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"

BIOTECANADA MOTION FOR LEAVE TO INTERVENE

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TAB 1

IN THE MATTER OF the Patent Act,
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AND IN THE MATTER OF
Alexion Pharmaceuticals Inc. ("Respondent")
and the medicine "Soliris"

BIOTECANADA MOTION FOR LEAVE TO INTERVENE

TAKE NOTICE THAT BIOTECanada submits this motion before the Patented Medicine Prices Review Board (PMPRB).

THE MOTION IS FOR an order granting BIOTECanada intervener status in this matter in order to permit BIOTECanada to file written submissions with the PMPRB in the form attached as **Exhibit A** to this motion, regarding its position and that of its members on this hearing.

THE GROUNDS FOR THE MOTION ARE:

Facts Upon Which this Motion is Based

1. BIOTECanada, on behalf of its member companies, has an interest in one of the issues in dispute in this proceeding.

2. BIOTECanada represents the interests of over 200 member companies located across the country, many of whom produce and/or market medicines which are used to treat serious illnesses and the manner in which the prices of those medicines are determined may be affected by the outcome of this proceeding.

3. BIOTECanada, on behalf of its member companies, is in a position to provide information that is relevant to these proceedings.

4. Previously, the proceedings were of general interest only to BIOTECanada. However, BIOTECanada has learned from monitoring the Board's website that the Board has recently issued Reasons for Decision in relation to a motion by the patentee, Alexion, to strike an expert report of Dr. Sumanth Addanki filed by Board Staff.

5. This report purports to propose a new method of determining the "therapeutic class" for SOLIRIS® by proposing a novel method of selecting comparators

for medicines intended to treat rare diseases (so-called 'orphan' drugs). This new method has the potential to affect the interests of BIOTECanada's members, as it is a departure from the PMPRB's Guidelines, a breach of procedural fairness and a breach of the principles of statutory interpretation.

6. If, as it appears, the PMPRB is going to change its entire approach to orphan drugs, in accordance with this new definition of "therapeutic class," BIOTECanada has an interest in presenting arguments with respect to the impact this change will have, as it will affect its members.

7. So far as we can determine from the public record, the issue of how to determine "therapeutic class" was not previously raised in these proceedings. In fact, in paragraph 7 of the Statement of Allegations, Board Staff plead that the Board's Human Drug Advisory Panel (HDAP) "… recommended Soliris as a Category 2 (breakthrough or substantial improvement) drug product … [and] did not identify any comparators for Soliris".

8. Furthermore, in paragraph 25, the Board Staff pled that it is appropriate for them to apply the approach and methodology in the 2010 Guidelines when considering the factors set out in s. 85(1) of the *Patent Act* in this case.

9. Accordingly, this is a novel issue not previously disclosed in the information posted to the Board's website and one which, as stated above, is of direct concern to BIOTECanada and its members.

10. Section 20 of the *Patented Medicine Prices Review Board Rules of Practice and Procedure Regulations*, SOR 2012-247.

The Test for Intervention

11. Rule 20(5) of the *Patented Medicines Prices Review Board Rules of Practice and Procedure*, (the *Rules*) sets out that:

> the Board may grant or deny the intervention and impose any conditions or restrictions on the intervention that it determines to be appropriate after considering relevant factors, including

> (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.[1]

12. The PMPRB has held that:

> As a general matter, and consistent with past practice at the Board, the Board would expect that other persons with an interest in the Board's hearings, in the sense contemplated by Rule 19, would be in one of the following three categories:
>
> 1. Persons who, in one manner or another, will bear some or all of the cost burden of the medicine in question, or the cost burden of other medicines where the prices of such medicines could be affected by the outcome of the proceeding;
>
> 2. Patentees, the maximum non-excessive prices of whose medicines will be affected by the specific outcome of the proceeding, or by the establishment of a point of principle pertaining the non-excessive pricing of medicines or the Board's jurisdiction; or
>
> 3. Organizations representing persons in the two previous categories.[2]

13. BIOTECanada is an organization representing patentees whose maximum non-excessive medicine prices will be affected by the specific outcome of this proceeding. Furthermore, the organization's members will be affected by a point of principle pertaining to the pricing and the Board's jurisdiction – specifically in relation to the new definition of "therapeutic class" proposed by the Board Staff in the Addanki Report.

14. BIOTECanada submits that it meets these criteria, as set out below.

BIOTECanada's Interest in this Proceeding

15. BIOTECanada represents the interests of over 200 member companies located across the country, many of whom produce and/or market medicines which

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[1] *Patented Medicines Prices Review Board Rules of Practice and Procedure*, SOR/2012-247, Rule 20(5), Tab 6.

[2] Sanofi Pasteur Limited and the medicines "Quadracel and Pentacel", PMPRB-07-D1 – QUADRACEL and PENTACEL, dated July 26, 2007, Tab 7.

are used to treat serious illnesses. Furthermore, many of BIOTECanada's members research, develop and sell drugs to treat rare diseases (orphan drugs) and the manner in which the prices of those medicines are determined may be affected by the outcome of this proceeding.

16. One of BIOTECanada's strategic objectives is to seek to establish a globally competitive regulatory policy framework to support all aspects of Canadian biotechnology.[3] The PMPRB is part of the regulatory policy framework that affects Canadian biotechnology.

17. An important part of this framework is its consistent application. BIOTECanada is concerned with the Board Staff's tendering of the Addanki report and its new definition of "therapeutic class" for the following broad reasons:

    (a) It changes the way in which the PMPRB conducts its scientific review of patented medicines. Effectively, this new definition removes the science from the review process when it comes to determining comparator products. This removal of the scientific basis for the review, and the creation of *ad hoc* and arbitrary criteria for conducting the review creates a great deal of uncertainty for BIOTECanada's members.

    (b) It seeks to apply different definitions of "therapeutic class" to different types of medicines. This creates uncertainty for BIOTECanada's members as they will not know which criteria the PMPRB is planning to apply to their medicine until after the process has started.

    (c) It permits a change in the definition of "therapeutic class" as between the initial determination of whether the patented medicine is sold at an excessive price, and any later evaluation of the price at which the same medicine is sold. This creates uncertainty for BIOTECanada's

[3] Affidavit of Andrew Casey sworn May 16, 2016 ("Casey Affidavit"), paragraph 6, Tab 3.

members as there is no way for them to predict when, and if, the criteria under which their medicines are being evaluated will change.

18. The purpose of a globally competitive regulatory policy framework is to create certainty, not uncertainty. This certainty is what makes such a framework globally competitive. To date, the PMPRB's Regulations and their application have generally been certain. The Guidelines are used, and the approaches between different drugs have been generally consistent. However, the approach suggested in the Addanki report jeopardizes that certainty, and is of great concern to BIOTECanada's members.

19. BIOTECanada submits that its intervention is necessary, as it can provide the perspective of the biotechnology industry as a whole in relation to this new definition of "therapeutic class." It appears as though the PMPRB may be trying to effect a policy shift, or regulatory change without any sort of statutory authority, or even a consultation period.[4] In BIOTECanada's submission, if this change is being effected through the SOLIRIS® proceeding, which is improper in any event, BIOTECanada's intervention may be the only representation the broader industry has on this issue.

Issues BIOTECanada Intends to Address

20. BIOTECanada intends to address solely the issue of the Board Staff's use of the methodology suggested in the Addanki report to provide a new definition of therapeutic class.

Commonly Understood Definition of "Therapeutic Class"

21. Section 85 of the *Patent Act* requires the Board to consider the price of other medicines in the same therapeutic class in both the relevant market (85(b)) and in countries other than Canada (85(c)).[5]

[4] Casey Affidavit, paragraph 25, Tab 3.
[5] *Patent Act*, R.S.C. 1985, c. P-4, section 85, Tab 5.

22. "Therapeutic class" is not a term defined by the *Patent Act*. However, it did not need definition, as "therapeutic class" is a term understood by all health professionals, and the pharmaceutical and biotechnological community to relate to the class of medicine intended to treat the same medical condition. [6] The therapeutic class is broken down by therapy.

The Addanki Definition of "Therapeutic Class"

23. Dr. Addanki proposes to begin his analysis with a list of orphan drugs from the United States.[7] He then limits that list through a number of factors, designed to show similarity to SOLIRIS®.

24. He starts with a limitation to drugs that treat populations of a similar size to SOLIRIS®.[8] He then excludes all drugs taken for a short period of time, because SOLIRIS® must be taken for life.[9] Further limitations are to drugs that show a significant advantage over other existing treatments; [10] and to drugs that treat terminal state diseases; and to drugs for which other treatments are available.[11]

25. At the end of these eliminations, only seven drugs remain.[12] To a non-scientific mind, this could seem like a reasonable number to use for comparison purposes. However, one should not be aiming for a particular number of comparators, one should be aiming for the correct comparators, no matter what the number. Any one of these limitations could have been substituted for another, different, arbitrary characteristic of SOLIRIS® to produce an equally small, but equally arbitrary list.

