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: (ALEXION'S MOTION RE: Strike Portions of the FURTHER AMENDED NOTICE OF APPEARANCE Filed by the Minister of Health)

Overview

1. Alexion Pharmaceuticals Inc. ("Respondent" or "Alexion) seeks an order striking out paragraphs 1 and 3 of, and Appendix A to, the "Further Amended Notice of Appearance" ("Further Appearance)" of the Minister of Health for British Columbia ("B.C. Minister") dated 26 June 2015.

2. The Further Appearance advances a different case, and seeks different relief, than Board Staff have asserted or sought in the Statement of Allegations ("Allegations"). Moreover, the remedy sought in the Further Appearance is contrary to remedial approaches articulated in the Guidelines and the Board's jurisprudence. The Further Appearance is thus contrary to Section 86(2) of the *Patent Act*, which limits the B.C. Minister's representations to "the matter being heard."

3. The Further Appearance violates the fundamental principle that a putative intervener "must take the case before the [tribunal"] as he or she finds it, and may not

widen or add to the issues to be determined."[1] The factual and legal issues raised in the Further Appearance will complicate the proceeding and defeat the purpose of ensuring the fair and expeditious conduct of the prosecution.

4. Additionally, it is evident from the Further Appearance that the B.C. Minister, and the other participating provincial ministers (the "Ministers"), are attempting to use the proceeding to obtain private commercial advantages. The Further Appearance directly acknowledges that provincial governments privately engage in downstream negotiations and pay prices for Soliris that are lower than the ex-factory list price. The Ministers' stated objective in this case is to push the list price lower so that deeper discounts can be negotiated downstream by the Ministers. In its jurisprudence, the Board has stated that it is inappropriate to permit interventions that involve parties attempting to obtain a commercial or competitive advantage. Furthermore, and in any event, downstream prices for patented products are outside the Board's constitutional jurisdiction as defined by the Federal Court in *Pfizer v. Canada*, which states that there is a "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." Finally, the use of a hearing to obtain a lower price in private downstream negotiations is a collateral purpose and amounts to an abuse of the Board's process, which is designed to determine whether ex-factory prices are excessive based upon public interest principles prescribed in the *Patent Act* and not to adjudicate commercial rights.

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[1] CED 4th (online), Parties (Ont.), "Federal Court of Canada: Intervention" (I.2) at § 14.

Background

5. On 20 January 2015, the Board issued its Notice of Hearing ("Notice") and Statement of Allegations ("Allegations") relating to Alexion Pharmaceuticals Inc. ("Alexion" or "Respondent") and the medicine Soliris. The Board's Notice stated that the "material facts relied upon by Board Staff" were described in the Allegations.

6. The principal assertion in the Allegations (and the only one specifically advanced by Board Staff) is that Alexion has sold Soliris to Canadians "at the highest international price among the comparator countries" listed in the Board's 2010 Compendium of Guidelines, Policies, and Procedures ("Guidelines"). Board Staff ask that Alexion be ordered to "stop selling Soliris at an excessive price" and disgorge revenues Alexion "has generated from the sale of Soliris at an excessive price."

7. Paragraphs 14 – 21 of the Allegations describe an investigation conducted by Board Staff based upon the Highest International Price Comparison ("HIPC") test contained in the Guidelines. The foundation for the alleged excessive pricing is the HIPC. There is no remedy sought in the Allegations for violation of any test other than the HIPC, which presumably applies the statutory factor found in subsection 85(1)(c) ("the prices at which the medicine...[has] been sold in countries other than Canada"). There has been no suggestion by Board Staff, at any time since commencement of the proceeding, that Alexion should disgorge any revenues other than allegedly excess revenues earned through application of the HIPC test.

