

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”**

RESPONSE TO NOTICE OF MOTION

RESPONSE OF: Minister of Health of British Columbia (“Minister of Health”)

THIS IS A RESPONSE TO the Notice of Motion of the Respondent, filed August 21, 2015.

Part 1: ORDERS CONSENTED TO

The Minister of Health consents to the granting of none of the orders set out the Notice of Motion.

Part 2: ORDERS OPPOSED

The Minister of Health opposes the granting of the orders set out in paragraphs 1 and 2 of the Notice of Motion.

Part 3: FACTUAL BASIS

1. On March 9, 2015, the Minister of Health filed a Notice of Appearance on behalf of the Minister of Health and the Minister of Health for Manitoba.
2. Paragraphs 3 and 4 of the Notice of Appearance stated as follows:
 3. The Ministers of Health intend to rely upon the material facts set out in the Statement of Allegations, and upon the documents noted in the List of Attachments to the Statement of Allegations.

4. The Ministers of Health also intend to rely upon the Affidavit of Eric Lun which will be filed at a later date.
3. On March 13, 2015, the Secretary of the Board wrote to the Minister of Health, advising that the Minister failed to meet the requirements of Rules 21(2)(a) and (b) of the Patented Medicine Prices Review Board Rules of Practice and Procedure (“the Rules”) when filing the Notice of Appearance. In the letter, it was suggested that the Minister of Health might seek an extension of time to file an amended Notice of Appearance that would meet the paragraph 21 requirements of the Rules.
4. On March 17, 2015, the Minister of Health submitted a request for an order extending the time for the Minister of Health to file an Amended Notice of Appearance. The request stated as follows:

“If granted the extension of time to file an Amended Notice of Appearance, the Minister will file an Amended Notice of Appearance providing details of further material facts that the Minister intends to rely upon.....These facts will be set out in detail in the Affidavit of Eric Lun, as referred to in the Notice of Appearance filed on March 9, 2015. The Affidavit of Eric Lun will be filed by the Minister at any time the Panel might order, whether with the Amended Notice of Appearance or at a later date in the proceedings.”
5. On March 26, 2015, the Board issued an order extending the time for the Minister of Health to file an Amended Notice of Appearance. The Order stated that the Minister of Health must file its Amended Notice of Appearance “along with supporting materials” no later than April 2, 2015.
6. On March 28, 2015, counsel for the Minister of Health wrote to the Secretary of the Board, inquiring whether the reference to “supporting materials” in the March 26 order was intended to apply to the affidavit of Mr. Lun, or whether the affidavit might be filed at a later stage in the proceedings.

7. On March 30, 2015, the Secretary of the Board wrote to counsel for the Minister of Health, stating "To all material so it captures the affidavit".
8. The Minister of Health filed the Amended Notice of Appearance on April 2, 2015. The Amended Notice of Appearance stated that the Minister of Health intended to appear and make representations with respect to the matter of the Board hearing on Soliris, and set out the basis on which those representations would be made. Paragraph 4 of the Amended Notice of Appearance stated that the Ministers of Health (the Minister of Health, on its own behalf and on behalf of the Ministers of Health for the Provinces of Ontario, Manitoba and Newfoundland and Labrador) intended to rely upon the Affidavit of Eric Lun.
9. Following the direction of the Board to file the affidavit along with the Amended Notice of Appearance, the Minister of Health filed the affidavit of Eric Lun on April 2, 2015 along with the Amended Notice of Appearance.
10. The Respondent brought a motion to cross-examine Mr. Lun on his affidavit. In response, the Minister of Health sought leave from the Panel to withdraw the affidavit from the record. At the hearing of the motion of the Respondent on June 23, 2015, the Panel suggested that the affidavit be withdrawn and "reformatted" and "repackaged" in such a way as to meet the requirements of Rule 21.
11. On June 26, 2015, the Minister of Health filed the Further Amended Notice of Appearance.

Part 4: POSITION OF THE MINISTER OF HEALTH

12. The Minister of Health opposes the motion for an order striking out portions of the Further Amended Notice of Appearance.
13. The Minister of Health has a statutory entitlement to appear and make representations at the hearing, and that entitlement is clearly distinguishable from the role that an intervener may play in a hearing. The Panel should not accept the

position of the Respondent that the role of a provincial minister of health under section 86(2) of the *Patent Act* is analogous to the role of a public interest intervener.