[6] Casey Affidavit, paragraphs 23-24, Tab 3.
[7] Addanki Report, paragraph 37.
[8] Addanki Report, paragraph 38.
[9] Addanki Report, paragraph 40.
[10] Addanki Report, paragraph 41.
[11] Addanki Report, paragraph 42.
[12] Addanki Report, paragraph 42.

26. There has never been an economic model interpretation of therapeutic class."[13]

27. Addanki's definition of "therapeutic class" is a fiction. It is not based in science. It is not what is known and understood by the pharmaceutical and biotechnological community.[14] It is not appropriate under any circumstances. Furthermore, Addanki purports to apply it only to orphan drugs; a select grouping of the medicines regulated by the PMPRB.

28. BIOTECanada seeks leave to intervene in this matter, as the Board Staff has put forward the Addanki Report and its purported new definition of "therapeutic class" as evidence in the pricing dispute with Alexion. If the PMPRB intends to use this new and inappropriate definition on a going forward basis, BIOTECanada's members will be greatly affected.

29. BIOTECanada has drafted written argument in support of its position in relation to the Addanki definition of "therapeutic class". That argument is attached as **Exhibit A** to this Notice of Motion. It sets out BIOTECanada's concerns under three main categories:

    (a) the definition of "therapeutic class" as commonly understood, exemplified by its use by Innovation, Science and Economic Development Canada, Health Canada, and the provincial formularies;

    (b) the principles of statutory interpretation as they apply to the term "therapeutic class" in the *Patent Act* as compared to the selective use of the term proposed in the Addanki report;

    (c) the principles of procedural fairness and legitimate expectations as they apply to the PMPRB changing its method of determining comparator products after a medicine is already on the market following an initial price determination; and

[13] Casey Affidavit, paragraph 24, Tab 3.
[14] Casey Affidavit, paragraphs 22-24, Tab 3.

(d) the principles of procedural fairness and legitimate expectations as they apply to the PMPRB changing its definition of "therapeutic class" in the Guidelines without public consultations.

There is No Prejudice in BIOTECanada's Intervention in this Proceeding

30. BIOTECanada represents a large number of the manufacturers whose drugs are regulated by the PMPRB. BIOTECanada is seeking no additional remedies. Nor is BIOTECanada seeking to raise any new issues. Thus, its voice cannot cause prejudice to any party.

31. To the contrary, it is the lack of a voice from BIOTECanada that will be prejudicial. The PMPRB appears to be trying to effect a change to the definition of the term "therapeutic class" as commonly understood in the industry, and as applied in its Guidelines. However, this change is being effected in the middle of the price analysis of SOLIRIS®; and without any consultation.

32. The PMRPB's website indicates that the Guidelines were developed in consultation with stakeholders, including Ministers of Health, consumer groups and the pharmaceutical industry.[15] If no consultation is planned on the change to be effected by the Addanki report, then this intervention may be the only opportunity the pharmaceutical industry has to have a voice in this fundamental change.

BIOTECanada's Intervention will Not affect the Fair and Expeditious Conduct of the Hearing

33. BIOTECanada is not proposing to appear at the hearing or present witnesses. It is only seeking to file the attached written representations.

34. The parties will be familiar with BIOTECanada's representations from their responses to this motion.

35. Thus, BIOTECanada's intervention will not delay the hearing in any way.

[15] Government of Canada, "Regulatory Process", <http://www.pmprb-cepmb.gc.ca/en/regulating-prices/regulatory-process>, Tab 8.

Conclusions

36. BIOTECanada's interest in this proceeding is apparent. The PMPRB has indicated, through the filing of the Addanki Report, that it is changing the definition of "therapeutic class" it applies in its Guidelines. Furthermore, the PMPRB appears to be changing its entire approach to orphan drugs.

37. These changes have a broader effect than just in the case of SOLIRIS®. These changes, and the manner in which the PMPRB is trying to make them, will affect all of BIOTECanada's members who research and develop patented medicines, and in particular orphan drugs.

38. This will lead to a great deal of uncertainty for BIOTECanada's members in relation to how the PMPRB will consider their medicines in the future. The scientific basis for determining "therapeutic class" is proposed to be removed and replaced with an arbitrary application of random criteria. This new system seems to be applicable only to certain types of medicines; potentially only those that are considered orphan drugs. Finally, the PMPRB appears to have changed this definition from its initial evaluation of SOLIRIS® to its present one, without any corresponding legislative changes.

39. BIOTECanada submits that these changes should not be permitted for the reasons described in the Written Argument at **Exhibit A**. In addition, BIOTECanada submits that since the PMPRB is seeking to effect these fundamental changes through the filing of an expert report, and not through proper channels (statutory, regulatory or guideline channels with appropriate consultations), it should be permitted to provide its submissions to the Board, as these may be the only "consultations" its members will receive on these issues.

40. BIOTECanada's intervention in this proceeding will not cause prejudice to any party. To the contrary, it will provide the views of a large portion of the PMPRB's users in relation to a policy change that the PMPRB is trying to

effect without consultation. It would be prejudicial to the industry to change the policy without BIOTECanada's intervention.

41. BIOTECanada's intervention will not cause any delay in the proceeding. As we are only seeking to file the attached written representations, our participation will be complete once an order issues allowing this motion.

42. Thus, we respectfully submit that BIOTECanada's motion to intervene in this proceeding be granted, and that the Board accept the Written Representations at **Exhibit A** to this motion on the merits of the proceeding.

Dated at Ottawa, Ontario this 18th day of May, 2016

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TAB 2

Exhibit A to
BIOTECANADA MOTION FOR LEAVE TO INTERVENE

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 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 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 filed an expert report of Dr. Sumanth Addanki (the Addanki Report).

4. This report purports to propose a novel method of determining the "therapeutic class" for SOLIRIS® by proposing a new method of selecting comparators for medicines intended to treat rare diseases (so-called orphan drugs). This new method has the potential to affect the interests of BIOTECanada's members generally, as it is a departure from the known definition of the term in industry, a departure from the PMPRB's Guidelines, a

breach of procedural fairness and a breach of the principles of statutory interpretation as discussed further below.

5. The Board Staff and Dr. Addanki appear to apply the new definition of "therapeutic class" only to orphan drugs. This new definition and approach will thus affect BIOTECanada's members as it:

   (a) Is not the accepted definition of "therapeutic class" known to industry;

   (b) Breaches the principles of statutory construction as it appears to provide for the term "therapeutic class" to have one meaning if the drug is not orphan and another if it is. Furthermore, there appears to be some ambiguity as to what meaning is to be ascribed if an orphan drug has comparators; and

   (c) Breaches the principles of procedural fairness as one definition of "therapeutic class" was used to determine the maximum non-excessive initial price of SOLIRIS®, and the new definition was used in a later determination of whether the ongoing, unchanged, price was excessive. No notice was given prior to this change, nor were public consultations held.

Issue

6. This written argument addresses solely the issue of the Board Staff's use of the Addanki report to provide a new definition of therapeutic class.

The *Patent Act*

7. Section 85 of the *Patent Act* sets out the factors that shall be taken into consideration by the Board in determining whether a medicine is sold at an excessive price.

> 85 (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:
>
> (a) the prices at which the medicine has been sold in the relevant market;
>
> (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
>
> (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
>
> (d) changes in the Consumer Price Index; and
>
> (e) such other factors as may be specified in any regulations made for the purposes of this subsection.[1]

8. The term "therapeutic class" is found in sections 8(b) and (c). Thus, the Board must interpret this term when determining whether a medicine is sold at an excessive price.

9. The *Patent Act* does not define "therapeutic class". BIOTECanada submits that this is because the term needs no definition. It is commonly understood by industry, Health Canada and Innovation, Science and Economic Development Canada to have a singular meaning.

10. The "therapeutic class" of a drug relates to the class of medicines intended to treat the same medical condition. The class is defined by the therapy which the medicine is used to treat. It is a scientific term.

11. The Addanki Report essentially ignores the scientific underpinnings of the term. Indeed it ignores the key word "therapeutic" which is a fundamental part of the term. Instead, it purports to ascribe an entirely new, non-scientific and arbitrary meaning, which it then uses as a basis to find so-called comparator drugs for SOLIRIS®.

[1] *Patent Act*, R.S.C. 1985, c. P-4 ("*Patent Act*"), s. 85.

The Addanki Definition of "Therapeutic Class"

12. Dr. Addanki argues that in a case where a patented medicine has no comparators that share its chemistry, mechanism of action, or approved indication (the scientific, and common understanding of "therapeutic class"), an economic interpretation of "therapeutic class" is appropriate.[2] On its face, this approach is wrong because "therapeutic class" already has a clear meaning understood by all the relevant parties.

13. Dr. Addanki proposes to begin his purported economic interpretation of the "therapeutic class" for SOLIRIS® with a list of orphan drugs from the United States.[3] He then arbitrarily limits that list through a number of factors, designed to show similarity to SOLIRIS®.