8. Alexion filed its initial Response on 9 March 2015. The Response (and now the Amended Response) asserts that the Introductory Maximum Non-Excessive ("MNE")

for Soliris approved by Board Staff, $223.21/ml, has not increased since Soliris was first introduced on the Canadian market in 2009. The Amended Response further notes that Alexion has foregone any price increases based on the Consumer Price Index ("CPI") since the product was introduced, meaning that the price of Soliris has actually decreased in relative terms since 2009. Indeed, as the Response notes, the allegation of "excessive" pricing under the HIPC is not based on actual price increases for Soliris in Canada or price decreases for Soliris in the comparator countries listed in the Guidelines: rather, the allegation is based solely upon fluctuations in the value of international currencies compared to the Canadian dollar. In sum, Alexion asserts in the Response that Board Staff are effectively comparing the relative value of currencies of various jurisdictions rather than the actual prices of Soliris in Canada and the comparator countries. In the absence of any price increases in Canada, or any price decreases in comparator countries outside Canada, Alexion asserts that it cannot be held responsible for any alleged excessive prices based upon currency fluctuations that are entirely beyond Alexion's control.

9. As defined in the Allegations and the Response, the only issue for the Hearing Panel to decide is whether Alexion can be made accountable for alleged excess revenues based on the HIPC test.

10. On 9 March 2015, the B.C. Minister filed an initial Notice of Appearance (" initial Appearance") on behalf of the B.C. Minister and Minister of Health for Manitoba (collectively the "Ministers"). The initial Appearance stated that the Ministers intended "to appear and make representations with respect to this matter" and would "make representations supporting the proposed Orders of the Board on the basis set out by

Board Staff in the Statement of Allegations of Board Staff."[2] While the initial Appearance made reference to relying upon an "Affidavit of Eric Lun which will be filed at a later date", it contained no suggestion that the Ministers would make "representations" concerning the "matter" going beyond the material facts alleged by Board Staff. Nor was there any suggestion that the Ministers would be referring to material facts or issues different from application of the HIPC issue mentioned in the Allegations. The Ministers gave no indication that they would seek relief in the proceeding different from the "proposed Orders" sought by Board Staff. The disgorgement remedy sought by Board Staff in the Allegations relates only to calculations based on alleged violations of the HIPC test, which involves comparing the difference between the Canadian price and the next highest price of Soliris among the comparator countries listed in the Schedule to the *Patented Medicines Regulations*.

11. On 17 March 2015, 8 days after the Ministers' Appearance was filed, the B.C. Minister requested the right to amend the Ministers' initial Appearance to expand the list of Ministers to include the Ministers of Health of Ontario and Newfoundland/ Labrador. In the accompanying cover letter, counsel for the B.C. Minister indicated that she would provide "details of further material facts that the Minister intend[ed] to rely upon" relating to:

> (a) recommendations made by the Common Drug Review (CDR) in relation to reimbursement of Soliris by public drug plans;
>
> (b) the process by which public drug plans review medicines such as Soliris for potential reimbursement;
>
> (c) the cost of Soliris in comparison to other publicly-funded medicines; and

[2] Notice of Appearance dated 9 March 2015.

(d) the importance of the public list price of a medicine in relation to negotiations and other reimbursement policies."

12. Based on the material facts alleged in the Allegations, and the counter-allegations in the Response, the "further material facts" the Ministers intended to rely upon were irrelevant to the investigation conducted by Board Staff. Nor did the facts bear any relationship to the issue to be determined by the Hearing Panel based on the Allegations and the Response: whether Alexion should disgorge allegedly excessive revenues based upon alleged violation of the HIPC test. Indeed, evidence concerning the CDR, review procedures of public drug plans, cost of Soliris compared with other publicly-funded medicines in Canada, and public list prices and reimbursement policies, bear no relation to any of the applicable factors under section 85 (1) as referred to in the Allegations or whether Alexion should disgorge allegedly excess revenues earned in contravention of the HIPC test.

13. Alexion objected to the proposed Amended Appearance on the grounds that it was irrelevant to Board Staff's HIPC assertions in the Allegations.

14. In an Order dated 26 March 2015, the Panel granted the Ministers' request to extend the time to file an Amended Appearance to 2 April 2015.

15. On 2 April 2015, the Ministers filed their "Amended Notice of Appearance" ("First Amended Appearance") together with an affidavit of Erik Lun dated 1 April 2015. The First Amended Appearance asked to the Panel to order Alexion to:

(a) "reduce the price of Soliris to a price that does not exceed the lowest price for Soliris among all comparator countries"; and

> (b) "offset cumulative excess revenues by paying to the federal government an amount equal to the excess revenues the Board estimates... [Alexion] has generated from the sale of Soliris at an excessive price, with the Board to use the lowest price for Soliris among all comparator countries as the basis for the calculation. [Underlining added.]

