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 REPLY SUBMISSIONS
(TO BOARD STAFF'S RESPONSE TO ALEXION'S MOTION RE: Strike Portions of the FURTHER AMENDED NOTICE OF APPEARANCE Filed by the Minister of Health)

1. Board Staff's 19 October 2015 Submissions are incorrect in fact and in law, rely on assumptions that are demonstrably untrue, and ought to be disregarded.

2. Board Staff's Submissions fundamentally misapprehend the role of provinces in the purchase of medicines and the constitutional mandate of the Board. The provinces do not "purchase" medicines and the transactions between patentees and provincial departments or agencies for reimbursement of the cost of medicines (and the effect of these transactions on "public funding") lies outside the Board's mandate. The Ministers—and Board Staff—cannot accomplish in a hearing what the courts have stated they cannot do through information requests: inquire into the financial relationship between patentees and provincial reimbursement entities. Without examining reimbursement practices, it is not possible to examine the impact of the ex-factory price of a medicine on provincial "public funding".

3. Board Staff's Submissions also fundamentally misapprehend the purpose and effect of the Minister's statutory rights under subsection 86(2). These rights are nothing more than a statutory right to intervene, no different from other statutory intervention rights —none of which give rise, in other contexts, to rights different from those afforded interveners in general. The intervention right in s. 86(2) is limited to making representations "... with respect to the matter being heard". The "matter" is the case initiated, under the Rules, by a "Notice of Hearing" attaching a "Statement of Allegations". Had Parliament intended to confer on provincial Ministers the right to make whatever new claims concerning "excessive pricing" they wanted, regardless of allegations in the Statement of Allegations, provincial Ministers would have been provided the right to initiate their own cases before the Board.

4. In other contexts where a statutory right to notice is afforded along with a right to be heard (for example in relation to constitutional questions) notified parties are still considered "interveners." The Supreme Court of Canada has stated that the purpose of these provisions would be undermined if interveners were permitted to change the issues for which notice was given.

5. In their submissions, Board Staff assert that if concerned Ministers are precluded from making whatever wide-ranging representations they want, statutory rights will be rendered "meaningless". This is inaccurate and exaggerated. Statutory intervention in other contexts does not give rise to the kind of wide-ranging rights Board Staff claims, yet it is not considered "meaningless". Indeed, a non-Ministerial intervener in this case, CLHIA, has been granted meaningful intervention.

6. In summary, Board Staff have confused the undisputed *procedural* right of concerned Ministers to intervene 'as of right' (that is, without the necessity of bringing a motion) with the *substantive* content of an intervention. The Rules make no such distinction: interveners as of right (the concerned Ministers) and interveners who have been granted leave to intervene (like CLHIA), are defined in the Rules as "parties". Contrary to assertions of Board Staff, the definition does not grant different rights to concerned Ministers from those granted to interveners generally. If substantive intervention rights were different, patentees would be exposed to multiple, and potentially incompatible, allegations that the prices of their medicines were "excessive", leading to prejudice and procedural unfairness. The prejudice is manifest in this case because Board Staff and the Minister are alleging incompatible allegations: in the Statement of Allegations and other documents before the Panel, Board Staff have quantified allegedly excessive prices based upon the "highest international price comparison " test but the Ministers have argued that the test ought to be the "lowest international price", a different concept not found in the *Patent Act*, Regulations, or Guidelines.

Errors Made Concerning The Constitutional Role of the Board

7. Board Staff allege that, "Provinces are the largest purchasers of drugs for Canadians". Further, Board Staff state that "...for this reason, provincial Ministers of Health are treated as a party in excessive price hearings and granted unique rights under subsection 86(2) ..." [Underlining added].

8. This is a mischaracterization of the role of the provinces. Provinces and provincial health Ministers do not "purchase" any medicines (except in special circumstances). Provinces do *reimburse* actual purchasers of drugs for whatever portion of drug costs a particular province has made the subject of reimbursement.

9. *Pfizer Canada Inc. v. Canada (Attorney General)*, [2009] F.C.J. No. 882 (Fed. T.D.) ("*Pfizer*") addressed this issue. In that case, the Federal Court ruled that Patentees do not "sell" drugs to the provinces. The following question was addressed:

> 71 With these principles of statutory interpretation in mind, the first question is whether it can be said that patentees *sell* patented medicines to the provinces.

The Court definitively held that the answer to this question was, "no". Provinces do not "purchase" drugs.

10. Moreover, the Court in *Pfizer* held that the Board has no jurisdiction to *inquire* into the financial relationship between the manufacturers and provinces. The Court held that this determination was necessitated by constitutional limitations on the Board's mandate:

> 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.