14. He starts with a limitation to drugs that treat populations of a similar size to SOLIRIS®.[4] He then excludes all drugs taken for a short period of time, because SOLIRIS® must be taken for life.[5] Further limitations are to drugs that show a significant advantage over other existing treatments; [6] and to drugs that treat terminal state diseases; and to drugs for which other treatments are available.[7]

15. At the end of these eliminations, only seven drugs remain.[8] In a non-scientific analysis, this may seem like a reasonable number to use for comparison purposes. However, one should not be aiming for a particular number of comparators, one should be aiming for the correct comparators, no matter what the number.

[2] Addanki Report, paragraph 19.
[3] Addanki Report, paragraph 37.
[4] Addanki Report, paragraph 38.
[5] Addanki Report, paragraph 40.
[6] Addanki Report, paragraph 41.
[7] Addanki Report, paragraph 42.
[8] Addanki Report, paragraph 42.

16. Any one of these arbitrary limitations could have been substituted for another, different, arbitrary characteristic of SOLIRIS® to produce an equally small, but equally arbitrary list.

17. Addanki's definition of "therapeutic class" is not based in science. It is not what is known and understood by the pharmaceutical and biotechnological community. It starts with the principle that "therapeutic class" can have different definitions depending upon the medicine being considered. It arbitrarily selects a starting point for this circumstance. It then arbitrarily adds limitations.

18. This approach is not appropriate under any circumstances.

Commonly Understood Definition of "Therapeutic Class"

19. Section 85 of the *Patent Act* requires the Board to consider the price of other medicines in the same therapeutic class in both the relevant market (85(b)) and in countries other than Canada (85(c)).

20. As discussed above, "therapeutic class" is not defined by the *Patent Act*, however, it is a term understood by all health professionals, and the pharmaceutical and biotechnological community to relate to the class of medicine as defined by the therapy for which that medicine is used.

21. "Therapeutic class" and "therapeutic classifications" are terms of art used consistently (until the Addanki report) by the PMPRB, the Ministry of Health, Innovation, Science and Economic Development Canada, and the provincial formularies in relation to medicines.

22. Until the filing of the Addanki Report, to our knowledge, the PMPRB has not ever tried to use a different definition of "therapeutic class" than the scientific term of art known to the industry and relevant professionals

PMPRB Guidelines Use A Scientific Definition of "Therapeutic Class"

23. In evaluating a patented medicine, the PMPRB's 2010 Guidelines, as updated in 2012 (Guidelines) indicate that the PMPRB is to conduct a scientific review, an evidence based process, to determine the level of therapeutic improvement of a new patented drug.[9] The Guidelines were published after consultation with stakeholders. Section C.3.1 of the PMPRB's (Guidelines) provides that a Human Drug Advisory Panel (HDAP) provides expertise and advice to Board Staff during that scientific review and recommends the level of therapeutic improvement of the new patented drug product, and identifies drug products for comparison purposes.[10]

24. This identification of drug products for comparison purposes is the identification of other drug products in the therapeutic class, as confirmed by section C.8 which sets out criteria for the selection of drug products to be used for comparison purposes:

> C.8.1 HDAP uses the World Health Organization (WHO) Collaborating Centre for Drug Statistics Methodology's Anatomical Therapeutic Chemical (ATC) Classification System in the selection of drug products to be used for comparison purposes.
>
> C.8.2 The chemical substances to be used for comparison purposes will typically be those identified under the ATC classification system at the sub-class level above the single chemical substance. This will normally be the fourth sub-class level. HDAP may also choose from the next higher sub-class or another sub-class. In some instances, it may be appropriate to select from the fifth or single chemical substance level.
>
> C.8.3 HDAP may omit from the comparison a chemical substance of the same ATC therapeutic class as the new patented drug product under review if, in HDAP's opinion, it is unsuitable for comparison. For example, drug products with a primary indication/use other than the primary indication/use of the new patented drug product under review may be omitted from the comparison.[11] [emphasis added]

[9] PMPRB Compendium – Policies, Guidelines Procedures Compendium, 2010 updated in 2012 ("Compendium"), Part. C, page 10.
[10] Compendium, Part C, s. C.3.1.
[11] Compendium, Part. C, ss. C.8.1-C.8.3.

25. This scientifically defined "therapeutic class" is the common understanding of the term. Moreover, this is an admission by the PMPRB as to the proper meaning of the term "therapeutic class".

PMPRB Has Applied the Scientific Definition of "Therapeutic Class" in Previous Decisions

26. In previous decisions, the PMPRB has applied the commonly understood, scientific definition of "therapeutic class" when determining comparable medicines:

> When a patented medicine is introduced to the market in Canada, the maximum non-excessive price ("MNE") of the medicine is determined by the staff of the Board based on either the price of comparable medicines, i.e. medicines in the same therapeutic class, or on the international prices of the medicine – median or the highest – as sold in the seven countries specified in the Regulations. … **As suggested by the Board´s Guidelines, the comparable medicines used by Board Staff to establish the introductory MNE of a Category 1 medicine and to conduct price tests under subsection 85(1) of the Act are determined pursuant to a scientific review designed to identify medicines that are clinically equivalent in addressing the approved condition for which they are used, and having comparable dosage form and strength.** These criteria establish the therapeutic class of the medicine for the purposes of paragraphs 85(1)(b) and (c) of the Act.[12] [emphasis added]
>
> A necessary starting point in the Panel´s analysis is a description of what constitutes a "therapeutic class" as that expression is used in paragraphs 85(1)(b) and (c) of the Act. **The Guidelines use the concept of therapeutic equivalence (termed "clinical equivalence") to define a therapeutic class**. … **The Panel concludes that clinical equivalence is the appropriate concept to use when defining a therapeutic class for the purposes of implementing paragraphs 85(1)(b) and (c) of the Act. It reflects the wording of the Act, in that a therapeutic "class" connotes a group of medicines that share a common feature or features**.[13] [emphasis added]
>
> He described the TCC Test as a methodology to determine which drugs are therapeutic comparators at the time the test is performed.

[12] ratiopharm Inc. and the medicine "ratio-Salbutamol HFA", PMPRB-08-D3-ratio-Salbutamol HFA dated May 27, 2011, paragraphs 66-68.

[13] sanofi-aventis Canada Inc. and the medicine "Penlac Nail Lacquer", PMPRB-07-D2-PENLAC, dated January 31, 2011, paragraphs 17-18.

> **The HDAP is not concerned with the pricing of drugs. Rather, it assesses which drugs have similar therapeutic purposes and characteristics such that they can be considered to be in the same therapeutic class**.[14] [emphasis added]

27. The PMPRB's consistent use of "therapeutic class" in relation to drugs that have similar therapeutic purposes and characteristics accords with industry's understanding of the term.

28. Furthermore, in the Copaxone case, the PMPRB specifically stated that the HDAP, which determines "therapeutic class" is not concerned with pricing. This is directly at odds with the Board Staff's reliance on the Addanki affidavit.

Health Canada Also Uses A Scientific Definition of "Therapeutic Class"

29. Health Canada, as Canada's drug regulator, also commonly refers to "therapeutic class" in relation to its approved drugs. The most clear example is Health Canada's website listing "Notice of Compliance (NOC) Database Terminology".[15] The explanation for "therapeutic class" states:

> A drug's Therapeutic Classification (Class) is assigned on the NOC according to its main therapeutic use.

30. This accords with BIOTECanada and its members' understanding that "therapeutic class" is linked to the therapy the medicine is approved to treat.

31. "Therapeutic Classification" is also defined in the explanation for "Drug Product Database (DPD) Online". This explanation indicates that The American Hospital Formulary Service (AHFS) and the Anatomical Therapeutical Chemical (ATC) Classification Systems are used to determine "Therapeutic Classification."

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[14] Teva Neuroscience G.P.-S.E.N.C. and the medicine "Copaxone", PMPRB-2010-D3-Copaxone, dated February 23, 2012, paragraph 29.

[15] Health Canada, "Notice of Compliance (NOC) Database Terminology", <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/noc-acc/term_noc_acc-eng.php>.

32. This is the same ATC classification system used by the PMPRB's own HDAP. Thus, in the past, the PMPRB and the HDAP have been consistent in their definition of the term.

33. When one reads Health Canada's other Guidance Documents, it is clear that whenever the term "Therapeutic Class" is used, it has the consistent scientific meaning relating to the therapy for which the medicine is used.[16]

34. The arbitrary economic definition of "therapeutic class" proposed by Dr. Addanki and the Board Staff cannot be substituted into these documents. This is further evidence that the Addanki report analysis should be disregarded.

35. Health Canada does not consider what medicines are similar from an economic perspective when assessing drug safety and efficacy. It considers those medicines that are similar from a therapeutic perspective. Thus, it refers to the therapeutic class of drugs.

Provincial Formularies Also Use A Scientific Definition of "Therapeutic Class"

36. Similarly, when one looks at provincial formularies, one can search for medicines by "Therapeutic Classification", while in others, the "therapeutic classification" is part of the drug listing.[17] These classifications relate to the

[16] See for example:

- Health Canada, "Guidance Document - Labelling of Pharmaceutical Drugs for Human Use" <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/label_guide_ld-eng.pdf>.
- Health Canada, "Guidance for Industry: Health Canada Addendum to ICH Guidance Document E11: Clinical Investigation of Medicinal Products in the Pediatric Population" <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/clini/e11_addendum-eng.pdf>.
- Health Canada, "Guidance Document - Fees for the Review of Drug Submissions and Applications", <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/fees-frais/fee_frais_guide-eng.pdf>.
- Health Canada, "Guidance for Industry: Management of Drug Submissions", <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/mgmt-gest/mands_gespd-eng.pdf>.