14. The Minister of Health is not limited to making representations only in relation to the specific issues raised by Board Staff in the Statement of Allegations. The Minister of Health is entitled to bring to the Board the Minister of Health's unique perspective as a public funder of medicines, as long as the representations made by the Minister of Health are with respect to the matter being heard by the Board.
15. The Minister of Health denies the allegations made by the Respondent that the Minister of Health is engaged in a collateral and improper use of the process before the Board. The Minister of Health seeks only to make such representations to the Board as the Minister of Health is statutorily entitled to make.
16. The Board is assisted in fulfilling its consumer protection mandate if the Minister of Health makes representations concerning the cost of medicines to public payors and the public funding process for medicines; if the Minister of Health is prevented from making those representations, the Board will be hindered in exercising its consumer protection mandate.

Part 5: LEGAL BASIS AND SUBMISSIONS

(a) The statutory entitlement of the Minister of Health differs from the role of interveners:

17. The Respondent seeks to equate the role of the Minister of Health before the Board with the role of a public interest intervener. An examination of the applicable provisions of the *Patent Act* and the Rules clearly illustrates that the position of the Respondent is unsupported. Furthermore, if the position of the Respondent were to be accepted by the Panel, the limitation on the ability of the Minister of Health to make representations would impede the Board in exercising its consumer protection mandate.

18. Section 86(2) of the *Patent Act* entitles the Minister of Health to appear and make representations with respect to the matter being heard:
 - (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.

19. Rule 21 of the Rules requires a concerned minister who intends to appear and make representations with respect to a matter that is before the Board to file with the Board and serve on all parties a notice of appearance. Rule 21(2) requires the notice of appearance to be accompanied by
 - (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.

20. Neither the *Patent Act* nor the Rules set any limits on the nature of the representations that a concerned minister may make, or on the facts that the concerned minister might rely upon.

21. The statutory entitlement of the Minister of Health to make representations to the Board with respect to the matter being heard is to be contrasted with the Rules that apply to persons who apply to intervene in a proceeding before the Board.

22. Rule 20 requires individuals who claim an interest in the subject matter of a proceeding to bring a motion to the Board for leave to intervene. A provincial minister of health is not required to make any such motion before appearing and making representations before the Board pursuant to section 86(2) of the Act.

23. Rule 20(2) requires individuals who apply for intervener status to set out specific information in the motion seeking that status. The motion must set out:

- (a) the name and address of the proposed intervener and of any counsel representing the intervener;
- (b) a concise statement of the nature of the proposed intervener's interest in the hearing and the reasons the intervention is necessary;
- (c) a concise statement of the facts upon which the motion is based; and
- (d) the issues that the proposed intervener intends to address.

While both a concerned minister and an individual seeking intervener status are required to provide "a concise statement" of material facts to the Board, a Notice of Appearance filed by a concerned minister is not required to include a statement of "the issues" that the concerned minister intends to address. In contrast, an individual seeking status as an intervener must provide details of the issues that the individual intends to address. If the Board is of the view that the issues that the proposed intervener intends to address are improper, inappropriate, irrelevant, or otherwise not acceptable, the Board could presumably deny the motion for intervention. In contrast, as long as the representations to be made by a concerned minister are "with respect to the matter being heard", the concerned minister is not subject to limitations on the issues that may be addressed. If a concerned minister was subject to such limitations, the Rules would require a Notice of Appearance filed by a concerned minister to be accompanied by a statement of the issues that the concerned minister intended to address.

24. Pursuant to Rule 20(5), the Board may grant or deny a motion for intervener status, and the Board may impose *any* conditions or restrictions on the intervention that it determines to be appropriate after considering relevant factors, including (but not limited to):

- (a) whether the person has an interest in the proceeding that is sufficient to warrant the intervention;
 - (b) whether the intervention will prejudice any party to the proceeding;
- and

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

By contrast, Rule 21, entitling a concerned minister to file a Notice of Appearance, does not provide the Board with the authority to impose any conditions or restrictions on the contents of the Notice of Appearance or on the representations that a concerned minister may make to the Board.

