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 Amend Statement of Allegations and Strike Certain Portions of Will-Say Statement) Heard on June 1, 2016

1. On June 1, 2016, the panel (the "**Panel**") of the Patented Medicine Prices Review Board (the "**Board**") seized with this proceeding heard a motion brought by Board Staff to: (i) amend its Statement of Allegations to include alternate remedies in the event that the Panel finds that the price of Soliris is excessive under sections 83 and 85 of the *Patent Act*[1]; and (ii) strike certain portions of a will-say statement of Barry Katsof filed by Alexion Pharmaceuticals Inc. ("**Alexion**" or the "**Respondent**") or alternatively, to provide particulars of certain portions of the statement.

2. For the reasons that follow, Board Staff's motion to amend its Statement of Allegations is granted and the hearing is adjourned for a limited period to allow Alexion an opportunity to respond to the amended Statement of Allegations. The new hearing dates will be set by the Panel in the near future. Board Staff's motion to strike or provide particulars of certain portions of the will-say statement of Barry Katsof is dismissed, without prejudice to any objections that may be made by Board Staff during the course of the testimony of Mr. Katsof at the hearing of this matter.

[1] RSC 1985, c. P-4.

Background

3. 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).

4. 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).

5. 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.

6. 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.

7. 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.

8. On May 20, 2016, Board Staff filed a Notice of Motion seeking to amend its Statement of Allegations and to strike or provide particulars of certain portions of a will-say statement of Barry Katsof filed by the Respondent, which was heard on June 1, 2016. The Panel issues the decision below.

1. Motion to Amend Statement of Allegations

Relevant Facts

9. In the Statement of Allegations dated January 15, 2015, Board Staff requests certain remedies in the event that the Panel determines that the price of Soliris is, or was, excessive, including the following relief:

i. An Order requiring Alexion to "reduce the price of Soliris within 30 days from the date of the Board's Order to a price that does not exceed the international median among the comparator countries";

ii. An Order requiring Alexion to "offset the cumulative excess revenues it has received during the period of 1 January 2012 to 30 June 2014 by making a payment to Her Majesty in Right of Canada, within 30 days of the date of the Board's Order, in the amount of [redacted]"; and

iii. "Any other remedies Board Staff may seek and the Board may permit".

10. On March 9, 2015, the Minister of Health for British Columbia, on his own behalf and on behalf of the Ministers of Health for other provinces (collectively, the "**Ministers of Health**") filed a Notice of Appearance in this proceeding. On June 26, 2015, the Ministers of Health filed a Further Amended Notice of Appearance.

11. 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." [emphasis added]

12. On October 28, 2015, the Panel heard a motion by Alexion to strike out the above paragraph of the Further Amended Notice of Appearance of the Ministers of Health, including the request for a remedy to reduce the price of Soliris to the lowest price among all comparator countries. The Panel dismissed Alexion's motion, noting at paragraph 47 of its decision that the Ministers of Health are entitled to make representations on the issue of any remedies that differ from those 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." [emphasis added]

13. On May 20, 2016, Board Staff brought a motion for leave to amend its Statement of Allegations to include alternate remedies. In summary, Board Staff seeks to amend the Statement of Allegations to include an alternate remedy for an Order requiring Alexion to reduce the price of Soliris to a price that does not exceed "the international lowest price among the comparator countries", as compared with reducing the price of Soliris to the international median price as set out in the Statement of Allegations.

14. Board Staff also seeks leave to amend the Statement of Allegations to include various possible amounts of the alleged cumulative excess revenues that Board Staff seeks in this proceeding. The amounts of alleged excess revenues sought by Board Staff ranges substantially from [redacted] to [redacted], depending on the methodology to be applied and the source of data utilized for such calculations.

15. As discussed further below, Board Staff seeks leave to amend the Statement of Allegations approximately one month prior to the commencement of a two-week hearing that was scheduled by the parties in December 2015.

Submissions of the Parties

16. Board Staff submits that the amendments to the Statement of Allegations merely change and update the amount of excess revenue that may be ordered as a remedy by the Panel. Specifically, Board Staff alleges that the "amendments conform to the evidence and disclosure already provided", the "relief sought by Board Staff in the amendments is the same as already sought by the Provinces in this matter" and "cause no prejudice to Alexion".

