PATENTED MEDICINE PRICES REVIEW BOARD

IN THE MATTER OF the *Patent Act*,
R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER OF
Alexion Pharmaceuticals Inc. (the "Respondent")
and the medicine "Soliris"

WRITTEN REPRESENTATIONS OF BOARD STAFF IN RESPONSE TO ALEXION'S MOTION TO STRIKE PARAGRAPH 7 AND THE AMENDED PORTION OF PARAGRAPH 9 OF THE AMENDED REPLY OF BOARD STAFF

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OVERVIEW

1. As Alexion has known from the outset, there is only one cause of action in these proceedings. That is whether Alexion is selling Soliris at an excessive price under the *Patent Act* (the "**Act**").

2. At paragraph 7 of its Amended Reply, Board Staff confronts Alexion's claim that the price of Soliris cannot be excessive under the Act. Board Staff pleads additional facts relating to Alexion's costs and such other factors to demonstrate that the excessive price of Soliris cannot be justified. The amendment is pleaded to defeat Alexion's claim and is therefore proper reply.

3. At the amended portion of paragraph 9 of the Amended Reply, Board Staff admits and states the applicable law known to the parties under section 85 of the Act. Board Staff did not actually have to plead section 85(2) of the Act or a point of law, but has done so for completeness and to clarify the issues in dispute between the parties. The amendment is therefore proper reply.

4. Alexion argues that the impugned amendments should be struck because they add a "new cause of action." However, a new cause of action is not a ground for striking pleadings under Rule 221 of the *Federal Courts Rules*. Furthermore, the impugned paragraphs of the pleadings relating to the Board's discretion under subsection 85(2) of the Act do not add a new cause of action. Subsection 85(2) merely sets out additional factors and the conditions by which the Board may exercise its discretion to determine the single issue, which is whether the price of Soliris is excessive under section 85 of the Act. Alexion, therefore, fails to

establish any basis for striking the impugned amendments under both the proper legal test and its own erroneous test.

5. Furthermore, Board Staff was not obligated to and could not anticipate any justification Alexion may have sought to advance under subsection 85(2) in its Statement of Allegations. It is Alexion who knows its own costs and any justification it may have for its excessive price. Alexion therefore had a full opportunity to respond by pleading its own facts, but chose not to do so. Alexion's tactical decision does not now bar Board Staff from relying on such facts in reply and to confront Alexion's claim.

6. Consequently, no basis exists for striking the impugned amendments nor is Board Staff required to seek leave to amend its Statement of Allegations for amendments that are proper reply. Alexion's motion can only be understood, therefore, as an attempt to limit Board Staff from making a full and substantial reply and to once again limit the Board in its inquiry into the price of Soliris under the Act.

7. For the foregoing reasons, Alexion's motion should be dismissed, and Alexion should amend its Amended Response (if it chooses to do so) to plead any additional facts relating to its costs or any other justification it may have for its excessive price.

PART I – STATEMENT OF FACTS

8. This motion is one of four pending motions that Alexion has currently filed with the Board in an attempt to thwart the Board's inquiry into the price of Alexion's medicine Soliris.

9. On 20 January 2015, the Notice of Hearing was issued and served on Alexion. The Notice of Hearing states: "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." In its Statement of Allegations, Board Staff seek an Order requiring Alexion to, among other things, stop selling Soliris to Canadians at a price that is excessive under the Act. From the outset, therefore, Alexion understood that the issue before the Panel was whether the price of Soliris was excessive under the Act, which includes subsection 85(2).

10. Following an extension, Alexion filed its original Response on 9 March 2015.

11. Further to its Order of 23 June 2015 regarding requests for particulars, the Panel granted leave to Alexion and Board Staff to file an Amended Response and an Amended Reply, respectively.

12. Nearly one month later, Alexion filed its Amended Response.

13. On 31 July 2015, Counsel for Board Staff filed a motion to strike paragraphs 37 and 38 of the Amended Response on the grounds that they were irrelevant, vexatious and an abuse of process.

14. On 21 August 2015, Alexion filed the following three motions: Alleged Conflict of Interest (which the Panel dismissed on 5 October 2015); Disclosure of Documents; and Motion to Strike Further Amended Notice of Appearance (of Her Majesty the Queen in the Right of the Province of British Columbia, as represented by the Minister of Health). These motions are in addition to a Motion relating to Confidentiality that Alexion previously filed.

15. Further to the Board's Order dated 5 August 2015, Board Staff filed its Amended Reply on 1 September 2015.

16. On 9 September 2015, Alexion filed this motion to strike two amendments (paragraph 7 and the amended portion of paragraph 9) of Board Staff's Amended Reply.

