*.

(c) Analysis

34. The Board has not previously considered subsection 86(2) and the scope of the participation rights that should be afforded to provincial ministers of health in proceedings under section 83 of the *Patent Act*. The parties agree that subsection 86(2) of the *Patent Act* provides provincial ministers of health with a right of intervention in respect of any hearing under section 83 of the *Patent Act*. Subsection 86(2) of the *Patent Act* provides:

> "The Board shall give notice to the Minister of Industry or such other Minister as may be designated by the regulations and to provincial ministers of the Crown responsible for health of any hearing under section 83, and each of them is entitled to appear and make representations to the Board with respect to the matter being heard."

35. In effect, subsection 86(2) recognizes that provincial ministers of health, as a primary source of funding for the purchase of patented medicines, are uniquely situated to provide information that may be relevant in the proper determination of the case. This subsection provides the Ministers of Health with a right of intervention, including the express right to appear and make representations to the Panel.

36. The PMPRB Rules contemplate that the representations and evidence of the Ministers of Health may be in addition to the evidence and representations that will be made by the parties. For this reason, Rule 21(2) of the PMPRB Rules requires the Ministers of Health to provide a concise statement of the representations, material facts and evidence upon which the Ministers of Health intend to rely:

> "A notice of appearance must set out the name and address of the individual on whom service of any document intended for the concerned minister may be effected and must be accompanied by

> (a) a concise statement of the representations that the concerned minister intends to make and the material facts on which the concerned minister is relying, and
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> (b) a list of the documents that may be used in evidence to support the material facts on which the concerned minister is relying."

37. Subsection 86(2) of the *Patent Act* and the PMPRB Rules are consistent with the Panel's view that the rights of the Ministers of Health are not confined to merely participating in this proceeding, but also include a right to an effective and meaningful intervention. As the *Patent Act* and PMPRB Rules indicate, the Ministers of Health have a broader role than simply presenting arguments on the issues expressly addressed by Board Staff and the Respondent. The Ministers of Health may also lead evidence and submit arguments on issues relevant to the matter before the Panel.

38. Alexion made a number of submissions to the effect that the language of the *Patent Act* limits the scope of representations by the Ministers of Health as subsection 86(2) provides that the Ministers of Health are only entitled to "appear and make representations to the Board with respect to the matter being heard".

39. First, it is not clear to what degree, if any, the phrase "with respect to the matter being heard" limits the scope of the evidence and representations that may be made by the Ministers of Health. It does not, in the Panel's view, prevent the Ministers of Health from introducing evidence and making representations beyond those found in the Statement of Allegations of Board Staff, provided that such evidence is relevant to the matter before the Panel.

40. Second, it is notable that the French version of subsection 86(2) of the *Patent Act* does not include any reference to "the matter being heard" or other similar limitation on intervention by the Ministers of Health:

> "Le Conseil avise le ministre de l'Industrie, ou tout autre ministre désigné par règlement, et les ministres provinciaux responsables de la santé de toute audience tenue aux termes de l'article 83 et leur donne la possibilité de présenter leurs observations."

41. Overall, the rights of participation of the Ministers of Health include the right to make representations and submit evidence on all issues that are relevant to the within proceeding, irrespective of whether such representations or evidence are expressly set out in the Statement of Allegations of Board Staff.

42. This should not be read to suggest that there are no limits on the representations and evidence that may be submitted by the Ministers of Health. The Panel is cognizant of its obligations pursuant to subsection 97(1) of the *Patent Act* to conduct its proceedings as expeditiously as the circumstances and considerations of fairness permit, and this includes the need to control its process and avoid steps that will unnecessarily prolong or complicate proceedings.

43. The Respondent relies on the decision of *Pfizer v. Canada (AG)* ("***Pfizer***")[4], and submits that the Panel lacks jurisdiction to consider any submissions that may be made by the Ministers of Health relating to downstream arrangements for the sale of medicines.

44. The applicants in *Pfizer* asserted that the Board's jurisdiction is limited to reviewing prices associated with the sales of patented medicines at the "factory gate" and the Board's jurisdiction does not extend to transactions involving third parties that may take place further downstream in the supply chain. The Federal Court agreed and found that the Board was acting outside of its jurisdiction by requiring the reporting of rebates or payments made to third parties by the manufacturers of patented medicines.

45. To the extent that a price reduction would result in a lower factory-gate price for Soliris, the Ministers of Health admit that, as a primary source of funding for the purchase of patented medicines, provincial governments could recognize financial savings. However, the Ministers of Health submit that they do not intend to use a statutory entitlement to make representations to the Panel in order to assert private economic interests, or in order to seek a commercial advantage.[5]

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4 2009 FC 719.

5 Response of Minister of Health of British Columbia dated October 19, 2015, para. 37.

46. As with any party, the representations and evidence that the Ministers of Health may submit in this proceeding must be relevant to the matters at issue in this proceeding. Further, the Panel agrees with Alexion that in this context, relevance must be determined with reference to the pleadings as filed by Board Staff and the Respondent.

47. This does not mean that the representations and evidence of the Ministers of Health are confined to the representations expressly outlined in the Statement of Allegations of Board Staff. The Ministers of Health are permitted to make representations that differ or contradict the submissions of Board Staff or the Respondent. For example, the Ministers of Health are entitled to make representations regarding the appropriateness of the remedies sought by Board Staff and why the remedies sought by Board Staff may be inadequate in the event that the Panel determines that the price of Soliris is excessive.

48. The Panel does not need to predetermine the issue of the relevance of any evidence that the Ministers of Health may elect to adduce at the hearing or to strike the Further Amended Notice of Appearance. The Further Amended Notice of Appearance merely provides notice of the intentions of the Ministers of Health with respect to their participation at the hearing and areas that the Ministers of Health may seek to address in their evidence and representations.