17. Board Staff further submits that amendments to increase the quantum of the amount of a claim should be permitted even at a late stage of the proceedings. In this regard, Board Staff cites the decision *Apotex Inc. v. Wellcome Foundation Limited*,[2] an appeal by the defendants from a Prothontary's order allowing the plaintiffs to file a further amended Statement of Issues to substantially increase the quantum of damages claimed. In granting the amendment, the Prothontary noted:

> "It is the interests of justice that an issue ought to be resolved in the forum best suited to get at the truth of the matter unless the Respondents are now prejudged in presenting their case on the issue to the extent that it would be unfair.
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> The Respondents claim prejudice caused by the proposed amendments. It is suggested there will be a need for further extensive discovery. They also claim that the amendments will cause further delay in a matter which has already taken far too long. The Respondents argue these are matters which should be taken into account and cannot be compensated for by costs.
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> […]
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> I find that there will be no prejudice to the Respondents as a consequence of these amendments as they have been apprised of them before completion of the first round of examinations for discovery and further examinations for discovery are contemplated. In contrast, GSK would be prejudiced if these amendments are not allowed, since GSK will be prevented from asserting the proper quantification of damages which it

[2] 2009 FC 949 (CanLII) [*Apotex*].

> would otherwise be entitled to assert. The amendments will also assist the referee in deciding the matters in controversy."[3]

18. The Federal Court upheld this decision and noted that "[i]n general an amendment should be granted provided that the opposite party is not prejudiced in a manner that cannot be compensated", "[e]ach amendment sought should be dealt with on a case by case basis", and "[a]mendments revising the quantum of damages sought upwardly are allowable, even at a late date."[4] The Court concluded that the issues raised by the amendments were best left for consideration at trial.

19. Alexion submits that the amendments are "breathtakingly prejudicial" to Alexion because they are a fundamental departure from the regulatory regime under which Alexion entered the Canadian market and established its business in Canada. Alexion also notes that it has already undertaken the significant time and expense of preparing several expert and fact witnesses and delivering their witness statements based on a defence to Board Staff's original case. Alexion states that if accepted, the amendments would force Alexion to "retool its entire defence and re-prepare each of its witnesses to defend against multiple novel case theories with less than a month to go before the hearing".

20. Alexion's principal submission is that a "fundamental change in Board Staff's case at this late stage in the proceedings is manifestly unfair, violates basic principles of due process, and is contrary to the interests of justice. Board Staff have had ample opportunities, and over a year, to amend their Allegations. Alexion has repeatedly sought particulars, including in motions before this Panel. There are no new facts justifying a fundamental change in the case at this late stage, which will clearly delay the fair and expeditious hearing of this matter."[5]

21. In response to Board Staff's motion, Alexion filed affidavit evidence of Anna Di Domenico, John Haslam and Neil Palmer. Relying on these affidavits, Alexion submits

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3 *Apotex Inc. v. Wellcome Foundation Limited*, 2009 FC 117 (CanLII), at 42 – 43 and 53.

4 *Apotex*, supra note 2, at 19.

5 Alexion's Written Submissions, at 5.

that the price for Soliris was set on the basis of expert advice regarding the *Patent Act* and related regulations, and the PMPRB's *Compendium of Guidelines, Policies and Procedures* (the "**Guidelines**"). Alexion alleges that Board Staff now attempts to treat Alexion differently from any patentee who has previously been involved in proceedings before the Board.

22. Alexion states in its written submissions that the significant amendment to the remedies sought by Board Staff "would also fundamentally change the nature of the potential risk to Alexion" in the event that the Panel determines that the price of Soliris is excessive and grants the remedy sought by Board Staff.[6]

23. Alexion relies on the decision of the Federal Court in *Scannar Industries Inc. (Receiver of) v. Canada*,[7] an appeal from an order granting leave to the plaintiff to file an amended statement of claim. The plaintiffs sought to amend the statement of claim, but the appellants argued that the amendments would cause prejudice because of the expiry of limitation periods, the amendments involved withdrawal of an admission, and that the plaintiffs were estopped from relying on the application of a different section of the *Income Tax Act*.