[17] British Columbia Formulary: https://pcbl.hlth.gov.bc.ca/pharmacare/benefitslookup/faces/Search.xhtml; Alberta Formulary: https://idbl.ab.bluecross.ca/idbl/load.do; Saskatechewan Formulary: http://formulary.drugplan.health.gov.sk.ca/; Manitoba Formulary: http://web22.gov.mb.ca/eFormulary/advancedSearch.aspx; Ontario Formulary: https://www.formulary.health.gov.on.ca/formulary/; Quebec Formulary:

therapy for which the drug is used and are based on known scientific classification systems. Indeed for British Columbia, one can search using ATC Therapeutic Classification, the same system used by the PMPRB's HDAP.

37. The provincial formularies, like the PMRPB, deal with drug pricing. However, they use the conventional, scientific definition of "therapeutic class", and not the arbitrary, economic analysis performed by Addanki.

Innovation, Science and Economic Development Canada's Other Departments Also Use a Scientific Definition of "Therapeutic Class"

38. The Competition Bureau, which administers the *Competition Act*, which like the *Patent Act* falls under the purview of Innovation, Science and Economic Development Canada, has published a Generic Drug Sector Study. In section 4, it lists pharmacy sales by therapeutic class.[18] Similarly, the "therapeutic class" relates to the therapies for which the medicines are used (cardiovasculars; antihyperlipidemic agents; psychotherapeutics; …). A further list is found in relation to hospital purchases.[19] It also classifies the medicines by therapy.

39. Similar types of lists, by therapy, are found in Innovation, Science and Economic Development Canada's Discussion Paper on Canada's Pharmaceutical Industry and Prospects. [20]

40. Thus, Innovation, Science and Economic Development Canada's understanding of the term "therapeutic class" outside of the PMRPB, accords with Health Canada's.

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https://www.prod.ramq.gouv.qc.ca/DPI/PO/Commun/PDF/Liste_Med/Liste_Med/liste_med_2016_05_04_en.pdf;; New Brunswick Formulary: http://www2.gnb.ca/content/dam/gnb/Departments/h-s/pdf/en/NBDrugPlan/NewBrunswickDrugPlansFormulary.pdf; Nova Scotia Formulary: http://novascotia.ca/dhw/pharmacare/documents/formulary.pdf; Prince Edward Island Formulary: http://www.gov.pe.ca/photos/original/hpei_formulary.pdf?_ga=1.242257735.43001454.1463413271;

[18] Competition Bureau Canada, "Canadian Generic Drug Sector Study", October 2007 ("Study"), Table 5, <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/02495.html>

[19] Study, Table 10, <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/02495.html>.

[20] Study, Table 3, <http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/hn01768.html>.

Summary on "Therapeutic Class"

41. Health Canada, Innovation, Science and Economic Development Canada and the provincial formularies all use a scientific definition of "therapeutic class" relating to the therapeutic use of the medicine. This is logical given that medicines are intended for therapy.

42. None of these governmental departments use an *ad hoc* collection of arbitrary medicines based on a non-scientific economic analysis that has no relation to the therapy for which the medicine is approved. This common term of art is not open to interpretation. It is understood by those who use it. To attempt to import a different definition for this term without any corresponding legislative amendment would effectively circumvent the due process, including consultation with the public, that is part of proper legislative change.

43. The PMPRB has also previously and consistently relied upon the scientific definition of "therapeutic class". In one case, it also specifically rejected the idea that the HDAP would consider pricing when determining therapeutic class.

44. Furthermore, Dr. Addanki's definition could not be substituted in any of the situations described above. First, the definition is limited to orphan drugs. The PMPRB's approach to drug pricing must be consistent, and cannot be if it takes one approach for orphan drugs and a different approach for all other medicines. This issue is discussed further below.

45. Furthermore, the US list of orphan drugs is not recognized in any official capacity by the *Patent Act*, Innovation, Science and Economic Development Canada, or Health Canada. Furthermore, it is but one of the countries the PMPRB is supposed to consider when comparing outside of Canada. Thus, it is not an appropriate starting point.

46. Finally, the arbitrary limitations proposed by Addanki are not generally applicable to other medicines which are part of the purview of the PMPRB. Some medicines are taken for both long and short periods of time, by different

patient populations. Similarly, some drugs are taken for both terminal state diseases and non-terminal state diseases. If one were to apply these arbitrary limitations to other every other drug regulated by the PMPRB, there would have to be almost no variation between the prices of any medicine. The comparator classes would be so big as to be unwieldly. Furthermore, they would cover every type of drug product from acne treatments to cancer therapies to erectile dysfunction treatments to high blood pressure therapies. Surely these vastly different therapeutic classes of drugs should have different price considerations. And, in fact, they do, under the PMPRB's current analysis.

47. Dr. Addanki's arbitrary, non-scientific approach should be disregarded on this basis alone.

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

48. Addanki and the PMPRB are proposing to develop a new definition of "therapeutic class" that applies solely to drugs, like SOLIRIS® that are used to treat rare diseases. This approach fundamentally disregards the basic principles of statutory interpretation.

49. As discussed above, section 85 of the *Patent Act* sets out the factors that shall be taken into consideration by the Board in determining whether a medicine is sold at an excessive price.

> 85 (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:
>
> (a) the prices at which the medicine has been sold in the relevant market;
>
> (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
>
> (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
>
> (d) changes in the Consumer Price Index; and

(e) such other factors as may be specified in any regulations made for the purposes of this subsection.[21]

50. The Board does not have any discretion to disregard any of these factors.

51. "Therapeutic class" arises in both s. 85(1)(b) and (c). The principles of statutory interpretation dictate that unless the contrary is clearly indicated by the context, it must have the same meaning in both sections.[22] There is no different context in these provisions.

52. Furthermore, this term must have the same meaning whenever it is applied.

53. The PMPRB does not have the jurisdiction to amend the *Patent Act* to use one definition of "therapeutic class" when considering whether orphan drugs are being sold at an excessive price, and another definition when considering whether all other drugs are being sold at an excessive price.

54. Similarly, the PMPRB cannot use one definition when considering breakthrough drugs which have no therapeutic class, and a different definition when considering other drugs, which do have a therapeutic class.

55. The PMPRB's Guidelines do provide guidance on how to address all of these issues in a scientifically based analysis. Furthermore, they provide for the same principles to be applied in all cases. Thus, there is certainty in the current Guidelines. Furthermore, these Guidelines were developed after consultation with stakeholders.

56. The PMPRB should not be permitted to change its approach in this arbitrary manner that increases uncertainty to the patentee at every turn. Furthermore, any such changes should also be subject to consultation with stakeholders, which would include BIOTECanada's members.

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[21] *Patent Act*, s. 85.
[22] *Thomson v. Canada (Deputy Minister of Agriculture)*, [1992] 1 S.C.R. 385 at paragraph 27.

Procedural Fairness and Legitimate Expectations

57. The PMPRB has breached the principles of procedural fairness and legitimate expectations by changing its approach to the determination of "therapeutic class" as between the initial determination of whether the price for SOLIRIS® is excessive and the later determinations as to whether the continuing price is excessive.

58. The Supreme Court has set out the considerations that are relevant to the common law duty of procedural fairness.[23] The Federal Court has held that the duty of fairness applies to the PMPRB's decisions.[24] The Supreme Court has held that:

> Where a government official makes representations within the scope of his or her authority to an individual about an administrative process that the government will follow, and the representations said to give rise to the legitimate expectations are clear, unambiguous and unqualified, the government may be held to its word, provided the representations are procedural in nature and do not conflict with the decision maker's statutory duty. Proof of reliance is not a requisite. It will be a breach of the duty of fairness for the decision maker to fail in a substantial way to live up to its undertaking.[25]

59. In this case, BIOTECanada submits that the PMPRB made a representation to Alexion that no comparators for SOLIRIS® were identified. The PMPRB used the HDAP's recommendations based on the scientific definition for "therapeutic class". The PMPRB's excessive pricing analysis should have continued on that basis.

60. Alexion had a legitimate expectation that further pricing analysis would also continue on the basis of the HDAP applying the scientific definition for "therapeutic class" when deciding if any comparators had entered the market.

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[23] *Baker v. Canada (Minister of Citizenship and Immigration*), [1999] 2 S.C.R. 817 at paragraphs 23-27.
[24] *Sanofi-Aventis Canada Inc. v. Canada (Attorney General)*, 2009 FC 965 at paragraph 41.
[25] *Canada (Attorney General) v. Mavi*, 2011 SCC 30, [2011] 2 S.C.R. 504 at paragraph 68 [citations omitted].

