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®"

BIOTECANADA WRITTEN REPRESENTATIONS ON THE MERITS

Facts

1. BIOTECanada, on behalf of its member companies, has an interest in at least one of the subject matters of this proceeding. BIOTECanada, on behalf of its member companies, is in a position to provide information that is relevant to these proceedings.

2. BIOTECanada's members include a wide variety of biotechnology organizations, most of which are in the business of researching and developing patentable technologies relating to medicines. Thus, their medicines would come under the jurisdiction of the Patented Medicine Prices Review Board (PMRPB) when they reach the market. Many of BIOTECanada's members produce and/or market medicines which are used to treat serious illnesses. Furthermore, many of BIOTECanada's members research, develop and sell drugs to treat rare diseases (orphan drugs).

3. In this proceeding, the Board Staff have amended their Statement of Allegations (the "Amended Statement").

4. The Amended Statement is not available publicly. However, portions of it have been cited in publically available documents. BIOTECanada is concerned about several of those amended provisions, as they purport to create new tests, not found in the Guidelines, for determining whether a medicine's price is excessive and how to calculate the excess revenues that should be forfeited.

5. These new tests have the potential to affect the interests of BIOTECanada's members generally, as they are a significant departure from the PMPRB's Guidelines. Furthermore, they are a breach of procedural fairness and a breach of the principles of statutory interpretation as discussed further below. In addition, they are outside the PMPRB's jurisdiction.

6. In particular, the Amended Statement seeks an order, *inter alia,* requiring:

   (a) Alexion to reduce its price for SOLIRIS® in Canada to the "lowest international price" (LIP) among comparator countries;

   (b) Alexion to forfeit "excessive revenues" based on either this LIP comparator (LIPC) or the Median International Price Comparison (MIPC); and

   (c) Alexion's forfeitures to be retroactive to the outset of its sales of SOLIRIS®.

Issue

7. This written argument addresses solely the issue of the Board Staff's use of the new tests in the Amended Statement to determine whether a medicine's price is excessive, and to then seek forfeiture of excessive revenues based on these new tests.

The Introductory Price is Determined using the MIPC Test

8. The Guidelines set out several different criteria for determining the test applicable to the introductory price of a new patented medicine (the Maximum Average Potential Price or MAPP), depending upon the level of therapeutic improvement assigned to the drug. However, each of these criteria involves an analysis of the MIPC test.[1]

[1] Patented Medicines Price Review Board, "Compendium of Policies, Guidelines and Procedures" (July/August, 2016) ("Guidelines"), Schedule 8.

9. When a party starts selling a patented medicine in Canada, it must submit to the PMPRB its pricing information on a regular basis. The Board Staff then determines the "National Average Transaction Price" (NATP) for the medicine based on this pricing information.

10. Schedule 11 of the Compendium sets out the criteria to be used to decide whether to commence an investigation:

> **Criteria for Commencing an Investigation**
>
> Board Staff will commence an investigation into the price of a patented drug product when any of the following criteria are met:
>
> 1. The National Average Transaction Price or any Market-Specific Average Transaction Price of a new drug product exceeds the Maximum Average Potential Price during the introductory period by more than 5%.
>
> 2. Excess revenues for a new or existing drug product are $50,000 or more.
>
> 3. PMPRB receives a complaint.[2]

11. Criteria 1 and 2 are based on the relevant tests used to calculate the MAPP. However, Criteria 3 is outside of this test. Thus, in theory, anyone could make a complaint about pricing. Once that complaint is made, the Board Staff will commence an investigation.

12. Any individual or group affected by the price of a patented medicine can submit a complaint.[3]

13. The PMPRB's entire methodology in setting the MAPP would be undermined if the remedy was to lower the price and require forfeitures based on the LIPC, or MIPC, when used as a test for years following the introduction. There would be no reason to even start with the MIPC. Every Party (including BIOTECanada's members) selling a patented medicine would open

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[2] Guidelines, Schedule 11.

[3] Patented Medicine Prices Review Board, "How to Make a Complaint", <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1014>.

themselves up to punitive forfeiture measures if it accepted the Guidelines as a determination of the MAPP for its medicines.

