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"**

WRITTEN SUBMISSIONS OF THE RESPONDENT

(CANADIAN LIFE AND HEALTH INSURANCE ASSOCIATION INC. MOTION FOR LEAVE TO INTERVENE)

PART 1 – Nature of Motion

1. In a motion dated 12 May 2015, Canadian Life and Health Insurance Association Inc. ("CLHIA") has requested an order for intervener status. Respondent Alexion opposes the request pursuant to Rule 20(4) of the *Patented Medicine Prices Review Board Rules of Practice and Procedure* (the "Rules").

PART 2 - Overview

2. Alexion opposes CLHIA's motion for intervener status because: (1) CLHIA has no interest in the proceedings; (2) the proposed intervention would prejudice Alexion; and (3) the proposed intervention will interfere with the fair and expeditious conduct of the proceeding.

3. CLHIA lacks the required interest to be granted the intervention order sought. CLHIA represents private insurers who have private contractual arrangements with

insured customers. Interests of private member insurers and their customers do not fall within the statutory mandate of the Board, which regulates the ex-factory prices of patented medicines. The Board has previously rejected a proposed intervention raising issues that fall outside the Board's statutory mandate. CLHIA's proposed intervention should similarly be rejected because the Board's jurisdiction does not extend to imposing remedial measures affecting private insurance contracts.

4. Furthermore, in its Notice of Motion the CLHIA does not indicate that it intends to address the central issues in the hearing, or provide "unique or useful" supplementary evidence. The intervention will prejudice the Respondent and interfere with the fair and expeditious conduct of the proceeding without providing any obvious benefits.

5. In the circumstances, the Panel should refuse the CLHIA's motion for intervention.

PART 3 – Facts

6. Alexion relies upon the facts stated in the grounds for its Notice of Motion and supporting affidavit of Anna Di Domenico dated 15 May 2015.

PART 4 – The Law

Test to be Applied

7. The three "relevant factors" the Board must consider in determining a request for leave to intervene under subsection 20(5) of the Rules are whether:

(a) the putative intervener has an interest in the proceeding sufficient to warrant the intervention;

(b) the intervention will prejudice any party to the proceeding; and

(c) the intervention will interfere with the fair and expeditious conduct of the proceeding.

8. Alexion submits that all three factors weigh against the Board granting the intervention sought by CLHIA.

Interest in the Proceedings

9. CLHIA has alleged in paragraph 7 of its Notice of Motion that, as an organization representing persons who "in one manner or another, will bear some or all of the cost burden of the medicine in question ..." [namely, private insurers], CLHIA has an "interest" in the proceeding.

10. CLHIA has cited for this proposition Board's decision in, PMPRB-07-D1-QUADRACEL and PENTACEL (*Quadracel*), in which GlaxoSmithKline (GSK) sought intervention in a case concerning allegations that the price of two vaccines manufactured by Sanofi Pasteur were "excessive."

11. There are three reasons the *Quadracel* decision does not assist CLHIA in this case: (a) the type of interest required for supporting intervention is not within the Board's statutory mandate (b) recent case law demonstrates that interests comparable to those of private insurers lie outside the Board's jurisdiction; and (c) CLHIA does not

propose to assist in the determination of whether the price of Soliris® is "excessive" and so cannot be said to provide any unique or valuable contribution to the Panel.

Type of Interest Supporting Intervention

12. CLHIA's Notice omits to mention that in *Quadracel*, the only case they cite, the Board refused leave to intervene.

13. The panel in that case concluded that the proposed intervener did not have a "material and direct" interest in the proceedings. The panel also held that, to be an intervener in such circumstances, the requesting party would have to demonstrate that it could make a unique contribution. GSK, the putative intervener in *Quadracel*, was a competitor of Sanofi Pasteur. The Board ruled that, where a proposed intervener has an interest that lies outside the statutory jurisdiction of the Board, intervention is not warranted:

> 20. Also, the panel does not believe that the Board has a mandate to consider whether the price of a medicine under its jurisdiction has been or will be, for competitive purposes, set by the patentee at a level that is somehow unfairly high or low relative to the price of a medicine competing in the same market, or to otherwise inquire into the fairness of the competitive strategy of one patentee relative to another. The Patent Act and the Board's Excessive Pricing Guidelines deal with the prices of medicines for the exclusive purpose of ensuring that those prices are not excessive. The Board's statutory mandate does not include setting maximum prices of medicines, or taking remedial measures against patentees, to foster competition, nor to inquire into whether the prices of medicines are, or have been, somehow unfair as a matter of competition policy. [Underlining added.]