61. However, instead, with the Addanki report, the PMPRB is changing the definition of "therapeutic class." This is a breach of procedural fairness. BIOTECanada's members have an interest in pursuing this issue, and if the PMPRB is applying this breach to Alexion, it may well do the same to another of BIOTECanada's members in the future.

62. There is a further breach of procedural fairness in the PMPRB changing the Guidance Document without a public consultation. 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.[26]

63. 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 going to be effected. BIOTECanada's members relied on the scientific definition of "therapeutic class" in the Guidelines.

Conclusions

64. In this case, the PMPRB, through the Board Staff filing of the Addanki report, has indicated that it is changing the definition of "therapeutic class" it applies in its Guidelines. Furthermore, it is changing that definition in an arbitrary and non-scientific, arbitrary manner, that seems open to change depending upon the medicine being considered.

65. BIOTECanada submits that this new definition of "therapeutic class" should be disregarded. Furthermore, having different definitions of the same term within the same statute, as it applies to different medicines is a breach of the principles of statutory interpretation, and should not be permitted. Finally, the PMPRB should not be permitted to change its definition of "therapeutic class"

[26] Compendium, Part C.

as between its initial assessment, and ongoing assessment of the price of a medicine; nor should it be permitted to do so without public consultations with its stakeholders.

Dated: May 18, 2016

Original signature redacted

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TAB 3

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 MOTION FOR LEAVE TO INTERVENE

AFFIDAVIT OF ANDREW CASEY

I, Andrew Casey, of the City of Ottawa, in the Province of Ontario,

MAKE OATH AND SAY AS FOLLOWS:

1. I am the President and Chief Executive Officer of BIOTECanada and have been since 2012. As such, I have knowledge of the matters set out in this affidavit.

2. I have a Bachelor of Arts degree in Political Science from Carleton University. I held a number of political assistant positions with a Member of Parliament and the Minister of State (Finance) between 1989 and 1993. Beginning in 1993 until 2004, I was Assistant Vice-President, Government Relations with the Canadian Life and Health Insurance Association. I also was the Vice President, Public Affairs and International Trade and Vice President, Government Relations and Communications for the Forestry Products Association of Canada from 2004 to 2012.

OVERVIEW

3. This affidavit is made in support of a motion by BIOTECanada for leave to intervene in this proceeding. BIOTECanada seeks leave to file written representations. That argument will be attached as Exhibit A to the Notice of Motion seeking leave. BIOTECanada has a significant interest in the new definition of "therapeutic class" and its application proposed by Board Staff through their filing of the report of Dr. Sumanth Addanki (the "Addanki Report").

BIOTECanada and its Members

BIOTECanada

4. BIOTECanada is a nation-wide, not-for profit, non-government association with over 200 member companies. It was founded in 1987 and its mandate is to promote the sustainable development of the biotechnology industry in Canada. In fulfilling this mandate, it advocates for its members, a community of researchers and innovators, on public policy issues, including pricing of their innovative, patented medicines in Canada.

5. The Canadian bioeconomy is worth 7% of Canada's GDP, or approximately 86.5 million dollars. It also represents, directly and indirectly, 1 million Canadian jobs.

6. On behalf of the member companies, BIOTECanada pursues the objective of leading the advancement of a globally competitive Canadian biotechnology ecosystem by seeking to:

   (a) Increase Canadian biotechnology innovation, research and commercialization;

   (b) Establish a globally competitive regulatory policy framework to support all aspects of Canadian biotechnology;

   (c) Establish Canada and Canadian biotechnology as a destination for investment capital.

7. BIOTECanada frequently works with all levels of government, international bodies, and interest groups on initiatives that may affect the protection of the biotechnology industry in Canada. BIOTECanada's activities in this regard have included the following recent matters:

   (a) making representations on biotechnology-related patent issues, including advocating legislative and regulatory change, before various provincial and federal government organizations and committees, such

as the House of Commons Standing Committees on Agriculture and Agri-Food, on Health, and on Finance;

(b) on-going consultations with the Federal Ministers of Innovation, Science and Economic Development, Health, Agriculture, Global Affairs Canada, and Natural Resources, Deputy Ministers and other officials, and the submission of position papers on a wide spectrum of biotechnology protection reform issues including making written submissions to Innovation, Science and Economic Development Canada and Health Canada regarding proposed regulations amending the *Food and Drug Regulations* and regulations amending the *Patented Medicines (Notice of Compliance) Regulations* (*the NOC Regulations*); and

(c) serving as an information resource and as a commentator on biotechnology issues to national and international media outlets such as CBC Radio and TV, Global Television, CTV, The Globe & Mail, The Hill Times, New Scientist Magazine, and Canadian Business Magazine.

8. In meeting its objective of establishing a globally competitive regulatory policy framework to support all aspects of Canadian biotechnology, BIOTECanada regularly interacts with PMPRB, CADTH and the pCPA. With respect to CADTH specifically, BIOTECanada is a member of CADTH's Industry Liaison Forum (ILF).

9. BIOTECanada is the convener and a member of the National Biotechnology Accord (the "Accord"), a coalition of regional and provincial biotechnology associations, whose members combined account for approximately 85% of the Canadian biotechnology community.

10. The Accord aligns regional and national organizations leading the development of the Canadian bio-economy. Representing all facets of

technology, these organizations forge a national entity working to secure the long term sustainability for Canadian biotechnology-based companies and organizations.

11. The Accord meets regularly to establish a national agenda geared to promoting the best of Canadian biotechnology to Canada and the world. Partnered projects include National Biotechnology Week, national and international conferences and advocacy supporting public policy initiatives in the biotechnology sector.

BIOTECanada's Members

12. The members of BIOTECanada include a wide variety of biotechnology organizations and work in all sectors of biotechnology, such as healthcare, agriculture, aquaculture, food, bioinformatics, research and industrial biotechnology. The majority of member companies are early stage, pre-commercial SME's. BIOTECanada's membership spans the country and includes both pre-commercial companies, such as Aquinox Pharmaceuticals, Xenon Pharmaceuticals, Zymeworks, Imstar, Transition Therapeutics, Agrisoma, and CO2 Solutions. The association also includes multinational companies such as Novartis, Pfizer, Celgene, Amgen, Sanofi-Genzyme, and BioAmber.

13. In addition to innovators and manufacturers, another important membership class includes organizations from the finance sector such as Versant Capital, Teralys Capital, CTI Life Sciences Fund – companies that directly invest in the small and medium enterprises (SMEs). Also included as members of BIOTECanada are academic and research institutions and other organizations engaged in activities relating to supporting the development and commercialization of biotechnology innovation. A list of BIOTECanada's current members is attached as **Exhibit "1"** to this affidavit.

14. 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).

15. In addition, many of BIOTECanada's members hold patents that relate to medicines, and would be reportable to the PMPRB if and when their product(s) eventually reach the market. Patent protection and patent-related matters are therefore considered to be essential to their business and to the industry as a whole.

BIOTECanada's Interest in this Appeal

16. The PMPRB, through the Board Staff's filing of the Addanki report, is changing its approach to determining whether a medicine has an excessive price. The Addanki report creates a new, arbitrary definition of "therapeutic class" for the purposes of analyzing the price of SOLIRIS®. This new definition is problematic for the following broad reasons:

    (a) it changes the way in which the PMPRB conducts its scientific review of patented medicines – thereby effectively removing the science from the review process when it comes to determining comparator products;

    (b) it seeks to apply different definitions of "therapeutic class" to different types of medicines; and

    (c) it permits a change in the definition of "therapeutic class" as between the initial determination of whether the patented medicine is sold at an excessive price, and any later evaluation of the price at which the same medicine is sold.

17. The removal of the scientific basis for the review, and the creation of *ad hoc* and arbitrary criteria for conducting the review creates a great deal of uncertainty for BIOTECanada's members. Without a scientific basis underlying the scientific term "therapeutic class," there is no certainty in the

PMPRB's application of "therapeutic class" to the medicines made and sold by BIOTECanada's members.

18. Applying different definitions of "therapeutic class" to different types of medicines creates uncertainty for BIOTECanada's members as they may not know which criteria the PMPRB is planning to apply to their medicine until after the process has started.

19. Changing the definition of "therapeutic class" as between these two time points creates uncertainty for BIOTECanada's members as it becomes impossible for them to predict when, and if, the criteria under which their medicines are being evaluated will change. Furthermore, this arbitrary change was made without any public consultations.

20. The test to be set out by the Board in this proceeding will have a direct and significant impact on BIOTECanada's members as commercially focused members rely on patents to protect their investments in research related to medicines. Thus, they generally fall within the jurisdiction of the PMPRB and will be subject to these changes.

21. The manner in which the prices of BIOTECanada's members' medicines are determined may be affected by the outcome of this proceeding.

22. Furthermore, the term "therapeutic class" is not open to multiple meanings.

23. Given the international operations of the commercially active members of BIOTECanada, the globally recognized definition – a class of medicines intended to treat the same medical condition – as described by the ATC or AHFS is what the industry understands to be the definition of "therapeutic class".