49. Indeed, Counsel for the Ministers of Health indicated at the hearing of this motion that the Ministers of Health have not yet determined the nature of any evidence that will be introduced at the hearing, or even if the Ministers of Health intend to submit <u>any</u> evidence at the hearing. Counsel for the Minister stated:

> "… as the hearing is ongoing, the Panel could find more information relevant and wish to hear more evidence… the Minister is saying that this motion that's being made right now should be dismissed, because it's premature. It's not clear how this Panel is in any position now to make a decision on even what are all the facts, what is relevant in this hearing as a whole,

> because that's going to be an ongoing, developing issue as the proceeding proceeds."[6]

50. In the event that the Ministers of Health submit evidence on issues that are not relevant to the matters before the Panel this will be addressed at the time and in the context of the full proceeding, and with the benefit of the evidentiary record from Board Staff and the Respondent.

51. The Panel therefore orders that Alexion's motion be dismissed.

Motion To Strike Amended Reply Of Board Staff

52. Alexion seeks an Order striking out paragraph 7 and the amended portion of paragraph 9 of Board Staff's Amended Reply dated September 1, 2015.

(a) Relevant Facts

53. On January 20, 2015, a Notice of Hearing was issued in this matter. The Notice of Hearing states, in pertinent part, that: "the purpose of the hearing is to determine whether, under sections 83 to 85 of the *Patent Act* (the 'Act'), the Respondent is selling or has sold the medicine known as 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."

54. The Statement of Allegations of Board Staff appended to the Notice of Hearing expressly refers to the factors listed in subsection 85(1) of the *Patent Act* in support of Board Staff's allegation that the price for Soliris is excessive. The Statement of Allegations states as follows:

> "Subsection 85(1) of the Act sets out the factors the Board shall take into consideration in determining whether a medicine is being or has been sold at an excessive price in any market in Canada. It states:
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> In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the

[6] Pre-hearing Transcript, Volume 4, pg. 426.

> Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:
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> (a) the prices at which the medicine has been sold in the relevant market;
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> (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
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> (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
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> (d) changes in the Consumer Price Index; and
>
> (e) such other factors as may be specified in any regulations made for the purposes of this subsection.
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> …
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> Since 2012 – and thus for the past three years – Alexion has been selling Soliris in Canada at the highest international price among the comparator countries. Further, Alexion has been selling Soliris to Canadians at a price that is appreciably higher than in the United States, where Soliris has been sold at one of the lowest international prices among the comparator countries.
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> Board Staff submits that when applying the factors under subsection 85(1) of the Act, there are grounds for the Board to conclude, pursuant to section 83 of the Act, that Alexion is selling or has sold the medicine known as Soliris in any market in Canada at a price that is or was excessive."

55. The Statement of Allegations does not refer to the factors listed in subsection 85(2) of the *Patent Act*. Subsection 85(2) of the *Patent Act* provides:

> "Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:
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> (a) the costs of making and marketing the medicine; and
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> (b) such other factors as may be specified in any regulations made for the purposes of this subsection or

> as are, in the opinion of the Board, relevant in the circumstances."

56. The Statement of Allegations of Board Staff does include the typical "basket clause" language that "Board Staff reserves the right to make such other allegations and submissions and to introduce such other documents as Board Staff may advise and the Board may permit".[7]

57. Following a brief extension, Alexion filed its Initial Response on March 9, 2015 (the "**Initial Response**") denying that the price for Soliris was excessive during the review period and alleging a number of errors on the part of Board Staff.

58. On April 10, 2015, Board Staff filed a Reply in response to Alexion's Initial Response. The Reply alleges in paragraph 6 that "based on the factors under subsection 85(1) of the [*Patent Act*], the Regulations and the Board's Guidelines, Alexion has been selling Soliris to Canadians at an excessive price since 2012". Again, the Reply does not refer to the factors listed in subsection 85(2) of the *Patent Act*.

59. In an Order dated June 23, 2015 relating to Alexion's motion for particulars, the Panel granted leave to Alexion and Board Staff to file an Amended Response and an Amended Reply, respectively.

60. Alexion's Amended Response was filed on July 17, 2015. The Amended Response is discussed further below in the context of Board Staff's motion to strike portions of this pleading.

61. On September 1, 2015, Board Staff filed an Amended Reply to the Respondent's Amended Response. In addition to the allegations relating to subsection 85(1) of the *Patent Act*, paragraph 7 of the Amended Reply alleges that Alexion has failed to justify its excessive price under subsection 85(2) of the *Patent Act* and provides the following specific allegations:

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[7] Statement of Allegations, para. 28.

> "(a) for as long as Alexion has been selling Soliris in Canada, it has spent a total of zero dollars on research and development costs in Canada; and
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> (b) it appears that from 2009 to 2014, Alexion's total cost of global sales for Soliris has been approximately 10 to 12 percent of its net product sales; and therefore, Alexion's gross profit margin for Soliris has been approximately 90%."

62. The amended portion of paragraph 9 of the Amended Reply also refers to subsection 85(2) of the *Patent Act*: "[w]here the Board determines that it is unable to determine whether the medicine is being or has been sold at an excessive price under subsection 85(1), it may take the factors under subsection 85(2) into account."

63. Alexion moves for an order striking out paragraph 7 and the amended portion of paragraph 9 of the Amended Reply on the basis that these paragraphs raise "entirely new allegations" relating to the factors outlined in subsection 85(2) of the *Patent Act*, and as such, do not constitute "a proper reply to any of the issues raised in the Response or Amended Response" of Alexion.