16. The Lun affidavit reiterated, in general terms, the "further material facts" outlined by the B.C. Minister's counsel in her letter of 17 March 2015. The affidavit also attached, as exhibits: the Canadian Expert Drug Advisory Committee Recommendation on Soliris for Indication of Paroxysmal Nocturnal Hemoglobinuria; the Canadian Drug Expert Committee Recommendation on Soliris for Indication of Atypical Hemolytic Uremic Syndrome; and the Common Drug Review Submission Status summary.

17. In his affidavit, Mr. Lun revealed that the Ministers had engaged in confidential negotiations with Alexion and negotiated lower prices for Soliris. In particular, he swore:

> 12. In agreeing to consider funding Soliris through government funding, the provinces and territories completed national negotiations for a confidential price for the product for its use in PNH. To secure confidential lower prices, participating jurisdictions each complete their own confidential product listing agreements with the manufacturer and therefore cannot disclose the terms or conditions of such agreements. However, the list price of Soliris is referenced in the negotiations in order to determine overall value. Therefore, an excessive list price results in provincial governments being inherently disadvantaged in the listing negotiations and in the subsequent ongoing funding of Soliris purchases. [Underlining added.]

18. As was the case with the 17 March 2017 letter, the allegations and facts stated in the First Amended Appearance and the Lun Affidavit bear no relationship to Board Staff's Allegations. In certain respects, the Ministers' allegations contradict those of Board Staff. In particular, Board Staff allege that the price of Soliris failed the HIPC test

found in the Guidelines—which provides that the price of a drug in Canada cannot be higher than the highest "international price" as chosen from among the 'basket' of comparator countries defined in the Guidelines. The remedy in an HIPC case is to request a price reduction to the highest average price and require a patentee to pay the difference between the actual price and the "non-excessive average price" (the "N-NEAP). The Ministers' Amended Notice, however, requests (in paragraph 1) an order that Alexion be required to "...reduce the price of Soliris to a price that does not exceed the lowest price among all comparator countries". The HIPC test applies the "highest", not the "lowest", price.

19. In effect, in the First Amended Appearance, the Ministers have requested an increase in the fine or penalty to be assessed against Alexion because the highest international price for Soliris based on the HIPC test is greater than the lowest international price for Soliris in the comparator countries. In addition to increasing the fine, the Ministers have openly acknowledged that they seek a decrease in the list price going forward to create a commercial advantage to provincial governments as purchasers of Soliris because a lower list price will give them an advantage in obtaining deeper discounts in future listing negotiations with Alexion.

20. On 10 April 2015, Board Staff delivered its Reply to Alexion's Response. Although Board Staff allege in the Reply that they rely on "the factors under subsection 85 (1) of the Act" for the allegation that "Alexion has been selling Soliris to Canadians at an excessive price since 2012" there are no specifics of how any provision other than s. 85 (1)(c) are applicable. Furthermore, there is no request for any remedy apart from a calculation based upon allegedly excessive revenues arising from alleged violation of

the HIPC test. In particular, there is no allegation that revenues are excessive because Soliris is "expensive" or sold at a price in Canada that is higher than the price in the United States for any given period.

21. Following receipt of the Amended Appearance, Alexion counsel indicated they wished to cross-examine Mr. Lun on his affidavit before bringing a motion to strike portions of the First Amended Appearance. The proposed cross-examination and motion to strike were raised in the case conference heard by teleconference on 29 April 2015. During the case conference, counsel for the B.C. Minister indicated that they would not voluntarily produce Mr. Lun for cross-examination and that Alexion would have to bring a motion for leave under Board Rule 26(2). Alexion was ordered by the Panel to deliver materials concerning leave to cross-examine Mr. Lun on 15 May 2015.

22. The motion to cross-examine Mr. Lun was delivered on 15 May 2015 and written representations were filed a week later on 22 May 2015. On 5 June 2015, counsel for the Ministers filed responding written representations seeking the Panel's leave to withdraw Mr. Lun's affidavit from the record. In their written submissions, the Ministers also indicated that they would "seek a ruling...on the mechanism" for the Ministers to provide representations to the Panel.

23. At the hearing of the motion on 23 June 2015, the Board permitted the Ministers to withdraw the Lun affidavit. The Panel directed counsel for the Ministers to file the Further Appearance by Friday, 26 June 2015.