14. Considering that companies have always been told to start with the MIPC, it is unconscionable for the Board to unilaterally change the system in this fashion.

15. Indeed, such rendering of the Guidelines as moot, is an end-run around the statutory requirement to hold public consultations before amending the Guidelines.[4] This statutory requirement is discussed further below. However, in effect, by purporting to apply the LIPC (or alternatively the MIPC) methodology to remedies, and make those remedies retroactive, the Board Staff has amended the terms in the Guidelines that set out how to calculate MAPP, and thus, NATP.

16. Furthermore, if accepted in this case, it would open every medicine being sold in Canada to the same process. Every Party (including BIOTECanada's members) selling a patented medicine in Canada could be subject to retroactive, punitive measures requiring them to forfeit previously proper revenues as excess due to the new application of the LIPC methodology to excessive price determinations.

17. This is improper and should not be countenanced. Furthermore, it is outside the Board's jurisdiction.

The Guidelines are Meant to be Used by Patentees for Voluntary Compliance

18. The Guidelines themselves state that one of their primary objectives is to ensure patentees are aware of the guidelines, policies and procedures used by the Board to review prices of patented medicines. In addition, the Guidelines are meant to uphold the principles of fairness, transparency, openness, and predictability.

> One of the primary objectives of the Compendium of Policies, Guidelines and Procedures (Compendium) is **to ensure that patentees**

[4] *Patent Act*, R.S.C., 1985, c. P-4 [hereinafter *Patent Act*], s. 96 [emphasis added].

> **are aware of the policies, guidelines and procedures under which Board Staff reviews the prices of patented drug products sold in Canada, and the procedures normally undertaken in the scientific and price review processes and when a price appears to be excessive.**
>
> From time to time, the PMPRB finds it necessary to update the Guidelines under which it operates to ensure that they remain relevant and appropriate, **as well as uphold the principles of fairness, transparency, openness, and predictability**. When considering Guidelines amendments, the PMPRB consults with its stakeholders through its Notice and Comment process.[5]

19. These objectives cannot be met if the Board Staff is permitted to retroactively amend the Guidelines through the remedies process in its investigations.

20. Furthermore, the PMPRB publishes Annual Reports every year. These Reports contain statements indicating that the Board's Guidelines are to be used by patentees to ensure that their pricing is not excessive. The 2009 Report states:

> Although patentees are not required to obtain approval of the price beforehand, they are required under the Act to ensure that prices of patented drug products sold in Canada are not excessive. **The Board's Guidelines detail how to determine whether a price is excessive.**[6]

21. The 2015 Report contains a similar statement:

> The Regulatory Affairs and Outreach Branch reviews the prices of patented drug products sold in Canada to ensure that they are not excessive; **encourages patentees to comply voluntarily with the Board's Guidelines**; implements related compliance policies; and investigates complaints into the prices of patented medicines. This branch also informs and educates patentees on the Board's Guidelines and filing requirements.[7]

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[5] Guidelines, p. 6 [emphasis added].

[6] Patented Medicine Prices Review Board, "Annual Report 2009" ("2009 Report"), <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=898> [emphasis added].

[7] Patented Medicine Prices Review Board, "Annual Report 2015" ("2015 Report"), <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1273#a5>.

22. Thus, the Board's public positon on its website, in its Guidelines, and in its Annual Reports, is that the Guidelines set out how a patentee can determine whether its price will be considered excessive. Furthermore, patentees are encouraged to voluntarily comply with the Board's Guidelines.

23. This public position is at odds with both the effective retroactive amendment to the Guidelines and the use of a different test to determine which revenues should be paid back if the Board deems a Party's price to be excessive.

24. In the Board Staff's Supplementary Reply to the Supplementary Response to Board Staff's Amended Statement of Allegations, the Board Staff states:

> To the extent that Alexion relied upon "publications, practices and representations" of the Board, it did so at its own peril.[8]

25. This statement is of great concern to BIOTECanada's members, given the principles of procedural fairness, legitimate expectations and detrimental reliance discussed herein. Furthermore, it is contrary to the Board's own statements that patentees are encouraged to voluntarily comply with the Guidelines.

