

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

ALEXION’S WRITTEN REPRESENTATIONS

(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)

Introduction

1. Board Staff requests an Order striking out paragraph 37 and the second sentence of paragraph 38 (the “impugned paragraphs”) of Alexion’s Amended Response (“Amended Response”).
2. Alexion requests an Order striking out paragraph 7 and the amended portion of paragraph 9 of Board Staff’s Amended Reply.
3. On 2 September 2015, Alexion delivered written representations dealing with Board Staff’s failure to observe disclosure obligations and the conflict of interest raised by Isabel Raasch’s involvement in the proceeding. The written representations previously delivered already address, in part, Board Staff’s request to strike the impugned paragraphs. Alexion therefore asks the Panel to refer to the previous written representations in conjunction with these submissions.

Overview

4. The Panel should dismiss Board Staff's motion. The issues raised in the impugned paragraphs are the subject of either interlocutory motions already before the Panel, or will be dealt with at the hearing. The allegations relate to the proper conduct of the proceeding, which is in the nature of a prosecution against Alexion for alleged abuse of its patent for Soliris. The pleadings in a prosecution before the Board do not require the same degree of formality as pleadings in a civil court proceeding.

5. In any event, proper characterization of Board Staff counsel's status—in particular whether they are, or are akin to, prosecutors—is relevant and within the Panel's jurisdiction. Characterization of Board Staff counsel's status, and the obligations flowing from that status, are important when considering Board Staff's document disclosure obligations, the type of allegations Board Staff can properly make in an excessive price proceeding, and the appropriate response by Board Staff to issues raised by interveners. The Panel must substantively address the allegations whether made in the Response or in interlocutory motion materials.

6. The test to strike pleadings in civil proceedings is notoriously difficult to meet. A party must show that it is "plain and obvious" that a claim or defence has no merit. Only in rare cases will pleadings be struck out as disclosing no reasonable basis for a substantive issue. Board Staff cannot meet the test in this case. Indeed, Alexion submits that a compelling case can be made that Board Staff counsel have not complied with their disclosure obligations, that Isabel Raasch has a conflict of interest, and that it is improper for Board Staff counsel to themselves advance legal positions, or

for Board Staff counsel to support legal positions advanced by interveners, that have no foundation in the *Patent Act* or the Guidelines.

7. While the impugned paragraphs raise issues about whether Board Staff have met their obligations, and use direct and forceful language, it is not plain and obvious that the allegations are scandalous, vexatious, or an abuse of process. The allegations should be adjudicated, whether in interlocutory motions or at the hearing, even if an adjudication may create inconvenience or discomfort for Board Staff and their counsel. It is not in the public interest for Board Staff, or their counsel, to be permitted to bring motions to strike pleadings as a means of immunizing themselves from legitimate criticism of their conduct of a proceeding.

8. On 1 September 2015, Board Staff counsel delivered an Amended Reply to the Amended Response ("Amended Reply"). The Amended Reply raises new allegations of excessive pricing that are not properly the subject of a reply pleading. Board Staff require the Panel's leave to amend the Statement of Allegations ("Allegations") to plead new excessive pricing allegations with sufficient particularity. Assuming leave to amend is granted, the principles of fairness and natural justice require Alexion to be provided the opportunity to respond to the new allegations.

Background Facts

a) Impugned Paragraphs

9. On 17 July 2015, Alexion delivered its Amended Response consistent with the Panel's direction in their order released on 23 June 2015. The Amended Response

includes allegations that Board Staff counsel have not been “conducting themselves in a manner consistent with ethical principles applicable to their prosecutorial role.”

10. In particular, Alexion alleges that Board Staff and their counsel—who are described in the Guidelines, the Board’s Annual Report, and in various case law as having a prosecutorial role—have taken an overly adversarial approach that conflicts with their prosecutorial obligations. To illustrate, Alexion cites Board Staff counsel’s refusal to make timely disclosure of documents. Alexion also alleges that Board Staff counsel are themselves advancing, and encouraging interveners to advance, positions inconsistent with the *Patent Act*, the *Patented Medicines Regulations*, the Guidelines, and jurisprudence dealing with the Board and its powers.