(b) Submissions of the Parties

64. Alexion submits that neither the Initial Response nor the Amended Response filed by Alexion raised issues regarding research and development costs, profit margins or the Board's discretion under subsection 85(2) of the *Patent Act*. On this basis, Alexion submits that the allegations relating to subsection 85(2) are "entirely new allegations and not proper reply to any of the issues raised in the Response or Amended Response" filed by Alexion.[8]

65. Board Staff submits that there is no basis for striking the impugned paragraphs of the Amended Reply. On this issue, Board Staff submits as follows:

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[8] Alexion's Written Representations dated September 9, 2015 (Board Staff's Motion to Strike Paragraphs 37 and 38 of the Amended Response and Alexion's Motion to Strike Paragraph 7 and the Amended Portion of Paragraph 9 of the Amended Reply), para. 32

(a) There is only one cause of action in this proceeding, "whether Alexion is selling Soliris at an excessive price under the *Patent Act*" and Alexion has been aware of this allegation from the outset;[9]

(b) In the impugned paragraphs of the Amended Reply, Board Staff is merely confronting Alexion's allegation that the price of Soliris is not excessive by pleading additional facts relating to Alexion's costs and such other factors to "demonstrate that the excessive price of Soliris cannot be justified";[10]

(c) Subsection 85(2) of the *Patent Act* is a defence and Board Staff is not obligated to anticipate defences that may be raised in its Statement of Allegations "or to anticipate what Alexion may raise by way of justification";[11] and

(d) Board Staff was not required to plead subsection 85(2) of the *Patent Act*, but "has done so for completeness and to clarify the issues in dispute between the parties".[12]

(c) Analysis

66. Subsection 85(1) of the *Patent Act* sets out a list of factors that the Panel shall take into account when determining whether the price for a medicine is excessive:

> "85. (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:
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> (a) the prices at which the medicine has been sold in the relevant market;

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9 Board Staff's Written Representations dated October 19, 2015 (Alexion's Motion to Strike Paragraph 7 and the Amended Portion of Paragraph of the Amended Reply of Board Staff), para. 1.

10 *Ibid*, para. 2.

11 Pre-hearing Transcript, Volume 4, pg. 494.

12 Board Staff's Written Representations, *supra* note 9, para. 3.

> (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
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> (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
>
> (d) changes in the Consumer Price Index; and
>
> (e) such other factors as may be specified in any regulations made for the purposes of this subsection."

67. Where, after taking into account the factors enumerated in subsection 85(1), the Panel is unable to make a determination regarding whether the price of a medicine is excessive, then the Panel may take into consideration the additional factors listed in subsection 85(2); namely, the costs of making and marketing the medicine.

68. Board Staff did not refer to the factors outlined in subsection 85(2) in its Statement of Allegations. Nor did Alexion refer to the cost of making and marketing Soliris in its Response. Rather, the first time that subsection 85(2) and the factors outlined therein were mentioned was in the Amended Reply of Board Staff.

69. Rule 19(2) of the PMPRB Rules states:

> "A reply must be set out in consecutively numbered paragraphs and must set out an admission or denial of each ground or material fact that was set out in the response."

This Rule indicates that the reply should be confined to responding to those grounds or material facts as set out in the response.

70. Analogous Canadian rules of civil procedure are more explicit in preventing parties from raising new grounds by way of reply, as opposed to by way of amendment to the original pleading. For example, Rule 25.06(5) of the Ontario Rules of Civil Procedure[13] requires that any new or additional allegations should be raised through an amendment to the original pleading as opposed to in a reply:

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[13] *Courts of Justice Act*, R.R.O. 1990, Regulation 194.

> "An allegation that is inconsistent with an allegation made in a party's previous pleading or that raises a new ground of claim shall not be made in a subsequent pleading but by way of amendment to the previous pleading."

71. As an example of this principle, Alexion cites the decision of *Drywall and Acoustic Lathing and Insulation Local 675 Pension Fund (Trustee of) v. SNC-Lavalin Group Inc.*,[14] where the Ontario Superior Court of Justice held as follows regarding the issue of a proper reply:

> "An allegation that is inconsistent with an allegation made in a party's previous pleading or that raises a new ground of claim shall not be made in a subsequent pleading but by way of amendment to the previous pleading: Rule 25.06(5); *Ross v. Coseco Insurance Co.* A plaintiff, rather than taking an inconsistent or alternative position in a reply, must amend his or her statement of claim to plead the inconsistent or alternative position in the alternative…
>
> The current Replies are adequate to meet the Defendants' defences, and it is not fair to slip new allegations into a reply for which the Defendants' have no opportunity to respond. Moreover, the unfairness is pronounced when the pleading of the Defendants' alleged wrongdoing suffers from the same deficiencies noted above of being a vague generalized allegation of being an international briber with no details of the alleged briberies." [citations omitted]

72. Board Staff submits that subsection 85(2) of the *Patent Act* is a defence to an allegation of excessive pricing and therefore, Board Staff is not required to affirmatively address this provision unless the defence is invoked by the Respondent. Counsel for Board Staff referred the Panel to the headnote in *Lake Erie and Detroit River Railway Co. v. Sales*[15] for the proposition that, "[i]t is highly improper, in a statement of claim, to anticipate and reply to matters of defence."[16] Board Staff further submitted that "[t]here is no new cause of action or new allegation of excessive pricing" and that Board Staff is not required to anticipate defences that Alexion may elect to raise.[17]

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14 [2014] O.J. No. 435 (QL), paras. 59 - 60.

15 (1896), 26 S.C.R. 663.

16 Pre-hearing Transcript, Volume 4, pg. 494.

17 *Ibid*, pg. 498.

73. The Panel disagrees with the submissions of Board Staff regarding this issue. As an initial matter, the Respondent has not raised subsection 85(2) of the *Patent Act* in its Amended Response as a defence or otherwise.