25. As illustrated above, there is a clear distinction between the statutory entitlement of a concerned minister to appear and make representations in a matter before the Board and the ability of an interested party to seek status as an intervener. The case law relied upon by the Respondent in support of its argument that the position of a concerned minister is analogous to a public interest intervener is therefore inapplicable.
26. The Minister of Health submits that the distinctively different treatment between individuals seeking status as interveners and provincial ministers of health is due to the unique position of provincial ministers of health. Only provincial ministers of health are able to provide information to the Board concerning the impact of drug pricing on provincial formularies which provide financial assistance to residents for the purchase of medications. Since provincial governments are a primary source of funding for the purchases of medications in Canada, information about the public funding process and the impact of drug pricing on public funders is highly relevant and important evidence for the Board to consider. The Minister of Health submits that this is the very type of information that Parliament must have intended that provincial ministers of health would provide to the Board. This is the very type of information that the Minister of Health intends to provide in its representations to the Board in this matter.
27. The Respondent seeks to equate the position of the Minister of Health with the position of a public interest intervener. The Minister of Health respectfully submits that if the Panel accepts the position of the Respondent, the Panel will be ignoring the intention of Parliament in providing provincial ministers of health with a statutory right to appear, and it will be ignoring the intention of the Board, in making the clear distinctions between Rules 20 and 21. Furthermore, if the Panel grants the order

sought by the Respondent, the Panel will preclude itself from understanding the unique perspective of the Minister of Health as a public funder of medicines in Canada.

(b)The representations by the Minister of Health are not limited to the issues raised in the Notice of Hearing and Statement of Allegations:

28. Section 86(2) of the *Patent Act* provides provincial ministers with an entitlement to appear and make representations to the Board “with respect to the matter being heard”.
29. The Respondent takes the position that the right of the Minister of Health to make representations is limited to and defined by the “material facts”, “allegations” and “order sought” by Board Staff. The position of the Respondent is that the Minister of Health may make representations that relate to the issues raised by Board Staff and in doing so, offer a different perspective on those issues, but the Minister of Health may not raise new issues or provide representations about any matters that are not set out by Board Staff in the pleadings. The Minister of Health submits that the Respondent’s position applies an overly restrictive meaning to the phrase “the matter being heard”. If accepted, the Respondent’s position would render meaningless the statutory entitlement of provincial ministers of health to make representations to the Board.
30. Contrary to what the Respondent submits, the “matter being heard” is, in fact, that matter described in Section A of the Notice of Hearing -- “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”. Pursuant to section 86(2), the Minister of Health has a statutory entitlement to make representations with respect to that matter. The representations that the Minister of Health intends to make, as set out in the Further Amended Notice of Appearance, are clearly with respect to that matter.

31. If the Panel were to limit the right of the Minister of Health to make representations in the manner suggested by the Respondent, it would have the effect of essentially rendering the statutory entitlement set out in section 86(2) meaningless. In this case, the Respondent seems to be taking the position that the only issue concerning which the Minister of Health may make representations is the application of the Highest International Price Comparison (“HIPC”) test. A provincial minister of health would have very limited information relating to the application of the HIPC test additional to the information that Board Staff would have. In fact, a provincial minister of health would likely not have any information related to the application of that test. If the position of the Respondent is accepted, the Minister of Health would have no entitlement to make any representations in relation to this proceeding. That is not in keeping with the intention of Parliament as expressed through section 86(2) of the *Patent Act*.
32. Furthermore, in taking the position that the Minister of Health is limited to making representations related to issues raised by Board Staff, the Respondent is mischaracterizing or misunderstanding the purpose of a hearing before the Board. In fulfilling its mandate, the Board is not limited to considering only Board Staff’s interpretation of the Board’s Guidelines and the Regulations; the hearing before the Board is hearing *de novo*, not an appeal of findings made by Board Staff.
33. Because the Board is to consider the factors set out in section 85(1) of the *Patent Act* in making its determination, the Minister of Health may make representations in relation to any of those factors. Furthermore, section 85(2) of the *Patent Act* permits the Board to take into consideration such other factors as are, in the opinion of the Board, relevant in the circumstances. The Minister of Health may therefore make representations in relation to matters other than those set out in section 85(1).
34. Similarly, if the Board finds that the price of the medicine Soliris is or has been excessive, the Board is not limited to ordering that the price of the product be reduced to the level that Board Staff is requesting. Pursuant to section 83 of the *Patent Act*, the Board may order the price of a product to be reduced to such level as the Board considers not to be excessive, whether that level is the level which Board Staff is requesting, the level which the Minister of Health is requesting, or

some other level. Given that fact, representations by the Minister of Health that the price be reduced to match the lowest price for Soliris among all comparator countries clearly may be taken into consideration by the Board.