11. Alexion also alleges in the Amended Response that the only basis for Board Staff advancing a prosecution in this case lies in a comparison of the price of Soliris in Canada with the price of the medicine when sold outside Canada. The comparative exercise must result in a determination whether the Canadian price is somehow excessive (or abusive), in which case Alexion may be required to disgorge about \$6.4 million of its Canadian revenues to the Crown. Alexion objects to Board Staff counsel using rhetorical assertions about Soliris being “expensive” and “priced higher in Canada than in the United States”, when such assertions have no relevance to the comparative analysis under the *Act*, the Regulations, or the Guidelines. Alexion further asserts that these statements are calculated to distract and/or deflect attention away from the only issue for which relief is sought by Board Staff: whether the price of Soliris was excessive between 2012 and 2014 even though the price was not deemed excessive in 2010 and 2011 when Soliris was sold in Canada at the same price.

12. Alexion also takes objection in the Amended Response to the activities of Isabel Raasch. On 13 July 2015, just days before the Amended Response was due, Alexion learned that Ms. Raasch, a former Gowlings partner hired by the Board in early July 2015, had become involved in the prosecution. Ms. Raasch was a Gowlings partner for several months coinciding with Gowlings' representation of Alexion and owed a duty of loyalty to Alexion. Alexion has addressed the serious nature of this issue, and applicable principles to deal with disqualifying conflicts, in its written representations delivered on 2 September 2015.

13. In the second sentence of paragraph 38 of the Amended Response, Alexion asserts Board Staff's disclosure failures should prevent Board Staff counsel from introducing new "excessive pricing" allegations.

b) Amended Reply

14. On 1 September 2015, Board Staff counsel delivered the Amended Reply. In paragraph 7, Board Staff allege, for the first time, that "Alexion has failed to justify its excessive price under subsection 85 (2) of the Act" followed by allegations concerning Alexion's research and development costs and profit margins. In paragraph 9, Board Staff counsel again make reference to section 85 (2) of the *Patent Act*, but without articulating any new "material facts" or other details supporting the allegation.

The Law

Rules

15. Sections 15, 18, and 19 of the Board's Rules, which concern pleadings, state in pertinent part, as follows:

NOTICE OF HEARING

15. (1) Proceedings are initiated by issuance of a notice of hearing signed by the Secretary.

(3) A notice of hearing must be accompanied by

(a) in the case of an allegation of a patented medicine sold at an excessive price, a statement of allegation set out in consecutively numbered paragraphs containing the material facts, the allegations in the order sought by Board staff in the proceeding...

RESPONSE

18. (1) A respondent who wishes to oppose the making of an order sought by Board Staff that is set out in a statement of allegation... within 20 days after being served with the notice of hearing, file with the Secretary and serve on all other parties a response that is dated and signed by the respondent.

(2) A response must be set out in consecutively numbered paragraphs and must include

(a) an admission or denial of each ground or material fact set out in the statement of allegation or notice of application;

(b) the grounds on which the proposed order is opposed in the material facts on which the respondent is relying...

REPLY

19. (1) if Board Staff wishes to reply to the response it must, within 20 days after being served with the response, file with the Board and serve on all other parties a reply that is dated and signed by Board Staff.

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

(3) If Board Staff does not file a reply, it is deemed to have denied each ground in each material facts alleged in the response.

16. Board Rule 5 deals with general discretion over a proceeding or part thereof:

5. (1) A proceeding or any part of a proceeding may not be defeated by reason only of a defect in form or procedure.

(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.

(3) For the purpose of ensuring the fair and expeditious conduct of any proceeding, the Board may vary, supplement or dispense with any requirements set out in these Rules.

17. While Board Rule 25 generally provides guidance to the Panel in relation to "interlocutory matters", it provides no direction on the substance of individual motions. The Board's rules contain no explicit power to strike pleadings, or parts thereof.

