

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”

**REPLY SUBMISSIONS OF THE MOVING PARTY, ALEXION
(TO THE WRITTEN SUBMISSIONS 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)**

Overview

1. Respondent, Alexion Pharmaceuticals Inc. (“Respondent” or “Alexion”), has moved to strike paragraph 7 and amended portion of paragraph 9 of the Amended Reply of Board Staff on the grounds that:
 - (a) The paragraphs contain new allegations of fact and/or law and new excessive pricing allegations that are not the proper subject of a Reply;
 - (b) Board Staff is required by the Rules to seek leave of the Panel to amend the Statement of Allegations; and
 - (c) Alexion continues to be prejudiced by Board Staff’s unfair refusal to: specify excessive pricing allegations; particularize which s. 85 factors they rely upon; state how the s. 85 factors they rely upon are engaged by this case; and, disclose the evidence they are relying on to prove the

excessive pricing allegations. By raising new allegations in the Amended Reply, Board Staff have compounded this prejudice.

2. Board Staff still fail to appreciate the distinction between an initial pleading, like a Statement of Claim in a civil proceeding, and a Reply. Moreover, Board Staff misapprehend their prosecutorial onus and fail to understand that Alexion, as the prosecuted party, has no onus to make or prove any claims.

Board Staff raise s. 85(2) for the first time in the Amended Reply

3. Research, marketing, and manufacturing costs, and s. 85(2) of the *Patent Act* ("the Act") were not raised in the Statement of Allegations as a basis of alleged excessive pricing. Nor did Alexion raise s. 85(2) in its Response. Contrary to paragraph 5 of Board Staff's argument, Alexion has never tried to "justify" the price of Soliris under s. 85(2). Alexion has only responded to particularized excessive pricing allegations based on international prices of Soliris.

4. Board Staff's Response to Alexion's motion to strike is erroneously predicated on the untenable assertion, not found in the *Patent Act*, the Regulations, the Guidelines, or any jurisprudence, that Alexion somehow has the onus to *disprove* excessive pricing. Alexion bears no such onus; it only defends the excessive pricing allegations in the Statement of Allegations. While Board Staff can respond to defences raised by Alexion, it cannot set up in a reply a defence that was never raised to argue that Alexion has not, or cannot, establish the defence. Board Staff's position on this issue is absurd.

5. Board Staff state in paragraph 4 of their argument that the amended Reply raises s. 85(2) "to defeat Alexion's claim". Alexion has not made any "claims". Only Board

Staff have made claims. Alexion is the Respondent and can only plead facts and law that refute the allegations made in the Statement of Allegations. Board Staff fail to recognize the elementary distinction that they are prosecutors and Alexion is the accused. Alexion has not, and could not, make any "claims" that Board Staff would respond to.

6. Alexion never raised s. 85(2), in its Response or otherwise. It is misleading for Board Staff to suggest that their Reply responds to a s. 85(2) "claim" raised by Alexion.

7. Section 85(2) has apparently been raised by Board Staff in the Amended Reply to avoid the requirement to seek the Panel's leave to amend the Statement of Allegations. This step would require Board Staff to justify why s. 85(2) is being raised at all, and particularly so late in the proceeding.

Raising a new theory of excessive pricing is not a proper reply

8. Board Staff assert at paragraph 4 of their Response that Rule 221 of the *Federal Courts Rules* does not list "raising a new cause of action" as a ground for striking out a pleading. While literally true, the argument misses the point. Rule 221 permits striking a pleading on *three* grounds that apply here:

Motion to strike

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

- (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.

9. Rules 221(d) through (f) all apply. By adding a new excessive pricing allegation or statutory factors, Board Staff have prejudiced or delayed a fair hearing, and have clearly departed from their Statement of Allegations, which did not refer at all to s. 85(2) of the Act.

10. Furthermore, improper assertions raised in a Reply could be stricken under Rule 221(1)(f) because raising a new allegation or claim in Reply is an abuse of process. The same holds true under the PMPRB's Rules, which state at s. 19(2) that a Reply may only set out admissions or denials of "each ground or material fact that was set out in the response". Alexion never raised s. 85(2) in the Response as a ground or material fact. Board Staff are attempting to use their Reply to add new grounds when they should be seeking the Panel's leave to add these grounds. This is an abuse of the right of reply.

Board Staff still fail to appreciate their obligation to plead particulars of the grounds on which they claim the price of Soliris is excessive

11. According to Board Staff's written argument on this motion, Board Staff is not required to plead any specific grounds or allegations of excessive pricing. According to Board Staff, (particularly in paragraphs 1, 3, and 20 through 26) it would have been sufficient for Board Staff to simply plead that Soliris was priced excessively, and nothing more. This cannot be the standard to which Board Staff's pleadings are held because

such sparse allegations would offend the rules of fairness and natural justice that require a respondent to know and effectively prepare for the case to be met.