11. The statutory right of intervention provided in subsection 86(2) of the *Act* is not because "Provinces are the largest purchasers of drugs for Canadians". Nor is the right predicated on the effect of drug prices "...on public funding" (as Board Staff claim in

para. 5 of their submissions). This interpretation conflicts with the constitutional mandate of the Board. As the Court noted in *Pfizer* , the Board's mandate is limited to the "ex factory" price, and does not extend to consideration of factors like rebates provided by manufacturers to the provinces. The Court expressly stated that requiring patentees to report such rebates was beyond the Board's jurisdiction.

12. Board Staff assert in para. 39 that, "The Minister is not here asking the Board to use something other than the ex-factory price to determine whether the price of Soliris is excessive. The Minister is ... pleading material facts relating to the costs of Soliris and its effects on public funding ... ". Any inquiry into the effects of prices of medicines on provincial "public funding" would, of necessity, require an analysis that goes beyond the "ex factory" price, and require analysis of matters—such as rebates offered to the provinces—that the courts have expressly stated lie beyond the Board's constitutional boundaries.

13. Board Staff's submissions, and the impugned sections of the Minister's Further Amended Notice of Appearance, are a colourable attempt by the Minister and Board Staff to circumvent the constitutional constraints on the Board's jurisdiction. In effect, they want patentees, in a hearing, to address issues concerning "downstream" pricing of drugs that lie beyond federal jurisdiction. The impugned parts of the Minister's Appearance must be struck out because the allegations are an invitation to the Panel to inquire into, and make rulings on, matters that are outside the Board's jurisdiction as defined in the *Pfizer* case.

Errors Concerning the "Matter Being Heard"

14. Board Staff's submissions on interpretation of the Minister's right of appearance established by subsection 86(2) betray a fundamental misunderstanding of the statutory scheme for hearings before the Board.

15. The *Patent Act* provides Ministers with an undoubted statutory right to "appear". While the Ministers have an absolute right to make an appearance, the representations they are entitled to make, however, are limited "to the matter being heard".

16. Board Staff are urging a creative interpretation of the legislation to permit Ministers to make unlimited representations. They argue that the "matter being heard" is whether the Patentee's price is excessive as opposed to the specific allegations made in the Statement of Allegations. This interpretation is absurd. It would, in effect, permit provincial Ministers to make whatever allegations they wished, regardless of the content of the Statement of Allegations. Had Parliament intended this, it would have conferred power on the Ministers to initiate their own proceedings against patentees.

17. Under Board Staff's theory, the Ministers could, after a Notice of Hearing and Statement of Allegations have issued, appear and allege an *entirely different case* against the same patentee. Had Parliament intended to provide the Ministers with such broad rights to allege a case against a patentee, they would have been permitted to initiate their *own* proceedings before the Board, without being requiring to bring their "case" within Board Staff's prosecution.

18. Board staff's position does not fit within established procedures. Under the Rules, a proceeding is *always* initiated by a Notice of Hearing and Statement of Allegations approved by the Chairperson at the request of Board Staff (see Rule 15). The procedure initiated by Board Staff establishes the "matter before the Board" in which provincial Ministers have an automatic right to appear. This procedure establishes the content of that "matter" by requiring detailed allegations in the "Statement of Allegations". Rules 15(1) and (3) state:

> 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 and the order sought by Board Staff in the proceeding;

19. Board Staff assert in paragraph 29 that Rule 21(2)(a) somehow grants a Minister "broad rights" to depart from the case as framed in the Statement of Allegations. In fact, the Rule simply states that the Minister may make "representations". There is no suggestion that the — "representations" can depart from the case framed by the Statement of Allegations. Rule 21(1) makes perfectly clear that the "representations" must be *in respect of the matter already before the Board*, and cannot be in respect of some entirely new case:

> 21. (1) A concerned minister who intends to appear and make representations <u>with respect to a matter that is before the Board</u> must, within 20 days after being served with the notice of hearing, file with the Board and serve on all parties a notice of appearance that is dated and signed by the concerned minister. [Emphasis added]

20. In their submissions, Board Staff inappropriately emphasize that a Minister is defined as a "party" in Rule 1, and thus presumably that the Ministers cannot be analogous to "interveners" (see paras. 23 and 33). This argument overlooks that any person granted leave to intervene is *also* defined in the Rules as a "party":

> "party" means
>
> (a) a respondent;
>
> (b) Board Staff;
>
> (c) a concerned minister; or
>
> (d) a person who has been granted leave to intervene under Rule 20.
> [Emphasis added]

21. In summary, the *only* factor differentiating a concerned minister from any other intervener is a statutory right of appearance. Ministers are not required to seek status as an intervener. A procedural right to appear and intervene without leave does not, however, provide concerned Ministers with the right to allege an entirely new case. As with interveners who must seek leave to intervene, Ministers are limited to the case as it already exists.