24. The Further Appearance filed by the Ministers' counsel on 26 June 2015 requests the same remedy as the First Amended Appearance. All references to Mr.

Lun's affidavit were deleted from the Further Appearance as were references to the additional "material facts" and further documents mentioned in the First Amended Appearance. Appendix A to the Further Appearance repeats, almost verbatim, the same material previously contained within the First Amended Appearance and in Mr. Lun's affidavit. Essentially, counsel for the Ministers has transposed what was previously submitted as sworn evidence, upon which they resisted cross-examination, as a schedule to a *pro forma* appearance. The transposed paragraphs from Mr. Lun's affidavit include references, in paragraph 10 of Appendix A, to negotiations by provincial governments to obtain discounted prices and the advantage that would be gained by obtaining a lower listing price for Soliris.

25. Disclosures and particulars delivered by Board Staff in response to the Panel's Order of 23 June 2015 confirm that Board Staff did not consider the price of Soliris to be "excessive", at $223.21/ml, in either 2010 or 2011. The remedies sought by Board Staff and the Ministers seek relief only from the point at which it is alleged that the HIPC test was violated commencing 1 January 2012. There is no allegation by the Ministers of any violation of section 85(1) of the *Patent Act* apart from the price of Soliris in Canada compared to other jurisdictions. Nor do the Ministers allege any excess revenues based upon any other *Patent* Act, Guidelines test, or related criteria. As currently framed, the hearing still deals with the narrow issue of how the Board should treat fluctuations in international exchange rates when considering the HIPC test.

26. The Ministers' allegations are unfocussed general complaints about the price of Soliris and have the potential to convert the hearing into a broad inquiry into procurement of patented medicines by public entities across Canada. The Board's

purpose, however, is to determine allegations within the statutory scheme of the *Patent Act* and, if applicable, the Guidelines. The Board is not a commission of inquiry into the price of Soliris, or any other patented medicine sold in Canada. The Ministers' allegations will greatly increase the complexity, and the time that will be required, to prepare for and conduct the hearing.

27. Furthermore, the Ministers' attempts to use the current proceeding to obtain downstream commercial advantages in their private negotiations with Alexion asks the Board "to look beyond the factory-gate price of Soliris" to "consider contractual arrangements involving patentees and entities further down the distribution chain." This is outside the scope of the Board's statutory jurisdiction and also amounts to an abuse of process because intervention in the prosecution is being used to advance private commercial interests.

Panel Should Strike Out Impugned Portions of Further Appearance

28. Subsection 86(2) of the *Patent Act* provides provincial ministers with a type of *amicus* standing in proceedings before the Board:

> 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. [Underlining added.]

29. The words "with respect to the matter being heard" clearly signify that the right to make representations is limited to the subject matter of the hearing based upon the Notice of Hearing and Statement of Allegations issued by the Board Secretary.

30. Board Rules 15 provides, in material part:

> Signed notice of hearing
>
> 15. (1) Proceedings are initiated by issuance of a notice of hearing signed by the Secretary.
>
> Personal service
>
> (2) A notice of hearing must be served personally on the respondent, all concerned ministers and on any other person that the Board may direct, in accordance with Rule 11.
>
> Statement of allegation or notice of application
>
> (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 allegations set out in consecutively numbered paragraphs containing the material facts, the allegations and the order sought by Board Staff in the proceeding...

31. The "matter being heard" is thus defined by the "material facts", "allegations", and "order sought" by Board Staff. None of the *Patent Act*, Board Rules, Guidelines, jurisprudence of the Board and Federal Courts, or principles of statutory interpretation provide any basis for a provincial minister's right to intervene for the purpose of adducing entirely new material facts, asserting separate allegations and case theories, or requesting relief or orders from a panel of the Board that are different from Board Staff's allegations in a statement of allegations.

32. The allegations in the Further Appearance make no sense in the context of the regulatory scheme. The scheme provides concerned ministers with a right to make representations after an investigation has been initiated by the Board Staff, a VCU has been rejected, and the Chairperson of the Board has recommended that a hearing be held. There is no statutory right conferred on provincial ministers to commence a

hearing on their own initiative. If the Ministers' theory were correct, the statutory scheme would, in effect, provide concerned provincial ministers with the right to initiate alternative investigations and hearings based on theories utterly unrelated to those raised by Board Staff— at least in cases where the Board has already, through its usual process, initiated its own case.