12. Board Staff also assert in their written argument (at paragraph 1) that "there is only one cause of action in these proceedings... whether Alexion is selling Soliris at an excessive price under the *Patent Act*". Board Staff further assert, (at paragraph 3) that "Board Staff did not actually have to plead section 85(2) of the Act or a point of law" in its Statement of Allegations in order to put research, development, marketing or manufacturing costs in issue."

13. According to Board Staff, all they must plead is a conclusion—"Soliris is excessively priced"—without pleading any of the predicates or factors applicable to reach that conclusion.

14. If this assertion is correct, Board Staff would not have to state any specific basis upon which they alleged a price to be excessive. Nor would they have to specify anything about *why* they assert a price to be excessive, just that the price "is excessive". On their theory, the following two sentences could constitute a fully sufficient Statement of Allegations:

Since 2012, Alexion Pharmaceuticals Inc. has been selling Soliris in Canada at an excessive price. Board Staff seeks an Order requiring Alexion, among other things, to stop selling Soliris at an excessive price and to offset the excess revenues that Alexion has generated.

15. This is not the standard to which Board Staff's pleadings are held according to the Federal Court. As explained in *CIBA-Geigy Canada Ltd. v. Canada (Patented*

*Medicine Prices Review Board)*¹, the doctrines of fairness and natural justice require Board Staff to make disclosure of the allegations and the documents they intend to rely on in making a case for excessive pricing:

In summary, when the statutory scheme of the Board is looked at, the Board is a regulatory board or tribunal. There is no point in the legislature creating a regulatory tribunal if the tribunal is treated as a criminal court. 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 upon.² [Emphasis added.]

16. Importantly, the Federal Court states that “the subject of the inquiry” (i.e. Alexion) has the right to know the case it must meet. This is not limited to being told that the price is allegedly excessive. A broad allegation of ‘excessive pricing’ tells Alexion nothing about the case it has to meet. Instead, particulars must be provided that include the theory, factors, tests, or grounds upon which Board Staff say the price of Soliris is excessive, so that Alexion knows *why* Board Staff allege the price of Soliris is excessive.

17. The current Statement of Allegations demonstrates that not even Board Staff believe the arguments they have raised in response to this motion. The Statement of Allegations identifies some specific grounds Board Staff intend to raise before the Panel and upon which they will ask the Panel to find Soliris is excessively priced, specifically the HIPC test:

15. In accordance with the 2010 Compendium of Guidelines, Policies and Procedures (“**2010 Guidelines**”), and the Highest International Price

¹ *CIBA-Geigy Canada Ltd. v. Canada (Patented Medicine Prices Review Board)*, [1994] 3 F.C. 425, [1994] F.C.J. No. 626 (QL) (T.D), aff'd at [1994] F.C.J. No. 884 (QL) (F.C.A.).

² *Ibid.*, at para. 32.

Comparison ("HIPC") test, Board Staff compared the National Average Transaction Price ("N-ATP") to the publicly available list prices of Soliris sold in the comparator countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States) listed in the Schedule of the *Patented Medicines Regulations* (the "Regulations").

16. Board Staff determined that in 2012 Alexion was selling Soliris in Canada at the highest international price among the comparator countries, contrary to the 2010 Guidelines.

17. Alexion was also selling Soliris in Canada at a price that was appreciably higher than in the United States, where Soliris was sold below the international median price among the comparator countries.

[...]

21. Alexion continues to sell Soliris to Canadians at the highest international price among the comparator countries. Alexion's price of Soliris in Canada has also remained appreciably higher than the price of Soliris in the United States.

22. 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: [quotation of text of s. 85(2) omitted.]

[...]

26. 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.

27. 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.

18. These allegations allege facts, tests to be relied upon, and factors to be considered in determining whether the price of Soliris is excessive.

19. If Board Staff really believed they could simply allege "excessive pricing" and put in issue any potential test or factor under the Act—let alone the undisclosed 'other' factors under s. 85(2)(b) that Board Staff have not yet disclosed to Alexion—then they would not have filed a detailed Statement of Allegations that relied upon HIPC, N-APT, and the text of s. 85(1).

20. If a motion is brought to amend the Statement of Allegations, and assuming an amendment is not too late, Board Staff would be required to provide similar particularity of any new allegations under s. 85(2).

Board Staff's suggestion of a sur-reply not an adequate remedy

21. Board Staff have suggested that, at most, Alexion should be permitted to file a sur-Reply to the Amended Reply. That remedy is inadequate for at least two reasons.

22. First, the Act and Rules contemplate a system in which Board Staff must normally have their Statement of Allegations approved before a prosecution is conducted. By raising new allegations in the Amended Reply, Board Staff have circumvented the Act's procedural requirement that all allegations be deemed in the public interest before the proceeding is commenced.

23. Second, the proper remedial route for raising new issues is to bring a motion to the Panel requiring leave to file an Amended Statement of Allegations. If a motion to amend is brought, Alexion would be permitted an opportunity to challenge the propriety and timing of the proposed amendments and Board Staff's failure to comply with the Rules.

Order Requested

24. Respondent Alexion requests the Board to strike paragraph 7 and the amended portion of paragraph 9 of the Amended Reply.

Original signature redacted

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