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 MINISTER OF HEALTH'S FURTHER AMENDED NOTICE OF APPEARANCE

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OVERVIEW

1. The Board's role is to protect Canadians from the financial detriment that results from the abuse of patent rights.

2. Provinces are the largest purchasers of drugs for Canadians. Their views and evidence are unique and assist the Board in exercising its consumer protection mandate. For this reason, provincial Ministers of Health are treated as a party in excessive price hearings and granted unique rights under subsection 86(2) of the *Patent Act* (the "**Act**") and the *Rules of Practice and Procedure* (the "**Rules**"). This includes the statutory right to make their own representations and to file their own evidence before the Board.

3. Alexion brings this motion to strike the Minister's Further Amended Notice of Appearance on the grounds that provincial participation in excessive price hearings must be restricted to providing "a different perspective" on Board Staff's Statement of Allegations, its material facts, and its remedy. In other words, the provincial Minister of Health is bound to what Board Staff pleads. This approach is wholly inconsistent with the plain wording of the provincial Minister's rights under subsection 86(2), which permits the Minister "to make representations with respect to the matter being heard", and the nature of excessive price hearings before the Board. If accepted, it would render provincial participation meaningless and would unduly limit the Board's ability to inquire into the price of a medicine and thereby to exercise its consumer protection mandate.

4. Moreover, Alexion wrongly asserts that the Minister of Health's position is inconsistent with Board Staff's. This fundamentally misunderstands the issue before the Board. Both Board Staff and the Minister's pleadings relate to the same cause of action; namely, whether the price of Soliris is excessive under section 85 of the Act. Accordingly, both positions are consistent with one another.

5. As a final attempt to restrict the Minister's representations, Alexion argues that the Minister's representations are advanced for ulterior and improper motives of "private gain". Alexion has no basis for these factual allegations. The Minister's representations relate to the costs of Soliris and their effect on public funding and thus Canadian consumers. The province also proposes a remedy under the Act that it considers appropriate. These are exactly the types of representations that Parliament intended for provincial Ministers of Health, as public payors, to make to assist the Board in exercising its consumer protection mandate. In short, they are plainly and obviously "representations with respect to the matter being heard".

6. For the foregoing reasons, it is evident that Alexion has no basis for striking the Minister's Further Amended Notice of Appearance. What Alexion really seeks is to limit the Board's inquiry into Alexion's price of Soliris. Its motion should therefore be dismissed.

PART I – STATEMENT OF FACTS

7. On 20 January 2015, the Board issued a Notice of Hearing in this matter. 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".

8. In accordance with subsection 86(2), the Notice of Hearing was also served on the Ministers of Health for each province. On 9 March 2015, the Minister of Health of British Columbia on its behalf and on behalf of the Minister of Manitoba filed a Notice of Appearance.

9. On 13 March 2015, the Secretary of the Board wrote to the Minister advising that the Minister's Notice of Appearance did not provide all the information required by Rule 21. The Minister was also advised that it could seek an extension of time to file an Amended Notice of Appearance.

10. On 17 March 2015, Counsel for the Minister of Health for British Columbia (on behalf of the Ministers of Health of British Columbia, Ontario, Manitoba and Newfoundland and Labrador) (the "**Ministers**") filed a request for an Order extending the time to file an Amended Notice of Appearance.

11. On 26 March 2015, the Board issued an Order granting the Ministers' request and extending the time for the Ministers to file an Amended Notice of Appearance along with supporting materials.

12. On 2 April 2015, the Ministers filed an Amended Notice of Appearance setting out the material facts the Ministers intended to rely on as well as the list of documents, along with the affidavit of Eric Lun.

13. Alexion brought a motion to cross-examine Mr Lun on his affidavit. In response, the Ministers sought leave from the Panel to withdraw the affidavit from the record. On 23 June 2015, following a hearing, the Panel granted leave to the Ministers to withdraw the affidavit and also to amend the Amended the Notice of Appearance.