74. Furthermore, subsection 85(2) is not a defence to an allegation of excessive pricing. As noted above, subsection 85(2) establishes an additional set of factors to be considered by the Panel in the event that it is unable to determine the issue based on the factors outlined in subsection 85(1) alone.

75. Section 85 contemplates the potential of a dual-stage review by the Panel consisting of an initial examination of the factors listed in subsection 85(1) and where necessary, an examination of the additional factors listed in subsection 85(2). In terms of the hearing procedure for each of these stages, one option would be to receive evidence and submissions on whether the price of Soliris is excessive based on a consideration of the factors listed in subsection 85(1) of the *Patent Act*. If the Panel is unable to determine the issue on the basis of the subsection 85(1) factors, then the Panel would receive evidence and arguments with respect to the factors identified in subsection 85(2) of the *Patent Act*.

76. In the Panel's view, dividing or "splitting" the case between the factors in subsections 85(1) and 85(2) in this manner is not an efficient or preferable way to proceed. Rather, the Panel should receive evidence and submissions regarding the factors listed in both subsections 85(1) and 85(2), to the extent relied upon by either party. Where a party submits evidence relating to the factors listed in subsection 85(2), the Panel will not have regard to such evidence unless it is unable to decide this matter based on a consideration of the factors listed in subsection 85(1) alone.

77. This manner of proceeding is consistent with the approach taken by the Board in prior cases. For example, in 2011, the PMPRB conducted a hearing into whether

ratiopharm Inc. ("**ratiopharm**") had sold a medicine known as ratio-Salbutamol HFA at an excessive price under sections 83 and 85 of the *Patent Act*.[18]

78. In addition to introducing evidence regarding the factors listed in subsection 85(1), ratiopharm also provided evidence under subsection 85(2) regarding the cost of making and marketing the medicine. The Panel ultimately determined that it did not need to have regard to the evidence submitted with respect to subsection 85(2) on the basis that the Panel could determine the issue through a review of the factors outlined in subsection 85(1) alone:

> "In accordance with subsection 85(2) of the Act, the Panel need only take into consideration the factors set out therein if it is unable to determine whether the medicine under review is being or has been sold at an excessive price after taking into consideration the factors referred to in subsection 85(1).
>
> ratiopharm introduced evidence with regard to the costs of acquisition of ratio HFA and with regard to the costs of making and marketing ratio HFA prepared by Cole Valuation Partners Limited ("Cole Partners"). Board Staff, for its part, submitted that it is neither necessary nor appropriate for the Panel to consider subsection 85(2) factors in the circumstances of this case since its evidence was that, since 2004, under all the factors identified in subsection 85(1) of the Act, implemented in accordance with the Board´s Guidelines, only when the full amounts of the CE and PEP claimed by ratiopharm are deducted to determine the ATP of ratio HFA is the price of ratio HFA lower than the price of Ventolin HFA. If the price of ratio HFA is compared to the CPI-adjusted VCU price of Airomir, to international prices and to the price resulting from the application of the Guidelines´ CPI methodology, even with the full amounts of the CE and PEP claimed by ratiopharm, the price of ratio HFA has been excessive since 2004.
>
> The Panel considers that it is in a position to reach a decision in this case on the basis of the subsection 85(1) factors. Moreover, ratiopharm, as the reseller of ratio HFA, has no evidence of the

[18] Board Decision - *PMPRB-08-D3-ratio-Salbutamol HFA – Merits* (May 27, 2011): http://www.pmprb-cepmb.gc.ca/view.asp?ccid=866.

> material costs of making ratio HFA nor has it such information within its knowledge or control."[19]

79. Clearly, evidence regarding both subsections 85(1) and 85(2) of the *Patent Act* is admissible in this proceeding. Indeed, at the hearing, Alexion acknowledged the relevance of evidence under subsection 85(2).[20] The Panel therefore anticipates that the parties will make representations and adduce evidence with respect to the factors listed in subsections 85(1) and 85(2) of the *Patent Act*.

80. The Panel agrees with the Respondent that allegations regarding the factors listed in subsection 85(2) should be included in the Statement of Allegations, instead of being raised explicitly for the first time in the Amended Reply. Although Board Staff did not follow the preferable procedure, the Panel has determined that Alexion's request to strike the impugned paragraphs should not be granted.

81. Rule 5 of the PMPRB Rules provides the Panel with broad discretion in respect of procedural matters:

> "Defect in form or procedure
>
> (1) A proceeding or any part of a proceeding may not be defeated by reason only of a defect in form or procedure.
>
> Unanticipated procedural matters
>
> (2) Any procedural matter or question that is not provided for in the Act, in these Rules or in any regulations made pursuant to the Act that arises in the course of any proceeding may be dealt with in any manner that the Board directs in order to ensure the fair and expeditious conduct of any proceeding.
>
> Board discretion
>
> (3) For the purpose of ensuring the fair and expeditious conduct of any proceeding, the Board may vary,

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19 *Ibid*, paras. 86 – 88.

20 Pre-hearing Transcript, Volume 4, pgs. 506 - 514.

> supplement or dispense with any requirement set out in these Rules."

Further, Rules 6(1)(a) and (e) of the PMPRB Rules provide that the Panel may "receive any evidence that it considers appropriate" and "decide any question of procedure".

82. One option available to the Panel is to strike the portions of the Amended Reply relating to subsection 85(2) of the *Patent Act* and require Board Staff to plead these allegations as part of its Statement of Allegations. Striking the impugned paragraphs and granting leave to amend the Statement of Allegations, and thus the corresponding Response and the corresponding Reply are not in the interest of a fair and expeditious hearing. This approach will add unnecessary delay and expense to the proceedings.