24. Therapeutic class has always referred to a class of medicines designed to treat the same medical condition. There has never been an economic model interpretation of a therapeutic class. BIOTECanada's members have relied

upon the PMPRB's application of the term "therapeutic class" as it is commonly understood by industry.

25. Accordingly, this Board's decision will introduce a new measurement method which will significantly impact the members of BIOTECanada. Furthermore, this new measurement method, if left to stand, will have significant impact on the industry going forward yet will have been introduced without any opportunity for public/industry input/comment.

SWORN BEFORE ME at the City of Ottawa, on the 16th day of May, 2016

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Commissioner for taking affidavits

Scott Thomley Widdowson, a Commissioner, etc., Province of Ontario, while a Student-at-Law. Expires January 21, 2019.

Original signature redacted

ANDREW CASEY

TAB 4

THIS IS EXHIBIT "1" TO THE

AFFIDAVIT OF ANDREW CASEY

SWORN MAY 16, 2016

Original signature redacted

A Commissioner, etc.

Scott Thornley Widdowson, a Commissioner, etc.,
Province of Ontario, while a Student-at-Law.
Expires January 21, 2019.

Company
3Sixty Public Affairs Inc.
AbbVie Canada
Accel-Rx Health Sciences
Acuitas Therapeutics
Aegerion Pharmaceuticals
Agricultural Institute of Canada
Agrisoma Biosciences Inc.
Ag-West Bio Inc.
Akshaya Bio Inc.
Alethia Biotherapeutics
Alexion Pharma Canada
Amgen Canada Inc.
AmorChem
Antibe Therapeutics Inc.
Appili Therapeutics
Aqua Bounty Canada Inc.
Aquinox Pharmaceuticals Inc.
AstraZeneca Canada Inc.
Atuka Inc.
Augurex Life Sciences Corp.
Aurinia Pharmaceuticals Inc.
AusBiotech Ltd.
Avir Pharma Inc.
Bayshore Specialty Rx Ltd
BELLUS Health Inc.
BioAlberta
BioAmber Canada Inc.
BioDextris
Bioenterprise Corporation
Biogen Canada Inc.
Bioindustrial Innovation Canada
Bio-K Plus International Inc.
BioMarin Pharmaceutical Inc
BioNB
BioNova
Biopharm Management Inc.
BIOQuébec
BioTalent Canada
Biotechnology Industry Organization
BioVectra Inc.
Blake Cassels & Graydon LLP
Blanchard Law Office
Bloom Burton & Co.
BMS Canada Risk Services
Borden Ladner Gervais LLP
Canada's Venture Capital and Private Equity Association
Canadian Seed Trade Association
Caprion Biosciences Inc.
Cardiome Pharma Corp.
CDRD
Ceapro Inc.
Celator Pharmaceuticals Corp.
Celgene
Celverum Inc.
Centre for Probe Development & Commercialization

Centre for The Commercialization of Antibodies And Biologics
Chelation Partners Incorporated
CO2 Solutions Inc.
Contextual Genomics Inc.
CQDM
Critical Outcome Technologies Inc.
CTI Life Sciences Fund
Cyclenium Pharma Inc.
Cynapsus Therapeutics Inc.
Dalton Pharma Services
DelMar Pharmaceuticals
Drug Development and Innovation Centre
Eisai Limited
Eli Lilly Canada Inc.
Encycle Therapeutics
enGene Inc.
EnvisionUp (BIOTECanada Website Management)
Ernst & Young LLP
ESSA Pharma Inc., Canada
ExCellThera
Farris Vaughan Wills & Murphy LLP
Fasken Martineau Dumoulin LLP
Fonds de Solidarité FTQ
Formation Biologics Inc.
Genentech
GenePOC Inc.
Genome Canada
Genzyme Canada
Global Public Affairs
GMD Pharma Solutions
Gowling WLG (Canada) LLP
Grifols
Highland Therapeutics
Hoffmann-La Roche Limited
Immunovaccine Inc.
ImStar Therapeutics Inc.
Innovation PEI
Innovative Targeting Solutions Inc.
InnovoXL Inc.
Institute for Research in Immunology and Cancer-Commercialization of Research
InSymbiosis Management Inc.
Intercept Pharma Canada
International Centre For Infectious Diseases
Intrinsik Health Sciences Inc.
Ipsen Biopharmaceuticals Canada Inc.
iTP Biomedica Corp
Janssen Inc.
Johnson & Johnson - JLABS
KalGene Pharmaceuticals Inc.
Kane Biotech Inc.
KMT Hepatech Inc.
Korea Biotechnology Industry Organization
KPMG
Laurent Pharmaceuticals Inc.
Life Sciences Association of Manitoba
Life Sciences Ontario (LSO)

LifeSciences British Columbia
Linnaeus Plant Sciences Inc.
MaRS Discovery District
McDougall Scientific Ltd.
McKesson Canada
MEDEC
MedGenesis Therapeutix Inc.
Medicago Inc.
Medicenna Therapeutics Inc.
Medicure Inc.
Medunik Canada
Merck Canada Inc.
Milestone Pharmaceuticals
MSI Methylation Sciences Inc.
National Research Council Canada
Neomed Institute
Neurodyn Life Sciences Inc.
New Zealand Biotech
Newfoundland And Labrador Association Of Technology Industries
Northern Biologics Inc.
Norton Rose Fulbright Canada LLP
Novartis Pharmaceuticals Canada Inc.
Novicol International Holding
Novo Nordisk Canada Inc.
Okanagan Specialty Fruits Inc.
Oncolytics Biotech Inc.
Ontario Bioscience Innovation Organization
Pangaea Group
Pan-Provincial Vaccine Enterprise Inc.
Patient Access Solutions Inc.
PBR Laboratories Inc.
Pfizer Canada Inc.
Phoenix Molecular Designs
PlantForm Corporation
POS Bio-Sciences
Precision NanoSystems Inc.
Prevtec Microbia Inc.
PricewaterhouseCoopers LLP
Prince Edward Island BioAlliance
Pro Bono Bio Inc.
ProMIS Neurosciences
ProNAi Therapeutics Canada ULC
PROOF Centre Of Excellence
Proteocyte Diagnostics Inc.
Qu Biologics
Raptor Pharmaceuticals
Renaissance Bioscience Corp.
RepliCel Life Sciences
Replikins Ltd
Research Canada
Resverlogix
Roubaix Strategies Inc.
Royal Bank Of Canada
Sanofi Pasteur Limited
ScarX Therapeutics
Sequence Bio

Sernova Corporation
Shire Pharma Canada ULC
Shoppers Drug Mart Specialty Health Network
SignalChem Lifesciences Corporation
SinoVeda Canada Inc.
Smart & Biggar/Fetherstonhaugh & Co.
Sobi Inc.
Soricimed Biopharma Inc.
Sound Insurance Services Inc.
SPharm Inc.
Takeda Canada Inc.
TEC Edmonton
Temple Therapeutics B.V.
Teralys Capital inc.
Teva Canada Innovation
Therapure Biopharma Inc.
Thrasos Inc.
Transition Therapeutics Inc.
Trillium Therapeutics Inc.
UCB Canada Inc.
University of Guelph
University of Manitoba
University Of Waterloo
Vaccine and Infectious Disease Organization-International Vaccine Centre
Valeant Canada LP
Valneva Canada Inc.
Vasomune Therapeutics
VBI Vaccines Inc.
Versant Ventures Canada Ltd.
Vertex Pharmaceuticals Inc.
viDA Therapeutics Inc.
Viventia Bio Inc.
VWR International
Wex Pharmaceuticals Inc
Wilson Sonsini Goodrich & Rosati
Xagenic Canada Inc.
Xenon Pharmaceuticals Inc.
Zenith Epigenetics Corp.
Zymeworks Inc

TAB 5

CANADA

CONSOLIDATION

CODIFICATION

Patent Act

Loi sur les brevets

R.S.C., 1985, c. P-4

L.R.C. (1985), ch. P-4

Current to April 28, 2016

Last amended on June 17, 2015

À jour au 28 avril 2016

Dernière modification le 17 juin 2015

Published by the Minister of Justice at the following address:
http://laws-lois.justice.gc.ca

Publié par le ministre de la Justice à l'adresse suivante :
http://lois-laws.justice.gc.ca

OFFICIAL STATUS OF CONSOLIDATIONS

Subsections 31(1) and (2) of the *Legislation Revision and Consolidation Act*, in force on June 1, 2009, provide as follows:

Published consolidation is evidence
31 (1) Every copy of a consolidated statute or consolidated regulation published by the Minister under this Act in either print or electronic form is evidence of that statute or regulation and of its contents and every copy purporting to be published by the Minister is deemed to be so published, unless the contrary is shown.

Inconsistencies in Acts
(2) In the event of an inconsistency between a consolidated statute published by the Minister under this Act and the original statute or a subsequent amendment as certified by the Clerk of the Parliaments under the *Publication of Statutes Act*, the original statute or amendment prevails to the extent of the inconsistency.

NOTE

This consolidation is current to April 28, 2016. The last amendments came into force on June 17, 2015. Any amendments that were not in force as of April 28, 2016 are set out at the end of this document under the heading "Amendments Not in Force".