PART II – STATEMENT OF LAW

A. No Basis Exists to Strike the Amendments

17. Rules 5, 6 and 32 of the Rules of Practice and Procedure (the "**Rules**") establish the Board's powers to deal with procedural motions, including by issuing decisions and making orders. Accordingly, the Rules authorize the Board to strike pleadings in appropriate cases.

18. Although the Rules do not expressly set out the grounds upon which pleadings may be struck, the Board may take guidance from the *Federal Court Rules*. Rule 221(1) of the *Federal Court Rules* provides as follows:

> 221. (1) 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
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> (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,
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> and may order the action be dismissed or judgment entered accordingly.

19. Significantly, Alexion does not argue that the amendments should be struck under any of the factors in Rule 221. Alexion does not argue that the amendments disclose no reasonable cause of action; are immaterial; vexatious; cause prejudice; constitute a departure from a previous pleading; or are otherwise an abuse of the Court process. This is because no such grounds

exist. Rather, Alexion argues that the amendments should be struck because they add "new causes of action." This is not a permissible basis for striking amendments to pleadings. Accordingly, Alexion has failed to meet its burden and its motion to strike must fail.

20. In any event, subsection 85(2) does not add a new cause of action. In *Letang v Cooper,* Lord Diplock offered the following well-established definition of "a cause of action:"

> A cause of action is simply a factual situation, the existence of which entitles one person to obtain from the Court a remedy against another person.[1]

21. In this case, there is only one cause of action — the allegations of excessive pricing under section 85 of the Act. Section 85 of the Act sets out the entirety of the excessive pricing regime. It also establishes the basis upon which a remedy may be obtained from the Board.

22. Section 85 of the Act states:

> 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;
> (*b*) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
> (*c*) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;

[1] *Letang v Cooper,* [1964] EWCA Civ 5 (15 June 1964) *[http://www.bailii.org/ew/cases/EWCA/Civ/1964/5.html]*

> (*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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> (2) 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;
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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.
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> (3) In determining under section 83 whether a medicine is being or has been sold in any market in Canada at an excessive price, the Board shall not take into consideration research costs other than the Canadian portion of the world costs related to the research that led to the invention pertaining to that medicine or to the development and commercialization of that invention, calculated in proportion to the ratio of sales by the patentee in Canada of that medicine to total world sales.

23. In *PENLAC*,[2] the Board explained the nature of its inquiry under section 85 of the Act as follows:

> On the other hand, the Guidelines are not binding on the Board. Furthermore, situations could arise that are not contemplated by the Guidelines, or changes in medicine or the marketing of medicines in Canada could give to situations that are no longer covered appropriately by the Guidelines. In each case where the review of the pricing of a medicine comes before a panel of the Board, the panel must determine whether the medicine is priced excessively within the terms of section 85 of the Act. To the extent that the Guidelines speak to this issue, the panel must determine whether the Guidelines provide for an appropriate and reasonable implementation of the factors in section 85 of the Act before establishing an MNE by the terms of the Guidelines. If the Guidelines do not result in an appropriate implementation of section 85 of the Act, the panel must depart from the Guidelines (emphasis added).[3]

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[2] *Sanofi-aventis Canada and the medicine "Penlac Nail Lacquer"* PMPRB-07-D2-PENLAC- Merits.
[3] *Ibid.* at para. 16.

24. Subsection 85(2) is part of section 85 and merely sets out additional factors (to those in 85(1)) that the Board may consider in exercising its discretion to determine whether the price of Soliris is excessive under the Act. It does not, therefore, establish a separate cause of action that may be brought under the Act.

25. Accordingly, *Drywall v SNC-Lavalin Group Inc*,[4] upon which Alexion relies, also does not apply. In that case, the plaintiffs actually sought to introduce a new cause of action that was impermissible both in the Statement of Allegations and therefore equally impermissible in reply.

26. No basis exists, therefore, to strike the amendments under the applicable legal test on a motion to strike under Rule 221 of the *Federal Courts Rules* or on Alexion's erroneous test to strike based on a "new cause of action". Furthermore, the amendments are consistent with the Rules and, therefore, proper reply.

B. The Amendments are Proper Reply

27. The Rules set out the requirements for pleadings. Rule 18(2) sets out the form and content of a response. The Rule provides that a response "must include an admission or denial of each ground or material fact set out in the statement of allegations or notice of application;" and "the grounds on which the proposed order is opposed and the material facts on which the respondent is relying."

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[4] *Drywall v SNC-Lavlin Group Inc.* 2014 ONSC 660.

Accordingly, the responding party may plead its own version of the facts in its response.