83. Alexion is now aware of Board Staff's allegations relating to subsection 85(2) as found in the Amended Reply. In fact, the language of subsection 85(2) itself provides notice to Alexion that the factors listed therein may be considered by the Panel in this proceeding.

84. The Panel therefore dismisses Alexion's motion to strike on the basis that the relevant paragraphs raise issues which are relevant to the proceeding. However, the Panel recognizes the importance of providing Alexion with an opportunity to respond to the allegations relating to subsection 85(2) of the *Patent Act* found in the Amended Reply. The Panel therefore grants Alexion the option to file a Surreply to respond to these allegations. For further clarity, the Surreply must be limited to the allegations raised in paragraph 7 and the amended portion of paragraph 9 of Board Staff's Amended Reply. In terms of scheduling, if Alexion wishes to file a Surreply, it shall do so within 10 days of this Order.

Motion for Disclosure

85. Alexion seeks an Order requiring Board Staff to provide disclosure of the following:

> (i) All evidence and documents underlying factual allegations and expert opinions Board Staff will be relying on at the hearing;

(ii) All documents Board Staff will use to examine their own witnesses in chief and to cross-examine Alexion's witnesses at the hearing; and

(iii) Any other evidence, documentary or otherwise, that Board Staff will be adducing or relying upon at the hearing.

(a) Relevant Facts

86. On February 12, 2015, Alexion's counsel requested Board Staff's counsel to disclose documentation underlying the allegations made in the Statement of Allegations. On February 20, 2015, Board Staff's counsel refused to disclose the requested documents on the basis that the request was premature. Counsel for Board Staff advised that documents would be disclosed within a reasonable time period after pleadings had closed.

87. On May 15, 2015, Alexion brought a motion requesting particulars of the allegations in the Statement of Allegations, which was opposed by Board Staff. The motion was heard on June 23, 2015 and this Panel ordered Board Staff to provide further particulars of certain allegations.

88. On July 3, 2015, Board Staff provided a number of documents together with the particulars ordered by the Panel.[21]

89. At a pre-hearing conference held on October 13, 2015, the Panel directed Board Staff and the Respondent to exchange documents on which they intended to rely, to the extent identified. The parties exchanged copies of documents prior to the hearing of this motion.

(b) Submissions of the Parties

90. Alexion submits that it is entitled to disclosure of documents at this time as procedural fairness and natural justice entitles Alexion to know the case to be met in this proceeding.

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[21] Alexion's Written Submissions dated September 2, 2015 (Motion re: Disclosure of Documents), para. 16.

91. Alexion submits that the duty of procedural fairness for Board Staff is higher than in other administrative or civil proceedings on the basis that the present proceeding is akin to a "regulatory prosecution" with serious financial consequences for the Respondent. This duty includes the opportunity to be heard and requires that Board Staff disclose all facts, documents, testimony, and other evidence they will rely on for purposes of the hearing. Specifically, at paragraphs 24 to 27 of its written submissions, Alexion alleges:

> "Board Staff have failed to act in conformance with their obligations as prosecutors acting in the public interest. Board Staff, and their counsel, have been overly adversarial in the prosecution of this case. They have a clear duty to disclose the documents and evidence they will be relying upon at the hearing but, for strategic reasons, are withholding disclosure with the apparent objective of surprising Alexion or gaining some other tactical advantage.
>
> The duty of procedural fairness, including the opportunity to be heard, requires Board Staff to disclose all facts, documents, testimony, and other evidence they will rely on for purposes of the hearing. Board Staff have consistently refused to disclose the documents and evidence they rely on in support of the Allegations. Their filings in this proceeding demonstrate Board Staff have misapprehended their role as prosecutors acting in the public interest. Instead of seeing themselves as regulatory prosecutors having duties of fairness and candour, they see their role as that of zealous plaintiffs' lawyers hoping to "win" a judgment confiscating Alexion's assets by any means necessary including for reasons that they have still failed to articulate.
>
> There is ample authority for the proposition that Board Staff, as a regulatory prosecutor, has a duty to comply with basic rules of procedural fairness. This means that Board Staff must act fairly and judiciously to ensure that Alexion has an opportunity to know the case it has to meet."

92. Board Staff has agreed to disclose the documents and evidence it relies on in support of the allegations and which it intends to rely upon at the hearing, to the extent identified, subject to the following two conditions:

(a) First, the obligation to disclose documents is not solely applicable to Board Staff, but is an obligation that also exists for the Respondent. Board Staff

alleges that Alexion is also required to disclose documents upon which it intends to rely at the hearing; and

(b) Second, the exchange of documents cannot take place until after the issues have been fully defined and following the close of pleadings. Board Staff submits that the purpose of the pleadings in any litigation is to define the facts and issues in dispute. Once the pleadings are complete, the parties are able to determine what documents they intend to rely upon at the hearing.

(c) Analysis

93. The Federal Court examined the procedural and substantive obligations for disclosure in proceedings before the Board in *CIBA-Geigy Canada Ltd. v. Canada (Patented Medicine Prices Review Board)* ("***CIBA-Geigy***")[22]. This case concerned an application for judicial review of the Board's order dismissing the request of CIBA-Geigy Canada Limited for disclosure and production of all documents relating to matters in issue in a hearing to determine whether a patented medicine was being sold at an excessive price.

94. The issue was whether CIBA-Geigy was only entitled to the documents upon which the Board intended to rely at the hearing, or whether it was entitled to all of "the fruits of the investigation" of Board staff. The Federal Court held that the applicant was entitled to know the case against it, but not to obtain all the fruits of the investigation. The Federal Court held that, the "obligations concerning disclosure imposed by the doctrine of fairness and natural justice are met if the subject of the inquiry is advised of the case it has to meet and is provided with all the documents that will be relied on." At paragraph 30 of the decision, McKeown J. stated:

> "The Board is supposed to proceed efficiently and to protect the interest of the public. This requires, inter alia, that a hearing shall not be unduly prolonged. Certainly, the subject of an excess price hearing is entitled to know the case against it, but it should

[22] [1994] 3 F.C.R. 425, aff'd [1994] F.C.J. 884 (FCA) (QL).