14. On 26 June 2015, the Ministers filed the Further Amended Notice of Appearance, in which the Ministers set out their concise representations and the materials facts they intend to rely on, consistent with Rule 21.

PART II – STATEMENT OF LAW

15. The modern rule of statutory interpretation provides that "the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament."[1]

16. Consistent with this rule of interpretation, the Minister has broad rights under subsection 86(2) of the Act to make independent representations before the Board and to file its own evidence. The Minister's rights are not, as Alexion argues, confined to what Board Staff has pleaded in its Statement of Allegations. As set out below, Alexion's interpretation of the province's role is contrary to the plain wording of the subsection 86(2), the *de novo* nature of excessive price hearings under the Act, and the Board's consumer protection mandate.

A. Provincial Participation Assists the Board in Exercising Its Consumer Protection Mandate

17. In *Celgene Corporation v Attorney General of Canada,*[2] the Supreme Court of Canada affirmed and described the Board's consumer protection mandate as "ensuring that the monopoly that accompanies the granting of a patent is not abused to the financial detriment of Canadian patients and their insurers…"[3]

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[1] *Rizzo and Rizzo Shoes Ltd.* (Re), [1998] 1 S.C.R. 27 at para. 21. See also, s. 12 of the *Interpretation Act* (R.S.C., 1985, c. I-21) ("Every enactment is deemed remedial, and shall be given such fair, large and liberal construction and interpretation as best ensures the attainment of its objects").
[2] *Celgene Corporation v. Attorney General of Canada,* [2011] 1 S.C.R. 3.
[3] *Ibid.* at para. 29.

18. The Board exercises its consumer protection mandate, in part, through its excessive price hearings. In *CIBA-Geigy v. Canada,*[4] the Federal Court (whose decision was affirmed by the Federal Court of Appeal) explained that excessive price hearings were concerned with economic regulation (not criminal prosecution) and were distinct from adversarial proceedings before a court. The court stated:

> [32] In summary, when the statutory scheme of this 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. ..It is not intended that proceedings before these tribunals be as adversarial as proceedings before a court.[5]

Further:

> [37] This is not a case where individual rights are an issue, it is a case of economic regulation, which is not in form or substance criminal, nor does it involve the procedural safeguards constitutionalized in section 7 of the *Charter.*[6]

19. Additionally, excessive price hearings before the Board are held in the public interest and are a fresh (or *de novo*) opportunity for the Board to determine based on all the evidence and applying its expertise whether the price of a medicine is excessive under section 85 of the Act, and what, if any, Order should be made. In *PENLAC,*[7] the Board described the nature of its inquiry 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

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[4] *CIBA-Geigy Canada Ltd. v. Canada (Patented Medicine Prices Review Board),* [1994] 3 FCR 425, aff'd [1994] F.C.J. No. 884 (FCA).
[5] *Ibid.* at para. 32.
[6] *Ibid.* at para. 37.
[7] *Sanofi-aventis Canada and the medicine "Penlac Nail Lacquer"* PMPRB-07-D2-PENLAC- Merits.

> 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).[8]

20. As the largest drug purchasers for Canadians, the provinces offer a unique perspective to the Board. This unique perspective assists the Board in exercising its consumer protection mandate. It is for this reason that Parliament granted the provincial Ministers of Health broad and unique statutory rights to make their own representations and to submit their own evidence in excessive price hearings, as is reflected in the ordinary wording of subsection 86(2) of the Act.

21. If, as Alexion argues, provincial participation in excessive price hearings was restricted to what Board Staff plead,[9] this would severely limit the Board in its ability to inquire into the price of a medicine and thus thwart the Board in exercising its consumer protection mandate.

B. The Provincial Minister of Health has Unique and Broad Statutory Rights in Excessive Price Hearings

22. Subsection 86(2) of the Act sets out the statutory rights of the provincial Minister of Health in an excessive price hearing. It states:

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[8] *Ibid. at* para. 16.

[9] Board Staff disputes that its position and that of the Ministers' is inconsistent in any way.