28. In its Amended Response, Alexion claims that the price of Soliris cannot be excessive under the Act. At the same time, Alexion deliberately chose not to rely on any material facts relating to its costs or any other justification it may have for its excessive price, even though the information was properly within its knowledge and it understood that the issue was whether the price of Soliris is excessive under the Act.

29. The purpose of the reply is to confront the response. In *Am Int. Inc. v. National Business Systems Inc.,* the Federal Court explained that an answer or reply "requires that a party shall plead specifically any matter that he alleges makes a claim or defence of the opposite party not maintainable, that if not specifically pleaded might take the opposite party surprise, or that raises issues of fact arising out of the preceding pleading."[5]

30. Rule 19 sets out the form and content of the reply. The Rule provides that a reply "must set out an admission or denial of each ground or material fact that was set out in the response." The *Federal Court Rules* also provide additional guidance as to the meaning of an "admission" or "denial" in a reply. Rule 183 states:

> 183. In a defence or subsequent pleading, a party shall
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> (*a*) admit every allegation of material fact in the pleadings of every adverse party that is not disputed;

[5] *Am International, Inc. v. National Business Systems Inc.* [1982] 2 F.C. 106 at para 2.

> (*b*) where it is intended to prove a version of facts that differs from that relied on by an adverse party, plead that version of the facts; and
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> (*c*) plead any matter or fact that
> (i) might defeat a claim or defence of an adverse party, or
> (ii) might take an adverse party by surprise if it were not

31. In admitting or denying a ground or material fact under Rule 19, Board Staff may thus, among other things, plead grounds or facts that might defeat the opposing party's claim. Board Staff may also plead material facts that the adverse party has not previously pleaded.

32. As it relates to the pleading of law, Board Staff is not required to plead a statute that declares the general law, as the Board can take judicial notice of it.[6]

33. Also, consistent with Rule 175 of the *Federal Court Rules,* a party is not required to plead a point of law, but may do so. As the Federal Court of Appeal explained in *Harmony Consulting Ltd. V G.A. Foss Transport Ltd.*:

> Although the purpose of pleadings…is to narrow the scope of the issues to be decided at trial so that the opposite party can prepare for trial, pleadings are also intended to deal only with the material facts upon which the parties rely to establish their legal positions… a party may include allegations as to the law, they never bind the Court on such issues. Further, a court is bound to decide questions of law on the basis of all the evidence presented or entered on the record without any objections.[7]

34. The impugned amendments are consistent with the Rules and the foregoing principles. At paragraph 7 of the Amended Reply, Board Staff confronts

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[6] *McBurney v. R*, [1985] F.C.J. No. 821 at p. 11.
[7] *Harmony Consulting Ltd. v. G.A. Foss Transport Ltd.*, 2012 FCA 226 at para. 41.

Alexion's claim that the price cannot be excessive and that it was beyond Alexion's control that the price was excessive under the Act. More specifically, Board Staff pleads that Alexion has failed to justify its excessive price under subsection 85(2) of the Act. It particularizes this ground by pleading material facts relating to the costs of Soliris and such other factors that might defeat Alexion's claim on an issue that was known to Alexion. The amendment is thus plainly proper reply.

35. At paragraph 9 of the Amended Reply Board Staff admits and agrees with Alexion that the Guidelines are not binding and that the Board must consider the factors under subsection 85(1) of the Act to determine whether the price of Soliris is excessive. Board Staff also admits that where the Board cannot determine that the price is excessive under subsection 85(1) of the Act, it may consider the factors under subsection 85(2). Although Board Staff is not required to plead the statute or a point of law, it has done so for certainty, completeness, and to clarify the issues between the parties. The amendment is plainly proper reply.

36. Further, Board Staff could not and were not obligated to anticipate any justification Alexion may have for its excessive price in its Statement of Allegations.

37. Alexion has always known that the issue before the Board is whether the price of Soliris is excessive under the Act. Alexion also knows its own costs and any other justification it may have for its excessive price and could plead to these facts. It has therefore had full opportunity to respond. It did so by making a

tactical decision not to plead these facts. Alexion cannot now bar Board Staff from relying on such facts to defeat Alexion's claim or as a basis for the Board's discretion under the Act. To hold otherwise would allow Alexion to use its tactical decision to prejudice Board Staff from advancing a full and substantial response to confront Alexion's claim.

38. Consequently, no basis exists for striking the amendments under Rule 221 of the *Federal Courts Rules* or for Board Staff to seek leave to amend its Statement of Allegations for amendments that are proper reply. Alexion's motion should therefore be dismissed, and Alexion should amend its Amended Response (if it chooses to do so) to plead any additional facts relating to its costs or any other justification it may have for its excessive price.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 19th day of October, 2015

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