> not be permitted to obtain all the evidence which has come into the possession of the Board in carrying out its regulatory functions in the public interest on the sole ground that it may be relevant to the matter at hand. The Board's function is not to obtain information solely for investigative purposes; its primary role is to monitor prices."

The Federal Court of Appeal upheld this decision.

95. As recognized by the Court in *CIBA-Geigy* and contrary to the Respondent's submission, Board Staff are not "prosecutors acting in the public interest". The purpose of this hearing is to determine whether 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. The regulatory or administrative nature of this proceeding is discussed further below in respect of the motion to strike by Board Staff.

96. As set out in *CIBA-Geigy*, the disclosure obligations of Board Staff are met if the Respondent is advised of the case it has to meet and is provided with all of the documents that will be relied on at the hearing of this matter.

97. Board Staff has already agreed to provide disclosure of documents upon which it intends to rely on the condition that Alexion is subject to the same obligation to disclose documents, and that the production will be made after pleadings have closed. In fact, the parties have already exchanged certain documents prior to the hearing of this motion. As a consequence, this is largely an issue of when the disclosure of documents should be made and on what conditions, if any.

98. Timely disclosure of relevant documents is necessary to avoid surprises and provide each of the parties with notice of the case to be met. To the extent that any documents have been identified that will be relied upon at the hearing, those documents should be exchanged between the parties in a timely fashion. Such an approach is also consistent with the Panel's overall obligation to conduct the proceeding in a fair and expeditious manner. The Panel also agrees with Board Staff that Alexion is subject to the same obligation to disclose documents upon which it intends to rely.

99. The Panel therefore orders that Board Staff and Alexion shall exchange documents that they will be adducing or relying upon at the hearing, to the extent identified, within 30 days of the date of this Order.

100. Further, the parties are subject to a continuing obligation of disclosure and shall provide documents on which they intend to rely as early as possible after such documents have been identified and in accordance with the schedule to be determined.

Motion to Request Confidentiality of Certain Documents

101. Alexion has requested an order designating as confidential sales data found in the exhibits to the Affidavit of Danielle Marshall, and a confidentiality order with respect to future evidence of a similar nature to be disclosed in the proceeding. At the hearing of the motion, the parties advised the Panel that they had reached an agreement to redact certain portions of the Affidavit and to maintain confidentiality over such information for the present time.[23] As noted below, the parties also agreed to the issuance of a confidentiality order to deal with designations of confidentiality of future documents, subject to certain conditions.

(a) Relevant Facts

102. Board Staff filed the Affidavit of Danielle Marshall in support of its June 5, 2015 written representations in response to Alexion's motion for particulars. This affidavit attached a number of documents as exhibits which contained sales data that was not publicly disclosed by Alexion.

(b) Submissions of the Parties

103. Alexion submits that public disclosure of Canadian and international sales data concerning Soliris would cause specific, direct, and substantial harm to Alexion's commercial interests, including by disclosing competitively sensitive information to Alexion's competitors.

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[23] Pre-hearing Transcript, Volume 4, pgs. 372, 613 – 618.

104. As noted above, Alexion has agreed to provide versions of these documents for filing on the public record with the confidential sales and financial data redacted.

105. Board Staff advised the Panel that it does not object to certain redactions from the affidavit material, mainly numerical figures, on a without prejudice basis.

(c) Analysis

106. In *Sierra Club of Canada v. Canada (Minister of Finance)*[24] the Supreme Court of Canada set out the general test for granting a confidentiality order under Rule 151 of the *Federal Court Rules* ("**Federal Court Rules**")[25], which provides that, on motion, the Court may order that material to be filed shall be treated as confidential. At paragraph 53, Iacobucci J., states:

> "A confidentiality order under Rule 151 should only be granted when:
>
> (a) such an order is necessary in order to prevent a serious risk to an important interest, including a commercial interest, in the context of litigation because reasonably alternative measures will not prevent the risk; and
>
> (b) the salutary effects of the confidentiality order, including the effects on the right of civil litigants to a fair trial, outweigh its deleterious effects, including the effects on the right to free expression, which in this context includes the public interest in open and accessible court proceedings."

107. Other administrative tribunals have taken a similar approach, holding that the test is whether a confidentiality order is necessary in order to prevent specific, direct harm (see *Canada (Commissioner of Competition) v. Sears Canada Inc.*[26]).

108. The Panel is committed to an open and public process. Rule 16(1)(c) of the PMPRB Rules provides that, "[a] notice of hearing issued by the Board must state that

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24 2002 SCC 41.

25 SOR/98-106.

26 2003 Comp. Trib. 27.

the hearing will be held in public unless, on representations made by a respondent, the Board is satisfied that specific, direct and substantial harm would be caused to the respondent by the disclosure of information or documents relating to the hearing".

109. The Panel is satisfied that based on the representations made by the parties and a review of the evidence filed to date, public disclosure of confidential or competitively sensitive information in this proceeding would likely cause specific, direct and substantial harm to the Respondent. On this basis, Alexion's motion requesting confidentiality of Canadian and international sales data concerning Soliris in the attachments to the Affidavit of Danielle Marshall is granted.

110. With respect to designations of confidentiality of documents adduced in the future, Board Staff does not object to Alexion's request for a confidentiality order provided that such an order will include a mechanism for the parties to resolve any disputes regarding confidentiality designations over specific documents or evidence before the Panel. Alexion and Board Staff have proposed competing forms of a protocol for addressing future claims of confidentiality.