14. While CLHIA is not a competitor of Alexion, its interests are analogous to that of GSK, the putative intervener in *Quadracel*. The Board has no statutory mandate over retail prices charged to private insurers who choose to extend coverage to claims for the

medicine at issue. CLHIA's interests relate purely to private insurance plan providers in their private contractual arrangements with insured customers. Proceedings before the Board are not the appropriate venue for private parties to exact price reductions for medicines they choose to cover under the insurance policies they issue. These are the very interests CLHIA addresses in its observations concerning the impact of the price of Soliris® on private insurance plans, sponsors, and private insurance plan customers: see paragraphs 10 through 13 of the CLHIA Notice of Motion.

15. CLHIA's members do not have a "material and direct" interest in the ex-factory price of drugs such as Soliris.® CLHIA's member companies sell insurance plans, under the terms of which the cost of medicines, ancillary medical services (physiotherapy, psychologists' services, dental services, etc.), and some medical devices are passed along – or 'flow through' – to their customers. The interests of insurance plan customers are the same as those of any resident of Canada and are already adequately represented by the Board. The interests of CLHIA's member companies relate to indirect effects of medicine prices on their profitability.

16. CLHIA's concerns (whatever their merits) lie outside the statutory mandate of the Board. An insurer's obligations under a private contract of insurance are as much outside the Board's mandate as the competition policy issues addressed by the panel in *Quadracel*.

The Statutory Mandate of the Board

17. CLHIA has argued in the Notice of Motion that intervention is justified because they represent persons who "in some manner or other, will bear some or all of the cost burden of the medicine in question …".

18. This argument is based on 'general remarks' made by the *Quadracel* panel reproduced at para. 7 of the Notice of Motion.

19. The *Quadracel* decision was rendered before the Federal Court clarified the Board's proper statutory mandate in *Pfizer Canada Inc. v. Canada (Attorney General)*, [2009] F.C.J. No. 882 ("*Pfizer*"). Alexion submits that the panel's 'general remarks' in *Quadracel* must be read in light of limitations on the Board's jurisdiction described in *Pfizer*.

20. In *Pfizer,* the Court held that the Board's jurisdiction was constitutionally limited to the "factory-gate" price of patented drugs and that the Board cannot look to "contractual arrangements involving patentees and entities further down the distribution chain":

> [83] I would also observe that my interpretation of the Patent Act and the Patented Medicines Regulations is consistent with the constitutional limitation on the Board's ability to look beyond the factory-gate price of patented medicines, to consider contractual arrangements involving patentees and entities further down the distribution chain.

While *Pfizer* involved reporting of rebates paid to public insurers, the same general principle holds true for private insurers. The Board's jurisdiction only extends to the "factory-gate" price and to the relationship between the manufacturer and its immediate customer. Private insurers, or a body representing private insurers, cannot have an

"interest" in these proceedings sufficient to warrant intervention. A private insurer's obligation to pay under a policy of insurance, and any arrangements private insurers make to contain (or indeed pass through) their claims costs or those of their policyholders, are issues that concern "... contractual arrangements involving ... entities further down the distribution chain". In determining the appropriateness of intervention, the Board must therefore take into consideration the "... constitutional limitation on the Board's ability to look beyond the factory-gate price of patented medicines...".

CLHIA Must Make a Useful Contribution

21. Quite apart from whether CLHIA's interests are within the ambit of the Board's jurisdiction, in the Notice of Motion CLHIA has raised nothing that could be considered as useful to the determination the Board must make.

22. The Board's determinations are framed by s. 85 of the *Patent Act*: and concern, in particular, whether, the price of Soliris® is "excessive" based on the factors enumerated in subsection 85(1).

23. CLHIA mentions nothing about any of the factors in subsection 85(1) of the *Act*. Rather, CLHIA expressly states that the issues it wishes to address are "...the types of remedies being sought by the PMPRB": see: Notice of Motion para. 14 and paras. 14 through 17. In summary, CLHIA's intervention does not address the merits of the dispute. The proposed intervention deals with the Panel's remedial powers *once the Respondent has been found to have sold the medicine at an excessive price*. In other words, CLHIA implicitly asks the Panel in its intervention request to prejudge the main issue before it is even decided.