Procedural Fairness and Legitimate Expectations

26. The PMPRB has breached the principles of procedural fairness and legitimate expectations by filing the Amended Statement seeking remedies that require Alexion to reduce its price for SOLIRIS® in Canada to the LIP (or MIP) among comparator countries; to forfeit excessive remedies based on this LIP (or MIP); and to make those forfeitures retroactive to the introduction of SOLIRIS® in Canada.

27. These new remedies are not found in the Guidelines, nor in the *Patent Act*.

[8] Patented Medicine Prices Review Board, "Supplementary reply of Board Staff to the Amended Statement of Allegations: August 11, 2016", <http://www.pmprb- cepmb.gc.ca/CMFiles/Hearings %20and%20Decisions/Decisions%20and%20Orders/supplementary_reply.pdf>, paragraph 19.

28. The *Patent Act* requires the Board to consult before it issues Guidelines. Thus, there is a breach of procedural fairness in the PMPRB purporting to change the Guidelines, through the implementation of these remedies, without a public consultation.

29. In this regard, the *Patent Act* states:

> 96 (4) Subject to subsection (5), the Board may issue guidelines with respect to any matter within its jurisdiction but such guidelines are not binding on the Board or any patentee.
>
> (5) Before the Board issues any guidelines, it **shall consult** with the Minister, the provincial ministers of the Crown responsible for health and such representatives of consumer groups and representatives of the pharmaceutical industry as the Minister may designate for the purpose.[9]

30. The Board has no jurisdiction to act in a manner contrary to the *Patent Act*, which it is clearly attempting to do in this case by contravening s. 96(5).

31. The Guidance Document states:

> The Board, following considerable deliberation and consultation with all stakeholders, pursuant to subsection 96(5) of the Act, published the PMPRB'S Guidelines pursuant to subsection 96(4) of the Act.[10]

32. Even the PMPRB acknowledges that changes to the Guidelines require consultations.[11] As discussed below, the PMPRB has opened a consultation with respect to the Guidelines.

33. The Board thus established a procedure for setting Guidelines. Stakeholders, including BIOTECanada's members had a legitimate expectation that further consultations would occur if any substantive changes to the Guidelines were

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[9] *Patent Act*, s. 96 [emphasis added].
[10] Guidelines, Part C.
[11] Patented Medicine Prices Review Board, "PMPRB Guidelines Modernization – Discussion Paper – June 2016" ("June 2016 Discussion Paper"), <http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines/discussion-paper>.

going to be effected. BIOTECanada's members relied on the methods for calculating MAPP and NATP in the Guidelines.

34. There is a further breach of procedural fairness and legitimate expectations in the Board Staff changing their approach to determining whether a price is excessive as between the initial determination of the MAPP and the remedies sought in the Amended Statement.

35. BIOTECanada submits that the PMPRB made a representation to Alexion when determining the MAPP for SOLIRIS®. That representation was based on the Guidelines and the use of the MIPC test. The PMPRB should continue its excessive pricing analysis and order remedies based on that representation.

36. Alexion relied on that representation, and had a legitimate expectation that further pricing analysis would continue on the basis of the MIPC test, as set out in the Guidelines. However, in suggesting the LIPC test be applied in this situation, the Board Staff are breaching the principles of procedural fairness.

37. If the Board Staff is breaching these principles as against Alexion, it may do so as against other BIOTECanada's members. Thus, BIOTECanada has an interest in pursuing this issue.

38. In addition to the general legal principles of procedural fairness, the Board's own enabling legislation requires the Board to act in accordance with the principles of fairness:

> 97 (1) All proceedings before the Board shall be dealt with as informally and expeditiously as the circumstances and **considerations of fairness permit.**[12]

39. Should the Board retroactively amend the Guidelines in the manner suggested by the Board Staff, the Board will be outside of its jurisdiction, and moreover, such amendment is against the principles of fairness, as described above.

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[12] *Patent Act*, s. 97(1).