111. The Panel has reviewed the submissions of Alexion and Board Staff on the protocol and has attached at Appendix "A" to this decision a protocol to address confidentiality designations of records adduced in the future.

Motion to Strike Portions of Alexion's Amended Response

112. Board Staff seeks an Order striking out paragraph 37 and the second sentence of paragraph 38 of Alexion's Amended Response dated July 17, 2015.

113. Paragraph 37 and the second sentence of paragraph 38 of the Amended Response raise various allegations, including:

(i) counsel for Board Staff are not in compliance with the Rules of Professional Conduct;

(ii) counsel representing Board Staff are "seeking to convict at all costs" by acting in an overly adversarial and uncooperative fashion by

"deliberately withholding" particulars and by non-disclosure of documents;

(iii) counsel for Board Staff are "deliberately" advancing legal arguments that the price of Soliris is excessive which Alexion disagrees with and effectively failing to deal "candidly" with the Board; and

(iv) assertions that counsel for Board Staff are relying upon irrelevant allegations.

(a) Submissions of the Parties

114. Board Staff submits that the impugned portions of Alexion's Amended Response are inflammatory allegations relating to the integrity of counsel for Board Staff. Board Staff submits that these allegations are either not relevant to the matters at issue in this proceeding, have already been determined by the Panel (more specifically, in the decision of October 5, 2015) or are otherwise frivolous, vexatious, scandalous or an abuse of process.

115. Board Staff submits that these allegations are premised upon the erroneous assertion that there has been a breach of Rule 5.1-3 of the *Law Society of Upper Canada Rules of Professional Conduct* ("**Rules of Professional Conduct**"), which deals with the obligations of Crown Attorneys and others involved in the prosecution of criminal and quasi-criminal matters. Board Staff submits that this is not a criminal proceeding and is thus not subject to the same standards of disclosure or the obligations of counsel engaged in criminal prosecutions.

116. Board Staff submits that the word "prosecute" can refer to both civil and criminal proceedings, and the usage of the word "prosecution" in its Annual Report does not bring Board Staff within the ambit of Rule 5.1-3. Board Staff submits that even if it was in breach of the Rules of Professional Conduct, the appropriate remedy is a complaint to the Law Society of Upper Canada.

117. Board Staff relies on *CIBA-Geigy*, *supra*, in which the Federal Court held that "[t]here is no point in the legislature creating a regulatory tribunal if the tribunal is treated as a criminal court."[27]

118. Board Staff submits that these allegations are not relevant to the issue of whether the price of Soliris is excessive, and will prejudice and delay the hearing by involving parties in the determination of issues that are not relevant to the merits of the case.

119. Alexion alleges that Board Staff and its counsel have a "prosecutorial" role but have improperly adopted an overly adversarial approach that conflicts with their obligations as a prosecutor. As discussed above, Alexion submits that this proceeding is similar to a criminal proceeding as it involves an expropriation of property and because in certain instances, Board Staff has described its process as a "prosecution".

120. Alexion submits that these allegations are relevant to the exercise of discretion by the Panel. Alexion argues that it is not plain and obvious that the allegations are scandalous, vexatious or an abuse of process, and thus should not be struck.

(b) Analysis

121. The parties have cited various authorities on the issue of the appropriate test to be applied in motions to strike pleadings, including: *Canada (A.G.) v. Inuit Tapirisat of Canada*[28]; *R. v. Imperial Tobacco Canada Ltd.*[29]; and *Sivak v. Canada* ("***Sivak***")[30].

122. The general test outlined by the Supreme Court of Canada for striking pleadings is the "plain and obvious" test: assuming that the facts as stated can be proved, it is plain and obvious that the pleadings disclose no reasonable cause of action.

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27 *CIBA-Geigy*, *supra* note 22, [1994] F.C.J. 884 (FCA) (QL), para. 5.

28 [1980] 2 S.C.R. 735 (QL).

29 [2011] 3 S.C.R 45.

30 2012 FC 272.

123. Pleadings may also be struck for other reasons. For example, Rule 221(1) of the Federal Court Rules explicitly provides:

> "On motion, the Court may, at any time, order that a pleading, or anything contained therein, be struck out, with or without leave to amend, on the ground that it
>
> (a) discloses no reasonable cause of action or defence, as the case may be,
>
> (b) is immaterial or redundant,
>
> (c) is scandalous, frivolous or vexatious,
>
> (d) may prejudice or delay the fair trial of the action,
>
> (e) constitutes a departure from a previous pleading, or
>
> (f) is otherwise an abuse of the process of the Court,
>
> and may order the action be dismissed or judgment entered accordingly."

124. The purpose of pleadings is to define the issues between the litigants and to give notice of the case to be met. In the Panel's view, the impugned paragraphs are not relevant to the matters at issue in this proceeding; in particular, the issue of whether Soliris is priced excessively under sections 83 and 85 of the *Patent Act*. The paragraphs at issue largely relate to matters that have already been determined by the Panel or that raise issues with respect to the motives and character of Board Staff. Speculation on Board Staff's motives is irrelevant to the issue of whether the price of Soliris was excessive during the review period.

125. In *Sivak*, the Court held that a scandalous, frivolous or vexatious pleading is one that is irrelevant, argumentative or inserted for colour, or includes unfounded or inflammatory remarks about the integrity of a party.[31] In the Panel's view, a number of impugned paragraphs fall within this description.

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[31] *Ibid*, para. 89.