24. The appeal was allowed and the court noted:

> "[C]ounsel for the plaintiffs had plenty of previous opportunities for raising the issue of the validity of the designations and that this motion is by no means "timely". The failure of the plaintiffs to raise the issue beforehand has caused the Minister to take a course of action which is impossible to alter. Specifically, since the reply to the opinion letter was provided and the 1985 return filed, the Minister has acted on the basis that the validity of the designations and these actions cannot be changed retroactively.
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> All of these considerations lead me to conclude that the proposed amendments regarding the designations would cause an irremediable injustice that could not be compensated by an award of costs. Accordingly, the appeal must be allowed".[8]

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6 Alexion's Written Submissions, at 16.

7 (1993) FCJ No 1194; affirmed (1994) FCJ No 984 (FCA) [*Scannar*].

8 *Ibid*, at 29 – 30.

25. The Federal Court of Appeal upheld this decision:

> "By that amendment the appellant sought to repudiate and put in issue the validity of its own actions and the representations it had made to the Minister relating thereto on which the Minister had acted. We agree with the judge that the proposed amendment, which was general in scope and not susceptible of being distinguished as between the various representations made, seeks to withdraw admissions that had been made in the pleadings. Those admissions could not have been made through inadvertence and were of a nature to confirm the representations which the appellant had previously made to the Minister; their withdrawal would itself cause prejudice to the latter." [emphasis added]

26. Alexion also relies on the decision of the Federal Court of Appeal in *Bristol-Myers Squibb Co. v. Apotex Inc.*,[9] an appeal by Apotex from an order dismissing its motion to amend its pleadings. Apotex sought to amend its pleadings approximately one month before the commencement of the trial of an action between the parties. The Federal Court of Appeal noted that the amendments were radical and included issues that were never canvassed during the examinations for discovery and pre-trial processes. The Court found that permitting the amendments would have been an injustice to Bristol-Myers, and noted:

> "The place for Apotex to identify the issues of lack of sound prediction and the broad inutility of nefazodone and its salts was in its 2007 pre-trial memorandum and at the pre-trial conference -- not in a pleadings amendment sought, despite the absence of any further discoveries or new facts, roughly three years later on the eve of trial. "New facts or other compelling circumstances" might allow a party to add new issues after a pre-trial conference (*Wenzel*, at paragraph 24) -- and even then there might be a significant burden to discharge -- but there are no new facts or compelling circumstances here."[10]

Analysis

27. Rule 6 of the *Patented Medicine Prices Review Board Rules of Practice and Procedure* (the "**PMPRB Rules**")[11] grants the Panel broad discretion with respect to

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9 2011 FCA 34. Note that there was also an appeal from Bristol-Myers decided in this decision.

10 *Ibid*, at 29.

11 SOR/2012-247.

procedural issues, including the granting of leave to amend pleadings. Rules 6(1)(d) and (e) of the PMPRB Rules provide:

> "In relation to any proceeding, the Board may:
> […]
> (d) permit the amendment of any document filed with the Secretary; and
> (e) decide any question of procedure."

28. The parties both rely on principles established by Canadian courts with respect to the issue of leave to amend pleadings, as well as procedural rules in other jurisdictions. For example, Rule 26.01 of the Ontario *Rules of Civil Procedure*[12] states: "[o]n motion at any stage of an action the court shall grant leave to amend a pleading on such terms as are just, unless prejudice would result that could not be compensated for by costs or an adjournment." [emphasis added]

29. The Federal Court of Appeal has set out the principles applicable for leave to amend pleadings in *Canderel Ltd. v. Canada (C.A.)*.[13] The court noted that "while it is impossible to enumerate all the factors that a judge must take into consideration in determining whether it is just, in a given case, to authorize an amendment, the general rule is that an amendment should be allowed at any stage of an action for the purpose of determining the real questions in controversy between the parties, provided, notably, that the allowance would not result in an injustice to the other party not capable of being compensated by an award of costs and that it would serve the interests of justice."[14] Citing *Ketteman v. Hansel Properties Ltd.*,[15] the Federal Court of Appeal noted:

> "Whether an amendment should be granted is a matter for the discretion of the trial judge and he should be guided in the exercise of the discretion by his assessment of where justice lies. Many and diverse factors will bear on the exercise of this discretion. I do not think it possible to enumerate them all or wise to attempt to do so. But justice cannot always be measured in terms of money and in my view a judge is entitled to weigh in the balance the strain the litigation imposes on litigants, particularly if they are personal litigants rather than business corporations, the anxieties

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12 RRO 1990, Reg 194.