The Board is Estopped from using the LIPC Test

40. The principles of estoppel and detrimental reliance apply to prevent the Board from using the LIPC test (or MIPC test, following introduction) to determine whether excessive pricing exists, and to determine the quantum of forfeiture.

41. The Supreme Court of Canada set out the essential factors for determining whether an estoppel exists:

> (1) A representation or conduct amounting to a representation intended to induce a course of conduct on the part of the person to whom the representation is made.
>
> (2) An act or omission resulting from the representation, whether actual or by conduct, by the person to whom the representation is made.
>
> (3) Detriment to such person as a consequence of the act or omission.[13]

42. In this case, the Board set the MAPP for Alexion to sell SOLIRIS® (and for BIOTECanada's members to sell each of their patented medicines) by using the MIPC test. This determination of the MAPP for a particular patented medicine is a representation intended to induce a course of conduct on the part of the patentee. The Board, in setting the MAPP is representing to the patentee, the price at which its medicine will not be considered excessive.

43. The patentee sets its initial selling price of its medicine based on the representation of the MAPP by the Board. This act satisfies the second criterion from the Supreme Court.

44. Finally, if the Board changes conduct such that the LIPC (or MIPC) test is used to determine excessive pricing, rather than the test used to determine the MAPP, the patentee who has relied on the Board's initial representation regarding the MAPP will be harmed.

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[13] *Canadian Superior Oil v. Hambly*, [1970] S.C.R. 932 at 939-40.

45. Thus, if permitted to change course, the patentee will have relied on the Board's representations to their detriment. This reliance applies to all of BIOTECanada's members.

46. Similarly, as described above, the Board represented to patentees every year in their Annual Report that the Guidelines are to be used by patentees to ensure that their pricing is not excessive, and encouraging patentees to comply voluntarily with the Guidelines. Patentees rely on those representations when determining their pricing.

47. Thus, if the Board changes conduct such that a different test, not found in the Guidelines, and outside of what is stated in the Guidelines, is suddenly used by the Board to determine whether pricing is excessive, the patentees who have relied on the Board's initial representations that the Guidelines are to be used, will be harmed.

48. Again, if permitted to change course, the patentee will have relied on the Board's representations to their detriment.

49. As a result, the Board is estopped from changing course in the manner described by the Board Staff in the Amended Statement. The LIPC test cannot be used to determine excessive pricing or forfeitures when the MIPC test was used to determine the price of the drug at the outset.

The Board Has No Jurisdiction to Order Remedies Based on a Test not found in the Guidelines

50. The Board was established by and its conduct is governed by the *Patent Act*.[14] The Board has no jurisdiction to act in any manner not set out in the *Patent Act* and in particular s. 96(5) as discussed above.

51. Thus, the Board is required to act in accordance with considerations of fairness, and is required to consult with stakeholders before amending the Guidelines. Any contrary actions would be outside the Board's jurisdiction.

[14] *Patent Act*, s. 91.

52. Thus, the Board has no jurisdiction to determine excessive pricing based on the LIPC test, and has no jurisdiction to grant the remedy sought by Board staff case, namely requiring forfeiture based on an application of the LIPC test.

The Principles of Statutory Interpretation Apply to the *Patent Act*

53. It is a fundamental principle of statutory interpretation that in order for legislation to have a retroactive effect, that intent must be expressly communicated. The Federal Court of Appeal has recognized that people choose their actions based on what is known at the time, and to change the rules later to catch those who planned under the former law is unfair.

> The concern of courts about unauthorized regulations that cause retrospective or retroactive effects or interfere with vested rights is founded upon aspects of the rule of law. "**Citizens choose how to act in the belief that the state will impose the legal consequences determined by the legal text discoverable at that time and not on other texts which were not in existence at the time of the relevant action**"... . **It is unfair to change the rules later and catch those who planned their affairs under the former law.**[15]

54. A similar principle must apply to the Guidelines published by Boards and Tribunals. Otherwise, the results would be similarly unfair.

55. Thus, even if the Guidelines had been amended, there could be no retroactivity without explicit intention in those amendments.