24. CLHIA clearly has nothing to contribute, whether in evidence or argument, to the statutory determination the Board must make about whether the price of Soliris is excessive. In *Quadracel*, the panel described the proper role of an intervener as providing some "element of evidence that was expected by the Board to be unique":

> 13. In addition, where a proposed intervener does not have a material and direct interest in the outcome of the proceeding in question, the Board would also require that an applicant for intervener status demonstrate the ability to contribute, to the proceeding, some element of evidence that was expected by the Board to be unique, or otherwise to be usefully supplementary to the evidence and argument expected to be adduced by Board Staff, the patentee of the medicine in question, or another person that is granted intervener status.
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> 14. It must be noted that Board Staff will generally represent the interests of persons who bear the cost burden of medicines under review, and patentees, by advocating their own interests, will typically represent interests that are not unique to them or to the particular medicine under review. Perhaps as importantly, the Board is aware of the impact of each of its decisions on persons other than those appearing before it in any given proceeding, and takes the interests of those persons into account whether or not they are independently represented in a proceeding.
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> 16. None of these factors removes the right of appropriate persons to be interveners in the Board´s proceedings, or detracts from the important role that interveners can play in the Board´s proceedings. However, those factors, and the Board´s statutory obligation pursuant to subsection 97(1) of the Patent Act to conduct its proceedings as expeditiously as the circumstances and considerations of fairness permit, and the Board´s need to control its process, do bear on the discretion that the Board will exercise when deciding, in a particular case, whether a person is an appropriate intervener in a proceeding.

In this case, CLHIA proposes no "element of evidence ...expected by the Board to be unique" for the determination the Board must make. The only issues raised in the section of its Notice of Motion relating to "Issues the CLHIA Intends to Address" are the Panel's choice of remedies following the *outcome* of the hearing. CLHIA apparently

hopes that outcome to be to the advantage of its private member insurers in terms of obligations to insureds under private insurance contracts.

Prejudice

25. The intervention will obviously prejudice Alexion. Rather than facing only the remedies sought by Board Staff, Alexion would be faced with two additional sets of proposed "remedies": the remedies proposed by the provincial government interveners and those now proposed by CLHIA.

26. The proposed intervention will multiply costs. For example, more expert witnesses will be required by Alexion to counter evidence proffered by CLHIA on remedial consequences of the Panel's decision under CLHIA's private contractual arrangements. The proposed intervention will also lengthen the proceedings and necessitate more legal fees. While CLHIA has stated in paragraph 18 that it merely seeks leave "to file a written submission", the submission will require a factual basis—which will require Alexion to respond with a factual basis of its own, giving rise to further cross-examinations and other possible motions.

27. Furthermore, CLHIA intends to raise issues dealing with potential changes to the Board's procedures and Guidelines—issues Alexion would not have to deal with in the absence of the intervention. Indeed, CLHIA calls for a *retroactive* application of Guideline changes to Soliris®, which would raise significant issues of procedural fairness.

28. The prejudice of granting the intervention is not outweighed by any proposed benefits to the Panel or the parties. For example, CLHIA does not propose to adduce any evidence, or advance arguments, concerning the statutory determination to be made at the hearing on the merits. CLHIA is concerned only with the choice of remedy should a determination be made that the price of Soliris® is excessive.

Interference with Fair and Expeditious Conduct of the Proceeding

29. Whatever schedules had otherwise been agreed-upon or ordered will become unworkable with the addition of an intervener proposing an entirely new and novel theory of the remedies in the case as well as a host of suggested changes to the Guidelines—none of which are based on the factors in the *Patent Act*.

30. Subsection 97(1) of the Act mandates that:

> 97.(1) All proceedings before the Board shall be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit.

31. Permitting the intervention proposed by CLHIA would greatly complicate the proceeding by raising issues irrelevant to the Panel's determination and beyond the Board's jurisdiction. For these reasons, Alexion respectfully asks the Panel to dismiss the intervention request.

Dated: 29 May 2015

Original signature redacted

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