13 1993 CanLII 2990 [*Canderel*].

14 *Ibid*, at 9.

15 [1988] 1 All ER 38 (HL).

> occasioned by facing new issues, the raising of false hopes, and the legitimate expectation that the trial will determine the issues one way or the other. Furthermore, to allow an amendment before a trial begins is quite different from allowing it at the end of the trial to give an apparently unsuccessful defendant an opportunity to renew the fight on an entirely different defence."[16]

30. The primary issues in this case are whether the amendments raise relevant issues and whether allowing the amendment will cause prejudice and injustice to Alexion that cannot be cured. For the reasons below, the Panel is of the view that the amendments raise issues that are in controversy between the parties and should be determined on the merits, do not cause an injustice to Alexion, and that any prejudice to Alexion can be addressed through an adjournment that provides Alexion additional time to respond to the amendments.

31. Alexion's focus in responding to the motion was that the proposed amendments are inconsistent with the Guidelines and prior positions of Board Staff. Alexion alleges in its written submission that "Alexion has taken firm positions on the basis of the Board's position (since 2009) and Board Staff's position (since the Statement of Allegations was served) that the Guidelines were the 'appropriate' approach and methodology."[17]

32. The issues of whether Board Staff's position in this case is consistent with the *Patent Act*, Guidelines and prior decisions of the Board are issues that will be addressed on the merits at the hearing of this matter, and do not constitute an appropriate basis for refusing to grant leave to amend the Statement of Allegations.

33. In any event, the applicability of the Guidelines to this case is an issue that has been in dispute throughout this proceeding. For example, Board Staff states in paragraph 8 of its Amended Reply:

> "Board Staff's position is and always has been that the price of Soliris is excessive under the Act. Alexion's "belief" as to Board's Staff's "apparent conclusions" is irrelevant as the only relevant issue in this proceeding is whether the price of Soliris has been excessive under the Act. In this

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16 *Canderel*, supra note 13, at 12.

17 Alexion's Written Submissions, at 14.

> regard, Alexion misunderstands the purpose of an investigation into excessive pricing and how that differs from a proceeding before the Board in the context of a hearing. Board Staff's interpretation of the Guidelines and the Regulations are not binding on the Board during a hearing. The hearing is a fresh opportunity for the Board to determine whether a medicine's price is excessive under the Act." [emphasis added]

34. Further, the issue of the appropriate remedy is relevant and applicable only if this Panel determines that the price of Soliris is excessive based on the factors in section 85 of the *Patent Act*. Thus, an amendment related to the appropriate quantum and calculation of any remedy should not affect the parties' submissions with respect to the issue of whether the price of Soliris is excessive under the *Patent Act*.

35. Alexion argues that the amendments to the Statement of Allegations do not relate solely to the potential remedies that may be issued, but impact on the underlying determination of whether the price for Soliris is excessive:

> "In *Apotex Inc. v. Wellcome Foundation Limited,* the amendments related only to the quantum of damages, and had no impact on the underlying claims regarding the validity of the patent. In contrast, Board Staff's proposed amendments materially change the very core of Board Staff's case (i.e., the test to be applied in determining if the price is "excessive") and do not relate solely to the relief claimed."[18]

36. The Panel disagrees with Alexion's submission on this issue. To clarify this point, the Panel requested and obtained confirmation from Board Staff at the hearing of the motion that the proposed amendments to the Statement of Allegations relate solely to the relief claimed and do not affect the determination of whether the price of Soliris is excessive based on sections 83 and 85 of the *Patent Act*. In other words, the proposed amendments relate only to the issue of the remedy that the Panel may order, and do not affect the substance of the primary inquiry of whether the price of Soliris is excessive based on the factors enumerated in section 85 of the *Patent Act*.

37. Further, the Panel notes that the issue of using the lowest price in comparator countries (or the "**LIPC**" test) as a potential remedy was raised by the Ministers of Health in their Further Amended Notice of Appearance dated June 26, 2015, close to a

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[18] Alexion's Written Submissions, at 35.

year ago. In fact, Alexion unsuccessfully attempted to strike out this portion of the Further Amended Notice of Appearance in October 2015. Similarly, at paragraph 7 of its written submissions on the within motion, Alexion submits that it "intended to argue that the remedy sought by the Provinces was improper, as argued in a previous motion before this Panel." Alexion was therefore aware of a potential remedy similar to that sought by Board Staff in the amended Statement of Allegations based on the use of the LIPC methodology.