The Plain and Obvious Test

18. Canadian courts have long held that a moving party seeking to strike a pleading must show that it is "plain and obvious" that the pleading is devoid of merit. For example, in *Canada (A.G.) v. Inuit Tapirisat of Canada*, [1980] 2 S.C.R. 735 (QL), Estey J. wrote for the unanimous Court that allegations or claims should be struck only in the clearest of cases:

On a motion such as this a court should, of course, dismiss the action or strike out any claim made by the plaintiff only in plain and obvious cases

and where the court is satisfied that "the case is beyond doubt": *Ross v. Scottish Union and National Insurance Co.* [(1920), 47 O.L.R. 308 (App. Div.).]

19. In *Chez FM, Inc. v. Telemidia Communications Inc.*, [1991] F.C.J. no. 948 (F.C. T.D.) (QL), the Federal Court interpreted the test as placing a "heavy onus" on the moving party to show that there is no doubt as to the viability of the claim or defence:

In the case of a motion to strike out a statement of claim pursuant to rule 419(1)(a) the words "plain and obvious" impose upon the applicant a heavy onus. The Court will not grant the motion where it entertains a doubt as to whether or not there exists a reasonable cause of action. Where time and skilful argument are needed to establish that something is "plain and obvious" it is doubtful that that something is "plain and obvious" after all. (*Burnaby Machine & Mill Equipment Ltd. v. Industrial Supply Co. Ltd. et al.* (*supra*) per Dubé J.)

20. The heavy onus on the moving party imposed by the "plain and obvious" test is the same whether the allegation is that the impugned pleading fails to disclose a reasonable claim or defence or is frivolous, vexatious, or an abuse of process. As stated in *Sussmann v. Ottawa Sun*, [1997] O.J. No. 181 (Sup. Ct. J.) at para. 21:

I am of the view that dismissing or staying an action as frivolous or vexatious or abusive of the Court's process must be reserved for the clearest of cases where on the face of the action and circumstances it is plain and obvious that the case cannot succeed.

21. It is respectfully submitted that Board Staff cannot meet the plain and obvious test for the impugned paragraphs, or any part thereof. It is not plain and obvious, or beyond doubt, that the impugned paragraphs have no merit or that the allegations are scandalous, vexatious, or an abuse of process. Indeed, the Panel may well accept the allegations, or some of the allegations, in the current round of interlocutory motions

concerning document disclosure and the conflict arising from Ms. Raasch's participation in the prosecution.

22. Application of the "plain and obvious" test on Board Staff's motion must be distinguished from Alexion's motion to strike portions of the Ministers' Amended Appearance. The scope of a statutory intervention by the Ministers is a threshold jurisdictional and legal question that is not subject to the "plain and obvious" test. By analogy, a motion may be brought under Ontario Rule 20.01(3)(a) or (b) to dismiss a legal proceeding on the grounds that the court has no jurisdiction over the subject matter of the action or that the plaintiff is without legal capacity to commence or continue an action, or under or under Rule 220 of the *Federal Courts Rules* to determine a question of law. The Alexion motion concerns whether the Panel has jurisdiction to adjudicate some of the Ministers' claims and whether the Ministers have the capacity to assert the claims.

23. There is a sound basis for the Panel to conclude that Board Staff and their counsel are in fact bound by the same type of obligations as a criminal prosecutor. Authoritative case law considering the pertinent sections of the *Patent Act* has always characterized excessive pricing as a species of "patent abuse". For example, in *Celgene Corp. v. Canada (Attorney General)*, [2011] 1 F.C.R. 78 (Fed. C.A.) the court stated:

16 The mandate of the Board is to ensure that patentees do not abuse the monopoly created by the grant of a patent with respect to a medicine by charging excessive prices to consumers in Canada. The regime administered by the Board replaced the system of compulsory licensing, which was abolished in 1993. Price regulation during the life of the patent, rather than the injection of competition through compulsory licensing, thus

became the means of protecting consumers from excessive prices for patented medicines. [Emphasis added.]