56. The PMPRB has opened a consultation with respect to the Guidelines, and the determination of pricing is one of the issues in the consultation.[16] However, that consultation is in the "discussion paper" phase. New Guidelines have not yet been published, even in draft form. The PMPRB has accepted submissions on its "PMPRB Guidelines Modernization – Discussion Paper –

[15] *Merck Frosst Canada & Co. v. Apotex Inc.*, 2011 FCA 329 at para. 53 [emphasis added; citations omitted].
[16] June 2016 Discussion Paper.

June 2016".[17] The date for publication of proposed changes has not even been announced.[18] Furthermore, the actual proposed changes will be subject to comment.[19]

57. The Discussion Paper refers to possible retroactivity in applying new pricing guidelines as one of its 12 questions for discussion in its consultations pursuant to section 96(5) of the *Patent Act*. Thus, the question is still open. Even if these new remedies can be found in the Discussion Paper, and even if the Discussion Paper can be read as having the same effect as the Guidelines, both of which are denied, there is certainly no explicit statement that these changes would be retroactive.

58. Furthermore, the references in the Discussion Paper are to lowering the price comparison for patented drugs that already have a therapeutic class.[20] In this case, SOLIRIS® was a 'first in class' drug. Thus, the new pricing implications generally set out in the Discussion Paper would not apply to SOLIRIS®.

59. The retroactive application of these purported amendments to the Guidelines, by the Board Staff, in seeking these remedies is contrary to the laws of statutory construction, and should not be permitted.

Conclusions

60. In BIOTECanada's submission, the Board Staff with its Amended Statement, have sought to amend the Guidelines. By using a different standard when determining revenues that should be paid back if a price is deemed excessive, other than that used when the initial MAPP is determined, the Board Staff have brought uncertainty into the process and created a situation where after years of selling at a particular price, a complaint may trigger an Investigation

[17] Patented Medicine Prices Review Board, "Rethinking the Guidelines", <http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines>.
[18] *Ibid.*
[19] *Ibid.*
[20] June 2016 Discussion Paper.

which leads to forfeiture of what had previously been deemed proper revenues.

61. This is a breach of both the principles of statutory interpretation, which prohibit retroactive application of the law unless explicitly provided in that law, and the principles of fundamental fairness and legitimate expectation in relation to the Guidelines that were relied upon by patentees. Furthermore, estoppel should apply to prevent the Board from changing course in this manner. In addition, such remedies are outside the Board's jurisdiction.

62. Thus, these new, retroactive, remedies sought by the Board Staff should not be granted.

Dated: December 20, 2016

Original signature redacted

Borden Ladner Gervais LLP
World Exchange Plaza
100 Queen Street, Suite 1300
Ottawa, Ontario

Jamie Mills/Beverley Moore
Tel: 613.369.4782/4784
Fax: 613.230.8842

Lawyers for BIOTECanada

Authorities

Tab Description

Statues, Rules and Regulations

1. *Patent Act,* R.S.C. 1985, c. P-4.

Authorities

2. *Canadian Superior Oil v. Hambly*, [1970] S.C.R. 932.

3. *Merck Frosst Canada & Co. v. Apotex Inc.*, 2011 FCA 329.

Guidance and Other Government Documents

4. Patented Medicine Prices Review Board, "Annual Report 2009", <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=898>.

5. Patented Medicine Prices Review Board, "Annual Report 2015", <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1273#a5>.

6. Patented Medicines Price Review Board, "Compendium of Policies, Guidelines and Procedures" (July, 2016).

7. Patented Medicine Prices Review Board, "How to Make a Complaint", <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1014>.

8. Patented Medicine Prices Review Board, "PMPRB Guidelines Modernization – Discussion Paper – June 2016", <http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines/discussion-paper>.

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10. Patented Medicine Prices Review Board, "Supplementary reply of Board Staff to the Patented Medicine Prices Review Board, "Supplementary reply of Board Staff to the Amended Statement of Allegations: August 11, 2016", <http://www.pmprb- cepmb.gc.ca/CMFiles/Hearings%20and %20Decisions/Decisions%20 and%20Orders/supplementary_reply.pdf>.