> 86(2) The Board shall give notice to the Minister of Industry or such other Minister as may be designated by the regulations and to provincial ministers of the Crown responsible for health of any hearing under section 83, and each of them is entitled to appear and make representations to the Board with respect to the matter being heard (emphasis added).

23. Aside from the patentee, only concerned ministers have automatic standing in hearings before the Board. Further, the combined effect of subsection 86(2), the definition of "party" in Rule 1, and Rule 21 is that any concerned minister becomes a party to any matter before the Board as long as the necessary Notice of Appearance has been filed.

24. Concerned ministers also have a broad right to make representations in excessive price hearings. This is made clear by the plain wording of subsection 86(2). The provision provides that the provincial Minister of Health is "entitled" to "make representations with respect to the matter being heard".

25. The "matter being heard" is in the public interest and is set out in the Notice of Hearing; namely, "whether under sections 83 and 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". The "matter being heard" thus also includes the remedy that the Board should order. Section 83 sets out the possible orders that the Board may make. This includes "causing the maximum price at which the patentee sells the medicine to be reduced to such a level as the Board considers not to be excessive", and requiring the patentee to pay excess revenues.

26. The ordinary meaning of the phrase "matter being heard" is not, therefore, restricted to Board Staff's Statement of Allegations or its remedy. (In fact, Alexion accepts this at paragraph 41 of its written representations when it states: "a hearing under the *Patent Act* relating to excessive pricing is a public process designed to determine, in the public interest, whether a manufacturer has engaged in excessive pricing at the factory-gate applying defined statutory criteria, tests articulated in the Guidelines, and guidance from the Board's jurisprudence to determine the maximum non-excessive ex-factory price").

27. Further, the phrase "with respect to", which connects "representations" to the "matter being heard", is to be given an expansive interpretation. In *R v. Nowegijick,*[10] the Supreme Court of Canada explained that a similar phrase ("in respect of") was wide in scope. The Court stated:

> The words "in respect of" are, in my opinion, words of the widest possible scope. They import such meanings as "in relation to", "with reference to" or "in connection with". The phrase "in respect of" is probably the widest of any expression intended to convey some connection between two related subject matters.[11]

28. Consequently, provincial Ministers of Health have unique and broad statutory rights to make representations so long as those representations are "with respect to" whether "under sections 83 and 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" (which in this case they are).

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[10] *R v Nowegijick,* [1983] 1 S.C.R. 29.
[11] *Ibid.* at p. 39.

29. Similarly, Rule 21(2)(a) also makes clear that provincial Ministers of Health have broad rights to make representations in an excessive price hearing. The Rule provides that a Notice of Appearance must be accompanied by a:

> (a) a concise statement of the representations that the concerned minister intends to make and the material facts on which the concerned minister is relying, and
>
> (b) a list of the documents that may be used in evidence to support the material facts on which the concerned minister is relying

30. The Rule thus expressly contemplates that the provincial Ministers of Health will make their own representations, plead their own material facts, and submit their own evidence.

31. The ordinary wording of subsection 86(2) of the Act and Rule 21(2)(a) thus reflects Parliament's clear intent that provinces be given broad statutory rights in excessive price hearings to assist the Board in exercising its consumer protection mandate.

a. Alexion's interpretation of subsection 86(2) is incorrect

32. Alexion's interpretation of subsection 86(2), which limits "matter being heard" to Board Staff's Statement of Allegations and thus to its evidence and proposed remedy, is contrary to the plain wording of subsection 86(2), the *de novo* nature of excessive price hearings, and the Board's consumer protection mandate. Neither the Act nor the Rules confines the representations that the provinces may make in excessive price hearings to Board Staff's Statement of Allegations.