38. Finally, the Guidelines are not binding on the Panel when determining any remedies to be issued. Rather, the Panel retains the jurisdiction to issue any remedy provided under section 83 of the *Patent Act*, irrespective of the Guidelines. The issue of the appropriate remedy to be granted in any case is a substantive issue that must be determined in the discretion of the Panel based on the merits and circumstances.

39. Although Alexion was aware of the remedy sought by the Ministers of Health and the Panel's overall jurisdiction regarding potential remedies, the proposed amendments to the Statement of Allegations are the first time in this proceeding that Board Staff has expressly sought a remedy based on the LIPC methodology. In addition, the proposed amendments include the specific amounts sought by Board Staff under a LIPC approach (and other potential approaches), as well as amounts based on the use of different data sources.

40. It was also not clear until recently what evidence, if any, the Ministers of Health would file with respect to the issue of remedies, and in particular, the LIPC. The witness statement of Eric Lun dated May 6, 2016 and filed by the Ministers of Health refers to evidence regarding the LIPC test (specifically, a reference at paragraph 49 to the pricing approach of Soliris in the United Kingdom).

41. In light of these developments, the Panel finds that Alexion should be provided with an opportunity to respond to the alternate remedies sought by Board Staff, and in particular, remedies based on the LIPC approach set out by Board Staff and as initially proposed by the Ministers of Health. The Panel recognizes that Alexion may require additional time to address the amendments by Board Staff and submit revised evidence

or even additional evidence to properly respond to the amendments by Board Staff regarding the issue of remedies.

42. Unfortunately, as described in further detail below, given that Board Staff has sought this amendment approximately one month prior to the commencement of the hearing of this matter, providing Alexion with additional time requires an adjournment of the hearing and certain of the pre-hearing procedures. Nevertheless, the Panel is of the view that such an adjournment is necessary to provide Alexion with a limited period of time to respond to the specific issues raised by the amendments to the Statement of Allegations.

2. Motion to Strike Certain Portions of Will-Say Statement of Barry Katsof

43. Board Staff also seeks an order striking out portions of paragraphs 7, 8, 9, 10 and 11 of the will-say statement of Barry Katsof, or in the alternative, seeks an order requiring Alexion to file an amended will-say statement containing particulars of the "vague allegations" contained in paragraphs 10 and 11 of the statement.

44. The relevant portions of Barry Katsof's will-say statement which Board Staff is seeking to strike are:

> "[...] With advances in molecular genetics and other areas of medical science, scientists are now able to better understand the causes of certain diseases (many of them uncommon, rare or 'ultra-rare' diseases, like PNH) and develop medicines targeted specifically at the cause (or presumed cause) of those diseases. The development of these medicines is as expensive, time-consuming, labour-intensive and risky as the development of medicines has ever been, but with these diseases, the patient pool of potential 'beneficiaries' of the research is very small. He will testify that the 'trend' in recent years has increasingly been to the identification of causes of rare diseases and the development of medicines targeted to those specific diseases.
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> [...] The aggregate cost to private payers and publicly-funded healthcare schemes of ultra-rare disease therapies for very small patient populations is extremely low. He will testify that it is the same in the United States, and other countries throughout the Western world and beyond. He will testify that Soliris is not the most expensive medicine available either in Canada or in other developed countries, and he will explain that Soliris and other

> ultra-rare disease medicines are paid for by private insurers and/or publicly-funded drug payment schemes in those other countries. He will say that the situation in Canada should be no different.
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> [...] He will explain that, unlike many other medicines that are paid for by private insurers or publicly funded drug payment schemes, Soliris is extremely effective in treating PNH and has a life-transformational benefit. [...] If value for money spent is a criterion by which a drug is evaluated then, in Mr. Katsof's view, and in the view of the Association which he heads, Soliris is one of the most cost effective medicines currently available on the market today.
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> Mr. Katsof will testify that provincial drug payment schemes waste a significant portion of their budgets funding medicines that are not as effective or are unnecessary in certain populations or sub-populations of patients and that whatever criticisms one may have about Soliris, efficacy, by any measure, is not a valid criticism. Mr. Katsof will provide examples of such waste.
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> Mr. Katsof will also provide additional relevant information relating to the utility and price of Soliris and other medicines."