33. Moreover, considering that the statutory right extends to all 10 provincial ministers of health (and to the federal Minister of Industry), the position advanced by the B.C. Minister has the potential to lead to the absurd result that 12 different theories of the case could be proposed whenever an investigation moves to a hearing—that of Board Staff, the federal Minister, and the 10 provincial ministers. This cannot have been Parliament's intention, which was evidently concerned to "ensure the fair and expeditious conduct of any proceeding."

34. The only sensible interpretation is that the "representations" made by concerned ministers be similar to *amicus* interventions by public interest interveners. Public interest interveners are entitled to make representations that offer a *different perspective* on the issues already raised between the parties but without introducing *new* issues as between Board Staff and the Respondent.

35. A recent case on this point in the federal court jurisprudence is *Alderville Indian Band v. Canada*, [2014] F.C.J. No. 857 (Fed. TD):

> The jurisprudence emerging after the new Court Rules were introduced in 1998 has indeed looked to previous cases for guidance. Although caution is warranted, the old cases are still helpful. As Prothonotary Hargrave noted in *Yale Indian Band v Aitchelitz Indian Band* (1998), 151 FTR 36 at paragraph 14 [*Yale Indian Band*], the substantial case law built around the

former Federal Court Rule 1716 could be used as guidance in the exercise of discretion under the new rule. In the course of his discussion Prothonotary Hargrave stated at paragraph 18:

In *Canada (A.G.) v Aluminum Co. of Canada* [1987] 3 W.W.R. 193, the British Columbia Court of Appeal, referring to various authorities, to the effect that intervenors [sic] ought not to be allowed to redefine issues, thus forcing the parties to deal with issues which are not their own, noted:

> "Interveners should not be permitted to take the litigation away from those directly affected by it. Parties to litigation should be allowed to define the issues and seek resolution of matters they determine appropriate to place in issue. They should not be compelled to deal with the issues raised by others." (p. 206)

36. The same point is made in *Pinnacle Estates Inc. v. Beam Inc.*, [2013] F.C.J. No. 1319 (Fed. TD):

> 11 First, it should be noted that, even if one admitted for discussion purposes that the allegations that were withdrawn from the initial statement of claim could be of some interest for the ends sought by the Constellation Group, the fact remains that these allegations no longer exist and that the Court must examine the present dispute between the plaintiff and the defendants Beam as it stands according to an analysis of the pleadings between these parties.
>
> 12 This aspect is relevant as it is known that any intervener must take the proceeding as it stands between the parties that are already involved. In fact, as noted in Maurice v Canada (Minister of Indian Affairs and Northern Development) (2000), 183 FTR 45, at paragraph 11, interveners cannot, as a result of their status, raise aspects that have not already been raised by the existing parties:
>
> > [11] <u>It is common ground that an intervenor takes the pleadings and record as it finds them</u>. While an intervenor may bring new viewpoints and special knowledge to a proceeding, <u>the intervenor may not litigate new issues</u> (Yale Indian Band v. Aitchelitz Indian Band (1998), 151 F.T.R. 36 (Proth.). I am confident that counsel for the applicant is well aware of the role that intervenors are allowed to play, and that the applicant will not seek to expand the parameters of the claim, which indeed, in any event, it may not do. [Emphasis added]

37. This form of intervention is particularly applicable in regulatory enforcement prosecutions in which relief in the nature of confiscation, forfeiture, and penalties is being sought. Indeed, in this case the Ministers are seeking a confiscation/penalty order that would have the effect of increasing the amount of allegedly "excess" revenues beyond what Board Staff are requesting. And while Board Staff have at least quantified their claims, the Ministers have not provided any details. The Ministers are presumably not subject to discovery – in fact they resisted cross-examination in this case – and are not otherwise accountable in the proceeding.

38. Furthermore, the Ministers admit in their pleadings that the purpose for seeking intervention is essentially to gain a commercial advantage by lowering the listing price to enhance their ability to negotiate lower discounts in downstream negotiations. A lower list price would create an advantage for the Ministers in negotiating product listing agreements with Alexion for future supplies of Soliris.