126. In *Levi Strauss & Co. v. Lois Canada Inc.*,[32] an appeal from the dismissal of an application to strike out a portion of the defendant's counterclaim, Mahoney J. in *obiter* states, "[i]t is well established that if wholly immaterial matter is set out in a pleading which raises irrelevant issues which may involve expense; trouble and delay, or is otherwise embarrassing or oppressive, then the irrelevant matter will be struck out as prejudicing the fair trial of the action".

127. In addition, the submissions of Alexion are premised on the assertion that proceedings before the Panel are akin to criminal prosecutions and as a result, Board Staff is subject to the same obligations as a prosecutor in criminal cases.

128. The Panel does not agree with the Respondent that the present matter is akin to a criminal prosecution. As recognized by the Federal Court of Appeal in *CIBA-Geigy*, proceedings under section 83 of the *Patent Act* are regulatory in nature:

> "… any criminal analogy to the [PMPRB] proceedings in the case at bar breaks down. There are admittedly extremely serious economic consequences for an unsuccessful patentee at a s. 83 hearing, and a possible effect on a corporation's reputation in the market place. But as McKeown J. found, the administrative tribunal here has economic regulatory functions and has no power to affect human rights in a way akin to criminal proceedings."[33]

129. Further, a number of these allegations have already been determined by the Panel; in particular, on October 5, 2015, this Panel issued its Reasons for Decision in response to Alexion's motion regarding alleged conflicts of interest, including of Isabel Jaen Raasch, Director, Legal Services and General Counsel for the Board. The Panel dismissed Alexion's motion on these issues.

130. The Panel therefore orders that paragraph 37 and the second sentence of paragraph 38 of Alexion's Amended Response be struck.

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[32] [1983] F.C.J. 925 (FCA) (QL).

[33] *CIBA-Geigy*, *supra* note 22, para. 8.

Conclusions

131. Based on the foregoing reasons, the Panel makes the following Orders:

(a) Alexion's motion to strike portions of the Further Amended Notice of Appearance of the Minister of Health for British Columbia is dismissed;

(b) Alexion's motion to strike paragraph 7 and the amended portion of paragraph 9 of the Amended Reply is dismissed. Alexion is granted leave to file a Surreply within 10 days of this Order to respond to the allegations related to subsection 85(2) of the *Patent Act* in the impugned paragraphs;

(c) With respect to Alexion's motion requiring Board Staff to provide disclosure of various documents and evidence, the Panel orders that Board Staff and Alexion shall exchange documents on which they intend to rely upon at the hearing, to the extent identified, within 30 days of the date of this Order;

(d) Alexion's request to designate as confidential certain attachments to the Affidavit of Danielle Marshall is granted. With respect to designating documents adduced in the future as confidential, a protocol outlining the procedure to be followed is attached at Appendix "A" to this decision; and

(e) Board Staff's motion to strike out paragraph 37 and the second sentence of paragraph 38 of the Amended Response is granted.

Dated at Ottawa, this 24th day of November, 2015.

Signed on behalf of the Panel by
Dr. Mitchell Levine

Panel Members:

Dr. Mitchell Levine
Carolyn Kobernick
Normand Tremblay

APPENDIX "A"

PROTOCOL FOR CONFIDENTIALITY CLAIMS

1. The Panel recognizes that the public disclosure, in whole or in part, of certain documents in this proceeding could cause specific and direct harm as such documents contain competitively sensitive and/or proprietary information.

2. If any party in this proceeding (together with and including any Intervener, "**Party**" or "**Parties**") files a document with the Board that contains confidential information (a "**Confidential Document**") such Party must ensure that "Confidential – Confidentiel" appears prominently on the cover and subsequent pages of the Confidential Document.

3. The Parties acknowledge that all documents filed in relation to this matter will be made public and published on the Board's website unless the document is designated as confidential in accordance with paragraph 2 above and representations are made by the Parties with regard to privilege and/or confidentiality (a "**Request for Confidentiality**") in accordance with this protocol.

4. Any Request for Confidentiality made in connection with a Confidential Document to be filed with the Board shall be made within seven (7) days after the other Parties receive notice of the filing with the Secretary of the Board. The Request for Confidentiality shall be filed with the Secretary of the Board, served on all Parties, and accompanied with the reasons for the Request for Confidentiality. Where a Party objects to providing a Confidential Document to any other Party, the Party filing the Confidential Document shall specify in the Request for Confidentiality that the Confidential Document is not to be disclosed to any Party pending the determination of the Request for Confidentiality.

5. A Request for Confidentiality shall contain sufficient details to explain fully the nature and extent of specific, direct and substantial harm that would be caused to the Party claiming confidentiality if the document is disclosed to the public.

6. A Party making a Request for Confidentiality in connection with a document shall indicate whether the Party objects to providing an abridged version of the document to the other Parties. If the Party making a Request for Confidentiality objects to providing an abridged version of the document to the other Parties, it shall state that Party's reasons for objecting to providing an abridged version of the document. If the Party making a Request for Confidentiality does not object to providing an abridged version of the document, that Party must provide an abridged version of the document together with the Request for Confidentiality to the other Parties.

7. If any Party opposes a Request for Confidentiality, the opposing Party must file written representations in response to the Request for Confidentiality within seven (7) days of receiving the Request for Confidentiality and must file its response with the Secretary of the Board.

8. The Panel will either render a decision with respect to the Request for Confidentiality or may direct the Parties to make further representations.

9. A Confidential Document filed with the Secretary of the Board will not be made public or disclosed to any other Party by the Board until the Request for Confidentiality has been determined.

10. Any document shall cease to be a Confidential Document if: (a) the document or the confidential information contained therein becomes publicly available (except if it becomes publicly available through a breach of this Protocol); (b) if the Parties agree in writing that the document shall no longer be considered confidential; or (c) the Panel determines that the document shall not be confidential.

11. This Protocol shall be subject to further direction of the Panel and may be varied by the Panel.