33. Further, provincial Ministers of Health are not analogous to "interveners". Concerned ministers are parties who have been given automatic standing and statutory rights. This reflects their special importance in an excessive price hearing. In contrast, "interested parties" must be granted leave and the Board may impose conditions on their intervention. The Rules and case law that apply to interveners do not therefore apply to provincial Ministers of Health. Had Parliament intended to limit provincial participation to intervener status, there would have been no need for subsection 86(2). Further, if Parliament had intended to limit the Minister's representations to Board Staff's Statement of Allegations, it would have expressly stated so. On the contrary, Parliament has granted the Minister broad rights of representation. The reason for this is that the province has a unique perspective to provide to the Board. Limiting provincial participation by tying its representations to Board Staff's Statement of Allegations would thwart the Board from inquiring into the price of a medicine and thus prevent it from exercising its consumer protection mandate.

34. Second, Alexion argues that the participation of potentially all the provinces would add to or widen the issues that need to be determined and would therefore undermine the fairness of the proceedings. There is one issue to be determined; namely, whether the price of Soliris is excessive under the Act. The argument also fundamentally misunderstands the *de novo* nature of the hearings before the Board and the fact that provinces have a statutory right to provide their own views and evidence to assist the Board in its fact-finding role to determine whether the price of a medicine is excessive. Provincial participation is therefore

important to the fairness of the proceedings. The Board's Rules also establish the procedure for the conduct of the hearing and the filing of evidence. Like all other parties, the provincial Ministers of Health must follow these Rules. The Rules thus ensure that the proceedings are conducted fairly and expeditiously.

35. Third, Alexion argues that the province must be limited to Board Staff's Statement of Allegations because otherwise it would be conducting its own investigation. However, Alexion confuses the investigation and the excessive price hearing before the Board. Once a hearing is commenced in the public interest, the Board has a fresh opportunity to consider the matter of excessive pricing under section 85 of the Act, and the province's own views and evidence assist the Board in its inquiry under the Act.

36. Consequently, Alexion's interpretation of subsection 86(2) is incorrect and must fail. If adopted, it would defeat the purpose of allowing provincial participation in an excessive price hearing.

C. Minister's Further Amended Notice of Appearance is Proper

37. As set out above, under subsection 86(2) the Minister may make representations with respect to the matter being heard, as set out in the Notice of Hearing.

38. The Minister's Further Amended Notice of Appearance pleads material facts that are consistent with the matter being heard, which is whether the price of Soliris is excessive under the Act and what, if any, order should be made. The Minister pleads facts relating to the costs of Soliris and its effects on public funding and

thus Canadian consumers. The Minister also proposes a remedy it considers to be appropriate in the circumstances; namely, that the price of Soliris be reduced to the lowest price among the comparator countries and that excess revenues be calculated in accordance with this price. These are plainly and properly representations with respect to the matter being heard under section 85 of the Act. Therefore, no basis exists to strike the Minister's Further Amended Notice of Appearance.

39. Given that Alexion's motion lacks any real merit, as a last attempt to restrict the Minister's representations, Alexion argues that the provinces have improper motives in making these representations because they seek to make a "private gain" from these proceedings. Alexion has no basis for making these factual allegations. Additionally, Alexion relies on case law that does not apply to this context. 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, as stated above, pleading material facts relating to the costs of Soliris and its effect on public funding and thus Canadians. The Minister also proposes a remedy based on the ex-factory price.

40. The representations the Minister makes are precisely the types of representations, based on the province's unique position as a public payor, for which the province has been given automatic standing in excessive price hearings. If Alexion's position is accepted, and the province could not plead to these facts or make representations as to the appropriate remedy, it would render the Minister's participation in any proceeding before the Board

meaningless and would thereby impede the Board in exercising its consumer protection mandate.

41. Insofar as Alexion raises issues that go to the relevance of material facts or the merits of the case, these are all matters to be determined in the context of the hearing as a whole. This includes what, if any, order should be made under section 83 of the Act, including the amount of any excess revenues and the maximum price that the Board considers not to be excessive.

42. For the foregoing reasons, Alexion has no basis for this motion to strike the Minister's Further Amended Notice of Appearance. Alexion's motion should therefore be dismissed.

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

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