24. When the Supreme Court of Canada considered the same case [*Celgene Corp. v. Canada (Attorney General)*, [2011] S.C.J. No. 1 (SCC)] Justice Abella wrote:

28 The Board's consumer protection purpose was affirmed in *ICN Pharmaceuticals Inc. v. Patented Medicine Prices Review Board* (1996), 108 F.T.R. 190, aff'd [1997] 1 F.C. 32 (C.A.), where Cullen J. said:

Sections 79 to 103 of the Patent Act, creating the Patented Medicine Prices Review Board, were enacted in response to the abolition of the compulsory licensing regime. Parliament's intent was certainly to address the "mischief" that the patentee's monopoly over pharmaceuticals during the exclusivity period might cause prices to rise to unacceptable levels. Accordingly, the words of these sections of the Patent Act should be read purposively... . [Underling in original SCC; para. 24.]

29 This is the approach to its mandate that the Board applied, one that took into paramount account its responsibility for ensuring that the monopoly that accompanies the granting of a patent is not abused to the financial detriment of Canadian patients and their insurers. [Underlining added.]

25. Recently, in *Sandoz Canada Inc v. Canada (Attorney General)*, [2014] F.C.J. No. 522 (Fed. TD), the Court wrote:

20 First, it is clear that the relevant provisions of the Act were enacted out of concern that patent holders could take undue advantage of their monopolies to the detriment of Canadian consumers. They "address the 'mischief' that the patentee's monopoly over pharmaceuticals during the exclusivity period might cause prices to rise to unacceptable levels" (*Celgene*, at para 28). The Board's paramount responsibility is to ensure "that the monopoly that accompanies the granting of a patent is not abused to the financial detriment of Canadian patients" (*Celgene*, at para 29). In short, the legislation aims to ensure that patent holders cannot take undue advantage of their monopolies and it should be interpreted in keeping with that purpose (*Shire Biochem Inc v Canada (Attorney General)*, 2007 FC 1316, at para 23). Accordingly, the Board should confine its role to reviewing prices charged by patent holders, who benefit from a time-limited monopoly, to determine whether those prices are

excessive. As Justice Johanne Gauthier stated, Parliament intended the Board "to control the market power of the monopoly created by the exclusivity of the patent" (*Sanofi Pasteur Limited v Attorney General of Canada*, 2011 FC 859, at para 6).

21 Second, while the federal government can regulate patents of invention, it has no overall jurisdiction to regulate the price of generic versions of patented medicines. That responsibility falls squarely on the provinces (*Katz Group Canada Inc. v Ontario (Health and Long-Term Care)*, 2013 SCC 64, at para 3). The provisions of the Act creating the Board have been upheld as constitutional on the basis that they fall within the federal jurisdiction over patents of invention. In 1991, Justice Dureault of the Manitoba Court of Queen's Bench found that the 1987 amendments to the Act extending the duration of patent protection and creating the Board (SC 1987, c 41) served a dual purpose -- to increase patent protection for new medicines, and to address the potential abuse of monopolies through excessive pricing by patent holders (*Manitoba Society of Seniors Inc v Canada (Attorney General)*, (1991), 77 DLR (4th) 485, at para 21, aff'd (1992), 96 DLR (4th) 606 (Man CA))....[Underlining added.]

26. Board Staff are thus generally charged with prosecuting cases where patentees are alleged to have engaged in "abuse", have "abused", or otherwise taken "undue advantage" of their patent.

27. In this case, Board Staff counsel must demonstrate to the Panel that Alexion engaged in patent abuse between 2012 and 2014 even though there is no allegation of abuse in 2010 and 2011 when Soliris was sold in Canada at the same price. The difficulty with Board Staff's position is underscored by the Guidelines, which acknowledge that "exchange rate variations" are "events beyond the control of the patentee." (See: Schedule 6, paragraph 3).

28. The impugned paragraphs essentially allege that Board Staff and their counsel have resorted to allegations outside the *Act* and Guidelines to overcome the problem that it is difficult, if not impossible, to allege any form of "abuse" when events giving rise

to the alleged abuse are exchange rate variations over which Alexion has no control. These allegations should clearly be adjudicated and not struck out.