39. Intervention attempts by parties asserting private economic interests have been unsuccessful. In *PMPRB-07-D1-QUADRACEL and PENTACEL Application for leave to intervene by GlaxoSmithKline Inc.*, the Board stated:

> 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.

The relative bargaining power or commercial advantages of patentees and other entities downstream from the factory-gate in this case raises similar concerns.

40. In any event, in *Pfizer v. Canada (AG)* 2009 FC 719, the Federal Court held that there was a "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." The Panel therefore lacks jurisdiction to consider the downstream arrangements raised by the Ministers.

41. Furthermore, Alexion respectfully submits that the Ministers' purpose of using the hearing to gain downstream commercial advantages amounts to an abuse of the Board's process. 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. The process was never intended to be a forum for adjudicating downstream economic interests, including the commercial interests of provincial governments who purchase patented medicines in private transactions. The Ministers' attempt to use the proceedings to gain competitive advantages and enhance commercial bargaining prospects in downstream transactions is a collateral and improper use of the process.

42. The statutory right to intervene does not confer on the Ministers the further right to, in effect, launch their own prosecution under the *Patent Act* or use a prosecution to obtain collateral commercial advantages that go beyond the ex-factory price. The statutory scheme envisages that the Ministers will bring their "unique perspective" to the issues established by the Statement of Allegations and disputed by Alexion, all within the ambit of the Board's statutory mandate.

43. All of these concerns demonstrate the fundamental unfairness of interveners like the Ministers being entitled to introduce entirely new evidence or case theories, raise issues that are beyond the Board's jurisdiction, and request separate remedies for their commercial advantage. Like all other public interest interveners, the Ministers in this case must "take the pleadings and record as they find them", make representations as to whether an ex-factory price is excessive based on established criteria, not assert private commercial interests or agenda that arise downstream of the ex-factory price.

Order Requested

44. Alexion respectfully requests that the Panel grant an order striking out paragraphs 1 and 3, and Appendix A to, the Further Appearance.

Dated: 2 September 2015

Malcolm Ruby
GOWLING LAFLEUR HENDERSON LLP
1 First Canadian Place
100 King Street West
Suite 1600
Toronto ON M5X 1G5

Malcolm N. Ruby
Tel: 416-862-4314
Fax: 416-863-3614
malcolm.ruby@gowlings.com

Alan West
Tel: 416-862-4308
Fax: 416-863-3480
alan.west@gowlings.com

Lawyers for the Respondent

TO: **PATENTED MEDICINE PRICES REVIEW BOARD**
Legal Services Branch
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa ON K1P 1C1
Tel: (613) 952-7623
Fax: (613) 952-7626

Guillaume Couillard *(Secretary of the Board)*
guillaume.couillard@pmprb-cepmb.gc.ca

Parul Shah *(Legal Counsel PMPRB)*
parul.shah@pmprb-cepmb.gc.ca

AND TO: **PERLEY-ROBERTSON HILL & MCDOUGAL LLP**
340 Albert Street, Suite 1400
Ottawa, ON K1R 7Y6
Tel: (613) 566-2833
Fax: (613) 238-8775

David Migicovsky
dmigicovsky@perlaw.ca

Christopher Morris
cmorris@perlaw.ca

Lawyers for Board Staff

AND TO: **MINISTRY OF JUSTICE**
Legal Services Branch
PO Box 9280 STN PROV GOVT
1001 Douglas Street
Victoria, B.C. V8W 9J7
Tel: (250) 356-893
Fax: (250) 356-8992

Ms. Sharna Kraitberg
Sharna.Kraitberg@gov.B.C..ca
Lawyer for Her Majesty the Queen in Right of the Province of British Columbia, as represented by the Minister of Health

Representative for the Interveners, the Provinces of Manitoba, Ontario, and Newfoundland and Labrador

AND TO: **CANADIAN LIFE AND HEALTH INSURANCE ASSOCIATION**
79 Wellington St. West, Suite 2300
P.O. Box 99, TD South Tower
Toronto, ON M5K 1G8
Tel: (416) 777-2221
Fax: (416) 777-1895

Craig Anderson
CAnderson@clhia.ca
Lawyer for Canadian Life and Health Insurance Association

TOR_LAW\ 8774442\4