45. Board Staff submits that Mr. Katsof is a lay witness and is not being called as an expert witness. Board Staff alleges that the paragraphs to be struck contain statements of opinion that would only be permissible if the witness was qualified as an expert. Alternatively, Board Staff seeks additional particulars of paragraphs 10 and 11 of Mr. Katsof's witness statement on the basis that these portions lack material details regarding allegations of how provincial drug payment schemes waste a significant portion of their budgets and information relating to the utility and price of Soliris and other medicines.

46. The exchange of witness statements prior to a hearing enables each party to understand the other side's case and assists the Panel in structuring the hearing. In this matter, the parties have filed will-say statements indicating the issues that witnesses intend to address in their testimony. These statements should be contrasted with more fulsome witness statements or affidavit evidence that function as substitutes for the examination-in-chief of a witness.

47. It is premature to seek to strike out or request particulars of certain portions of a will-say statement of Mr. Katsof. The will-say statements filed in this matter do not

constitute evidence. Accordingly, to the extent that Board Staff wishes to object to any of the statements found in the will-say statement, the appropriate procedure is to raise an objection during the hearing to any portion of the testimony of Mr. Katsof.

48. The Panel has noted the objections raised by Board Staff to portions of Mr. Katsof's will-say statement and the Panel is aware that Mr. Katsof is not being proffered as an expert witness. Board Staff's motion to strike out or request particulars of certain portions of Mr. Katsof's will-say statement is thus dismissed, without prejudice to any objections that may be made by Board Staff during the course of the testimony of Mr. Katsof at the hearing.

3. Importance of Case Management

49. Section 97(1) of the *Patent Act* provides: "All proceedings before the Board shall be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit."

50. Given the recent developments in this matter, the Panel feels that it is important to remind Board Staff and Alexion of the importance of case management and the role of the parties in ensuring that proceedings before the Board are discharged in accordance with the Board's mandate to resolve matters as expeditiously as fairness permits.

51. Under Rule 22 of the PMPRB Rules, each proceeding before the Board requires a case management conference within 45 days of the issuance of the notice of hearing for the purposes of, *inter alia*, fixing the hearing schedule and filing of evidence. Case management is widely accepted as a key factor in successfully reducing delays and increasing judicial efficiency. Among other objectives, case management is designed to organize and expedite the proceeding and reduce litigation costs.

52. Consistent with these objectives, the Panel issued a Scheduling Order on December 7, 2015. The Scheduling Order was determined in consultation with and on consent of both Board Staff and Alexion. The Scheduling Order set out the hearing dates and remaining steps leading up to the hearing of this matter.

53. In many respects, Board Staff's proposal to amend the Statement of Allegations approximately one month prior to the commencement of the hearing has necessitated an adjournment and the delay of this proceeding.

54. Further, although the hearing dates were established in December 2015 for the hearing, the Panel was only advised at the most recent pre-hearing conference (six months later) that an additional nine hearing days are required for this case, amounting to twice as much hearing time as originally agreed upon by the parties, with additional days for closing arguments. The requirement for additional hearing days beyond those agreed upon by the parties in December will further delay this proceeding.

55. Although the Panel has adjourned this hearing for the reasons set out above, all participants shall be required to strictly comply with the revised schedule once established, and the Panel will not allow for any further delay of this proceeding. In particular, to ensure that this proceeding is dealt with as expeditiously as fairness permits, once the hearing dates have been established by the Panel, no further adjournments of this hearing will be granted by the Panel.

Conclusion and Order

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

(a) Board Staff's motion to amend its Statement of Allegations is granted;

(b) The hearing of this matter is adjourned to a date to be determined to allow Alexion an opportunity to respond to the amended Statement of Allegations. The Panel will confer with the parties to set a schedule for the hearing, including the deadlines for filing any additional evidence; and

(c) Board Staff's motion to strike or provide particulars of certain portions of the will-say statement of Barry Katsof is dismissed, without prejudice to any objections that may be made by Board Staff during the course of the testimony of Mr. Katsof at the hearing of this matter.

Dated at Ottawa, this 10th day of June, 2016.

Original signed by Dr. Mitchell Levine

Signed on behalf of the Panel by
Dr. Mitchell Levine

Panel Members:

Dr. Mitchell Levine
Carolyn Kobernick
Normand Tremblay