29. The potential consequences to Alexion in the proceeding are very serious. The disgorgement order sought, almost \$6.4 million, is greater than fines meted out by Canadian criminal courts for violations of environmental, competition, and workplace safety laws: See, for example: *R v Syncrude* (poisoned waterfowl - \$3 million fine); 3 *R v Furukawa Electric Co.* (auto parts bid-rigging -\$5 million fine); *R v NSK Ltd.* (auto parts bid-rigging - \$4.5 million fine); *R v Maxzone Auto Parts (Canada) Corp.* (auto parts cartel - \$1.5 million fine); and *R v Metron Construction Corp.* (workplace swing stage accident - \$750,000 fine).

30. A \$6.4 million disgorgement order payable to the Crown based upon “abuse” of a patent in circumstances where events giving rise to the alleged excessive revenue are beyond the control of the patentee raises significant, and troubling, legal questions. But rather than candidly acknowledging the problematic nature of the prosecution, Board Staff counsel:

- (a) commenced a prosecution without evidence to support the Allegations;
- (b) resorted to irrelevant allegations (that Soliris is “expensive” and priced higher in Canada than in the United States);
- (c) refused to disclose how s. 85 (1) of the *Act* is engaged in the circumstances; and
- (d) failed to disclose documents and evidence they will rely on at the hearing; and

(e) raised new arguments in their Amended Reply pleading.

31. In their most recent proposed timetable, Board Staff have, in effect, sought substantial additional time to prepare their case when they should have had the evidence to prove the Allegations before the Notice of Hearing and Allegations were issued.

Amended Reply

32. Neither the initial Response, nor the Amended Response, raised issues about research and development costs, profit margins, or the Board's discretion under section 85 (2) of the *Act*. These are entirely new allegations and not a proper reply to any of the issues raised in the Response or Amended Response. Indeed, the new allegations contravene Rule 19, which limits a reply to an "admission or denial of each ground or material fact that was set out in the response."

33. Analogous Canadian rules of court require parties to raise new grounds of claim by way of amendment to an original pleading—and not in a subsequent pleading (like a reply).¹

34. This is not a matter of procedural formality, but of basic fairness. It is unfair to make new claims to which another party has not had an opportunity to respond. The rationale was recently described in *Drywall and Acoustic Lathing and Insulation Local 675 Pension Fund (Trustees of) v. SNC-Lavalin Group Inc.*, [2014] O.J. No. 435 (Ont. S.C.):

¹ See for example Ontario *Rules of Civil Procedure*, sub-rule 25.06(5); see also rule 180 of the *Federal Court Rules*.

59 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.* (2003), 67 O.R. (3d) 463 (S.C.J.). 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: *McComb v. American Canada Inc.*, [1986] O.J. No. 2616 (H.C.J.); *Levinson v. Levinson*, [1943] O.J. No. 514 (H.C.J.); *Burford v. Cosa Corp. of Canada Ltd.*, [1955] O.W.N. 8 (H.C.J.).

60 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.

35. The unfairness and prejudice to Alexion of permitting new claims under the guise of a "reply" is all the more manifest at this stage of the case. For several months Alexion has repeatedly attempted, and Board Staff counsel have repeatedly refused, to provide particulars and disclosure of Board Staff's case.

36. Board Staff's attempt to bolster their case in an improper reply at the last opportunity before close of pleadings (and after refusing Alexion's reasonable attempts to obtain disclosure) is particularly objectionable. Board Staff's counsel knew, or should have known, the case against Alexion before launching the prosecution; a prosecutor acting fairly does not invent new grounds of attack during the course of the proceeding.

37. Board Staff should have sought leave from the Panel to amend the Allegations to assert what are essentially new grounds. This would have permitted Alexion to make submissions on whether the new grounds should be admitted at all, whether the new grounds were sufficiently particularized, and whether Alexion should be given the right to file a response.

38. Given that s. 85(2) of the *Act* was not previously mentioned in the Allegations, Response, Reply, or Amended Response, it is plain and obvious that paragraphs 7 and 9 of the Amended Reply are not properly the subject of reply and should be struck out.

Conclusion

39. Alexion respectfully submits that: (a) Board Staff's motion to strike the impugned paragraphs in the Amended Response should be dismissed; and (b) Alexion's motion to strike paragraph 7 and the amended portion of paragraph 9 of the Amended Reply should be granted.

Dated: 9 September 2015

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