CARACTÈRE OFFICIEL DES CODIFICATIONS

Les paragraphes 31(1) et (2) de la *Loi sur la révision et la codification des textes législatifs*, en vigueur le 1er juin 2009, prévoient ce qui suit :

Codifications comme élément de preuve
31 (1) Tout exemplaire d'une loi codifiée ou d'un règlement codifié, publié par le ministre en vertu de la présente loi sur support papier ou sur support électronique, fait foi de cette loi ou de ce règlement et de son contenu. Tout exemplaire donné comme publié par le ministre est réputé avoir été ainsi publié, sauf preuve contraire.

Incompatibilité — lois
(2) Les dispositions de la loi d'origine avec ses modifications subséquentes par le greffier des Parlements en vertu de la *Loi sur la publication des lois* l'emportent sur les dispositions incompatibles de la loi codifiée publiée par le ministre en vertu de la présente loi.

NOTE

Cette codification est à jour au 28 avril 2016. Les dernières modifications sont entrées en vigueur le 17 juin 2015. Toutes modifications qui n'étaient pas en vigueur au 28 avril 2016 sont énoncées à la fin de ce document sous le titre « Modifications non en vigueur ».

Factors to be considered

85 (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:

(a) the prices at which the medicine has been sold in the relevant market;

(b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;

(c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;

(d) changes in the Consumer Price Index; and

(e) such other factors as may be specified in any regulations made for the purposes of this subsection.

Additional factors

(2) Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:

(a) the costs of making and marketing the medicine; and

(b) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances.

Research costs

(3) In determining under section 83 whether a medicine is being or has been sold in any market in Canada at an excessive price, the Board shall not take into consideration research costs other than the Canadian portion of the world costs related to the research that led to the invention pertaining to that medicine or to the development and commercialization of that invention, calculated in proportion to the ratio of sales by the patentee in Canada of that medicine to total world sales.

1993, c. 2, s. 7.

Hearings to be public

86 (1) A hearing under section 83 shall be held in public unless the Board is satisfied on representations made by the person to whom the hearing relates that specific, direct and substantial harm would be caused to the person

Facteurs de fixation du prix

85 (1) Pour décider si le prix d'un médicament vendu sur un marché canadien est excessif, le Conseil tient compte des facteurs suivants, dans la mesure où des renseignements sur ces facteurs lui sont disponibles :

a) le prix de vente du médicament sur un tel marché;

b) le prix de vente de médicaments de la même catégorie thérapeutique sur un tel marché;

c) le prix de vente du médicament et d'autres médicaments de la même catégorie thérapeutique à l'étranger;

d) les variations de l'indice des prix à la consommation;

e) tous les autres facteurs précisés par les règlements d'application du présent paragraphe.

Facteurs complémentaires

(2) Si, après avoir tenu compte de ces facteurs, il est incapable de décider si le prix d'un médicament vendu sur un marché canadien est excessif, le Conseil peut tenir compte des facteurs suivants :

a) les coûts de réalisation et de mise en marché;

b) tous les autres facteurs précisés par les règlements d'application du présent paragraphe ou qu'il estime pertinents.

Coûts de recherche

(3) Pour l'application de l'article 83, le Conseil ne tient compte, dans les coûts de recherche, que de la part canadienne des coûts mondiaux directement liée à la recherche qui a abouti soit à l'invention du médicament, soit à sa mise au point et à sa mise en marché, calculée proportionnellement au rapport entre les ventes canadiennes du médicament par le breveté et le total des ventes mondiales.

1993, ch. 2, art. 7.

Audiences publiques

86 (1) Les audiences tenues dans le cadre de l'article 83 sont publiques, sauf si le Conseil est convaincu, à la suite d'observations faites par l'intéressé, que la divulgation des renseignements ou documents en cause causerait di-

TAB 6

CANADA

CONSOLIDATION

CODIFICATION

Patented Medicine Prices Review Board Rules of Practice and Procedure

Règles de pratique et de procédure du Conseil d'examen du prix des médicaments brevetés

SOR/2012-247

DORS/2012-247

Current to April 28, 2016

À jour au 28 avril 2016

Published by the Minister of Justice at the following address:
http://laws-lois.justice.gc.ca

Publié par le ministre de la Justice à l'adresse suivante :
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31 (1) Every copy of a consolidated statute or consolidated regulation published by the Minister under this Act in either print or electronic form is evidence of that statute or regulation and of its contents and every copy purporting to be published by the Minister is deemed to be so published, unless the contrary is shown.

...

Inconsistencies in regulations
(3) In the event of an inconsistency between a consolidated regulation published by the Minister under this Act and the original regulation or a subsequent amendment as registered by the Clerk of the Privy Council under the *Statutory Instruments Act*, the original regulation or amendment prevails to the extent of the inconsistency.

NOTE

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CARACTÈRE OFFICIEL DES CODIFICATIONS

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31 (1) Tout exemplaire d'une loi codifiée ou d'un règlement codifié, publié par le ministre en vertu de la présente loi sur support papier ou sur support électronique, fait foi de cette loi ou de ce règlement et de son contenu. Tout exemplaire donné comme publié par le ministre est réputé avoir été ainsi publié, sauf preuve contraire.

[...]

Incompatibilité — règlements
(3) Les dispositions du règlement d'origine avec ses modifications subséquentes enregistrées par le greffier du Conseil privé en vertu de la *Loi sur les textes réglementaires* l'emportent sur les dispositions incompatibles du règlement codifié publié par le ministre en vertu de la présente loi.

NOTE

Cette codification est à jour au 28 avril 2016. Toutes modifications qui n'étaient pas en vigueur au 28 avril 2016 sont énoncées à la fin de ce document sous le titre « Modifications non en vigueur ».

(b) the grounds on which the proposed order is opposed and the material facts on which the respondent is relying;

(c) the name and address of the person on whom service of any document in relation to the proceeding may be effected.

b) les motifs d'opposition au projet d'ordonnance et les faits pertinents sur lesquels se fonde l'intimé;

c) les nom et adresse de la personne à qui les documents relatifs à l'instance peuvent être signifiés.

No response filed

(3) If a respondent has not filed a response within the period set out in subsection (1), the Board may, where the Board is satisfied that a copy of the notice of hearing was served on the respondent and where the Board has received any evidence that it required the respondent to provide, make any finding and issue any order that the Board considers appropriate under section 83 of the Act.

Absence de défense

(3) Dans le cas où l'intimé ne dépose pas de défense dans le délai prévu au paragraphe (1), le Conseil peut, s'il est convaincu qu'une copie de l'avis d'audience a été signifiée à l'intimé et s'il a reçu les éléments de preuve qu'il a exigés, formuler la conclusion et rendre l'ordonnance qu'il juge indiquées en application de l'article 83 de la Loi.

Reply

Filing of reply

19 (1) If Board Staff wishes to reply to the response it must, within 20 days after being served with the response, file with the Board and serve on all other parties a reply that is dated and signed by Board Staff.

Content of reply

(2) A reply must be set out in consecutively numbered paragraphs and must set out an admission or denial of each ground or material fact that was set out in the response.

No reply filed

(3) If Board Staff does not file a reply, it is deemed to have denied each ground and each material fact alleged in the response.

Réponse

Dépôt

19 (1) Si le personnel du Conseil souhaite répondre à la défense, il dépose auprès du Conseil et signifie aux autres parties une réponse datée et signée par lui, au plus tard vingt jours après avoir reçu signification de la défense.

Contenu

(2) La réponse est divisée en paragraphes numérotés consécutivement et contient la reconnaissance ou la dénégation de chacun des motifs ou des faits pertinents exposés dans la défense.

Absence de réponse

(3) Si le personnel du Conseil ne dépose pas de réponse, il est réputé avoir nié chacun des motifs et des faits pertinents exposés dans la défense.

Intervention

Motion for leave to intervene

20 (1) Any person who claims an interest in the subject-matter of a proceeding may, within any period and under any conditions that the Board may specify, bring a motion to the Board for leave to intervene in the proceeding.

Content of motion for leave to intervene

(2) A motion for leave to intervene 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;

Intervention

Requête — autorisation d'intervenir

20 (1) Toute personne qui prétend avoir un intérêt dans une question soulevée dans l'instance peut, par requête, dans le délai et selon les conditions fixés par le Conseil, demander à celui-ci l'autorisation d'intervenir.

Contenu de la requête

(2) La requête pour obtenir l'autorisation d'intervenir contient les éléments suivants :

a) le nom et l'adresse de l'intervenant éventuel et de tout conseiller juridique le représentant;

(c) a concise statement of the facts upon which the motion is based; and

(d) the issues that the proposed intervener intends to address.

b) un exposé concis de la nature de son intérêt dans l'affaire et des raisons pour lesquelles l'intervention est nécessaire;

c) un exposé concis des faits sur lesquels la requête est fondée;

d) les questions que l'intervenant se propose de soulever.

Filing of motion

(3) A motion for leave to intervene must be filed with the Board and served on the parties in accordance with Rule 10.