(c) The Further Amended Notice of Appearance does not constitute an abuse of process and the Minister of Health is not engaged in a collateral purpose

35. At paragraph 38 of the Written Submissions of the Respondent, the Respondent states that the Minister of Health admits in its pleadings that the purpose for seeking intervention is essentially to gain a commercial advantage by lowering the listing price to enhance the ability of the Minister to negotiate lower discounts in downstream negotiations. The Minister of Health denies having made any such admission, and denies that this is the purpose for the Minister of Health making representations to the Board.
36. In paragraph 10 of Appendix A to the Further Amended Notice of Appearance, the Minister of Health does indicate that participating jurisdictions negotiate confidential product listing agreements with the Respondent in relation to Soliris. In providing that information, the Minister of Health is not admitting an intention to gain a commercial advantage to enhance the ability of the Minister of Health to negotiate lower discounts in downstream negotiations. The discount negotiated by participating jurisdictions with the Respondent is a separate issue from the factory-gate price of Soliris. Even if the Board were to order a reduction in the price of Soliris, that would not “enhance the ability” of the Minister to negotiate a lower discount in downstream negotiations.
37. To the extent that a price reduction would result in a lower factory-gate price for Soliris, the Minister of Health admits that, as public payors, provincial governments could recognize financial savings. However, this does not mean that the Minister of Health is using the statutory entitlement to make representations to the Board in order to assert private economic interests, or in order to seek a commercial advantage.
38. The representations that the Minister of Health seeks to make, as set out in Appendix A of the Further Amended Notice of Appearance, are intended to bring

before the Board the unique perspective of a public funder of medication. The Minister of Health is not seeking to have the Board adjudicate downstream economic interests.

39. The submissions of the Respondent are essentially that the Minister of Health cannot provide information to the Board about the cost and process of public funding of Soliris because to do so would be a collateral and improper use of the process before the Board. If the Panel were to accept these submissions, it would render section 86(2) of the *Patent Act* essentially meaningless. As noted above, the provincial ministers of health are in a unique position to provide information and evidence to the Board concerning the impact of drug pricing on provincial formularies which provide financial assistance to provincial residents for the purchase of medications. The position of the Minister of Health is that it is in recognition of this unique role that Parliament determined it would be appropriate to provide provincial ministers of health with an entitlement to make representations before the Board. In making these representations, provincial ministers of health may assist the Board in fulfilling its consumer protection mandate. If the Minister of Health is not permitted to make representations detailing the cost of medicines to public payors or the process by which public payors determine whether to fund medicines, the Minister of Health is not able to bring the Minister's unique perspective to the Board's attention and the Board is impeded in exercising its consumer protection mandate.

(d) The determination of the appropriate representations to be provided by the Minister of Health should not be made prior to the hearing:

40. By bringing its motion to strike portions of the Further Amended Notice of Appearance, the Respondent seeks to unduly and prematurely limit the representations that the Minister of Health may make. The position of the Minister of Health is that at this stage in the proceedings, the Respondent is unable to establish that there are irrelevant portions of the Further Amended Notice of Appearance. The relevance of the evidence is to be determined in the context of the hearing, when the parties have had an opportunity to present their evidence. Until evidence has been presented by the parties, there is no context for any determination to be made by the Board on the question of relevance.

Dated: October 19, 2015

Original signature redacted

Sharna Kraitberg
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This Response to Notice of Motion is filed by Counsel for the Minister of Health of British Columbia by Sharna Kraitberg whose place of business and address for service is Ministry of Justice, Legal Services Branch, 1001 Douglas Street, Victoria, BC V8W 9J7, Tel: (250) 356-8931, Fax: (250) 356-8992