22. The case articulated in the Statement of Allegations is the "matter being heard." Concerned ministers are entitled to make "representations" and to bring "material facts" to the attention of the Board in relation to issues framed by the Statement of Allegations. As with other interveners, however, ministers are not free to create or define entirely new issues, or stray beyond the bounds of the issues already framed.

23. Giving a government entity a statutory right of intervention is not unknown in Canada. For example, the relevant attorneys general, provincial and federal, have a

statutory right to intervene in matters that raise a constitutional question (see s. 109 of the Ontario *Courts of Justice Act*). Provincial attorneys general also have the statutory right to intervene in judicial review proceedings (see subsection. 9(4) of the Ontario *Judicial Review Procedure Act)*. In neither case does the statute expressly name the relevant attorney general as an "intervener"—but all cases and commentary portray intervention as their role: see, for example, Lokan & Dassios, *Constitutional Litigation in Canada* (looseleaf) at 3.4(3)(a). As an "intervener an attorney general is subject to precisely the same rules as interveners generally—they may not widen the ambit of the proceeding, add to points at issue, or re-frame the matter." A "concerned Ministers under the *Patent Act* is subject to the same constraints.

24. The leading case on the limited rights of an intervener (in this case, on a constitutional issue) is the decision of the Supreme Court in *R. v. Morgentaler*, [1993] 1 S.C.R. 462 ("Morgentaler"), where the Court noted:

> 1. ... The purpose of an intervention is to present the court with submissions which are useful and different from the perspective of a non-party who has a special interest or particular expertise in the subject matter of the appeal. See Reference Re Workers' Compensation Act, 1983 (Nfld.), [1989] 2 S.C.R. 335.
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> 2 An intervener is not entitled, however, to widen or add to the points in issue. [Emphasis added]

25. The Court in *Morgentaler* also commented on the purpose of the combination of a statutory right of notice and intervention granted to attorneys general (which, as noted, is very similar to the rights of notice and intervention granted to provincial Ministers under the *Patent Act*), *and why such rights are wholly incompatible with an intervener changing the issues as originally framed*:

> 3. ... It can be assumed that the various Attorneys General based their decisions to intervene or not to intervene on the constitutional questions as framed. It is possible that their decisions would have been different had the POGG been put in issue in the constitutional questions. In any event, to introduce the issue without amending the constitutional questions would contravene this Court's rules with respect to constitutional questions, the main purpose of which is to give notice to Attorneys General as to the constitutional issue which the Court is asked to decide. [Underlining added]

26. The "notice" provided to the Ministers under the *Patent Act*, consists of the "Notice of Hearing" and the "Statement of Allegations". The Ministers are provided with notice to permit them to exercise their statutory right to intervene in "matter being heard".

27. In summary, the purpose of provisions combining notice with a right of intervention, like s. 86(2), is to give the various parties entitled (Ministers in this case) notice *of the issues already in the proceeding*, so they can decide whether or not to exercise their rights to comment on *those issues*. The purpose would be undermined if a Minister was entitled to widen or add to the issues.

The Submissions are Predicated on the Province's Participation being Otherwise "Meaningless"

28. Board Staff state repeatedly, and mistakenly, in their submissions that, unless their interpretation is adopted, participation of the Ministers before the Board would be "meaningless".

29. Intervention before the Board by various parties is contemplated in the Rules. As indicated above, CLHIA is a non-Ministerial intervener in this case. Participation as an intervener is "meaningful" to assist the Board in arriving at conclusions (as it is with intervention in other contexts and proceedings). If Board Staff's representations were

adopted, intervention would be so broad as to render "meaningless" distinctions between direct parties to the dispute and interveners.

30. Were the approach advocated by Board Staff to be adopted, it would permit multiple cases being litigated at the same time before the Board concerning the same medicine. There would be nothing to stop each and every "concerned Minister" from advancing his or her own different, and possibly incompatible, allegations. This cannot be what Parliament intended. Subsection 97(1) of the Act states: "All proceedings before the Board shall be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit". Forcing patentees to answer to multiple incompatible case theories would constitute a truly extraordinary procedure that does not exist in any other administrative context and is entirely incompatible with the purpose of subsection 97(1) of the *Patent Act*.

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