Dépôt de la requête

(3) La requête pour obtenir l'autorisation d'intervenir est déposée auprès du Conseil et signifiée aux parties conformément à la règle 10.

Filing of representations

(4) The parties who are served with a motion for leave to intervene may make submissions with respect to the motion by filing their submissions with the Board and serving a copy of the submissions on the person seeking leave to intervene.

Dépôt des observations

(4) Les parties auxquelles la requête pour obtenir l'autorisation d'intervenir est signifiée peuvent déposer auprès du Conseil leurs observations et en signifier copie à la personne qui demande l'autorisation d'intervenir.

Factors considered by the Board

(5) Subject to section 87 of the Act, if a person has moved to intervene in a proceeding, the Board may grant or deny the intervention and impose any conditions or restrictions on the intervention that it determines to be appropriate after considering relevant factors, including

(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.

Facteurs à considérer par le Conseil

(5) Sous réserve de l'article 87 de la Loi, lorsqu'une personne a demandé par requête l'autorisation d'intervenir dans une instance, le Conseil peut autoriser ou refuser l'intervention et imposer des conditions ou restrictions à l'intervention qu'il juge indiquées après l'examen des facteurs pertinents, notamment :

a) la question de savoir si la personne a un intérêt dans l'instance qui est suffisant pour justifier l'intervention;

b) la question de savoir si l'intervention causera un préjudice à une partie à l'instance;

c) la question de savoir si l'intervention portera atteinte au déroulement équitable et expéditif de l'instance.

Appearance by Minister

Filing of notice of appearance

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

Comparution d'un ministre intéressé

Dépôt d'un avis de comparution

21 (1) Tout ministre intéressé qui a l'intention de comparaître et de présenter ses observations sur une question dont est saisi le Conseil dépose auprès de celui-ci et signifie à toutes les parties un avis de comparution daté et signé par lui, au plus tard vingt jours après avoir reçu signification de l'avis d'audience.

TAB 7

Decision: PMPRB-07-D1-QUADRACEL and PENTACEL
Application for leave to intervene by GlaxoSmithKline Inc.

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER OF sanofi pasteur Limited (the "Respondent") and the medicines "Quadracel and Pentacel"

Introduction

1. This proceeding concerns the pricing by sanofi-pasteur Limited ("sanofi pasteur") of the medicines Quadracel and Pentacel, vaccines used for the immunization of infants against diphtheria, tetanus, whooping cough, polio and *haemophilus influenzae type b* disease (the "medicines").

2. The Statement of Allegations produced by Board Staff in this proceeding alleges that sanofi pasteur sold, and engaged in a policy of selling, the Medicines at excessive prices during the period 2002-2006.

3. GlaxoSmithKline Inc. ("GSK") has sought intervener status in this proceeding. GSK brought a motion for such status, sanofi pasteur filed submissions opposing the motion, and GSK filed responding submissions.

Positions of the parties

4. GSK notes that it and sanofi pasteur are the only two suppliers of quadravalent and pentavalent vaccines in Canada. GSK argues that, as the only other supplier of these vaccines than sanofi pasteur, it has a significant interest in pricing "irregularities" in sales by sanofi pasteur of the Medicines.

5. GSK also takes the position that, with its experience and expertise in what is alleged to be a unique market for these vaccines, it could provide the Board with relevant information concerning that market, the manner in which that market is and was served by sanofi pasteur and GSK, and the remedy that would be appropriate, given that market, if the Board were to find that sanofi pasteur had sold the Medicines at excessive prices.

6. In its reply submissions, GSK also urged the Board to conclude that the Board's mandate to protect consumers from excessive prices of patented medicines includes ensuring that its decisions promote, and do not dissuade, competition in the marketplace. GSK suggested that there could be a link between the allegedly excessive prices charged by sanofi pasteur in the 2002-2006 period and the price that sanofi pasteur bid for the contract to sell vaccines to Canada from 2007 forward, and that this link could involve anti-competitive conduct by sanofi pasteur.

7. sanofi pasteur has submitted that GSK has not identified any legitimate interest in the proceeding, or any contribution that GSK could make to the hearing that would be useful to the Board. sanofi pasteur argues that GSK is seeking intervener status because GSK is a competitor of sanofi pasteur with respect to the Medicines and is trying to use this proceeding as a way to achieve a competitive advantage over, or impose a competitive disadvantage on, sanofi pasteur.

General Analysis

8. Rule 19 of the (proposed) *Patented Medicine Prices Review Board Rules* provides that the Board may grant leave to intervene to a party that "has an interest in the subject-matter" of the proceeding.

An excessive price hearing before a panel of the Board involves a dispute between Board Staff and a patentee about whether the patentee is, or has been, selling the medicine in question at an excessive price. Jurisdictional issues sometimes also arise in an excessive price hearing.

9. In the course of an excessive price hearing, the Board determines the maximum non-excessive price of the medicine and whether the patentee is or has been selling the medicine in any market above that price. If a finding of excessive pricing is made, the Board has the authority to order the patentee to take such measures as will offset the excessive revenues that have been earned, such as a payment to the Crown or a reduction in the price of the medicine.

10. In an excessive price hearing, Board Staff prosecutes the case by establishing that the price of the medicine exceeds or exceeded the Board's Excessive Price Guidelines, that the Guidelines properly implement the relevant provisions of the *Patent Act,* and, where jurisdiction is in issue, that the Board has jurisdiction. The patentee has an obvious interest in the case and a statutory right to make representations rebutting the allegations of Board Staff.

11. It can be noted that the *Patent Act* provides, in subsection 86(2), that the Minister of Health and the provincial health ministers have a right to notice of, and to intervene in, excessive price hearings.

12. As a general matter, and consistent with past practice at the Board, the Board would expect that other persons with an interest in the Board's hearings, in the sense contemplated by Rule 19, would be in one of the following three categories:

1. Persons who, in one manner or another, will bear some or all of the cost burden of the medicine in question, or the cost burden of other medicines where the prices of such medicines could be affected by the outcome of the proceeding;
2. Patentees, the maximum non-excessive prices of whose medicines will be affected by the specific outcome of the proceeding, or by the establishment of a point of principle pertaining the non-excessive pricing of medicines or the Board's jurisdiction; or
3. Organizations representing persons in the two previous categories.

13. In addition, where a proposed intervener does not have a material and direct interest in the outcome of the proceeding in question, the Board would also require that an applicant for intervener status demonstrate the ability to contribute, to the proceeding, some element of evidence that was expected by the Board to be unique, or otherwise to be usefully supplementary to the evidence and argument expected to be adduced by Board Staff, the patentee of the medicine in question, or another person that is granted intervener status.

14. It must be noted that Board Staff will generally represent the interests of persons who bear the cost burden of medicines under review, and patentees, by advocating their own interests, will typically represent interests that are not unique to them or to the particular medicine under review. Perhaps as importantly, the Board is aware of the impact of each of its decisions on persons other than those appearing before it in any given proceeding, and takes the interests of those persons into account whether or not they are independently represented in a proceeding.

16. None of these factors removes the right of appropriate persons to be interveners in the Board's proceedings, or detracts from the important role that interveners can play in the Board's proceedings. However, those factors, and the Board's statutory obligation pursuant to subsection 97(1) of the *Patent Act* to conduct its proceedings as expeditiously as the circumstances and considerations of fairness permit, and the Board's need to control its process, do bear on the discretion that the Board will exercise when deciding, in a particular case, whether a person is an appropriate intervener in a proceeding.

The jurisprudence

17. sanofi pasteur placed reliance on a number of cases in which the Federal Courts made relatively restrictive pronouncements on the circumstances in which persons should be permitted to intervene, typically in judicial review applications.

GSK argued that this jurisprudence pertained to litigation that constituted "private disputes" or "disputes between private parties", and was inapplicable to the proceedings of the Board. The panel does not agree that applications for judicial review of tribunal decisions or ministerial conduct in the Federal Courts constitute private disputes, and takes some guidance from the discussions of intervener status in this jurisprudence.

18. However, the Board also notes the cases cited by GSK to the effect that the scope for intervention in a tribunal hearing can be broader than in a court proceeding. The Board would note that this is true of the Board's proceedings given the polycentric nature of the interests that are likely to be given consideration in an excessive price hearing.

GSK's application to intervene

19. It is the view of the panel that GSK has not established any grounds on which it has an interest in the outcome of the proceeding that warrants GSK's status as an intervener. The panel has also concluded that GSK could not assist the Board with the matters in issue in this proceeding by the contribution of evidence or insight that is not expected to be provided by the parties to the proceeding.

20. Also, the panel does not believe that the Board has a mandate to consider whether the price of a medicine under its jurisdiction has been or will be, for competitive purposes, set by the patentee at a level that is somehow unfairly high or low relative to the price of a medicine competing in the same market, or to otherwise inquire into the fairness of the competitive strategy of one patentee relative to another. 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.

21. The panel was able to reach its decision on GSK's application without reliance on the submissions of sanofi pasteur concerning the motives of GSK in seeking intervener status in this proceeding. The mere fact that GSK is a competitor of sanofi pasteur, and that GSK would pursue its own interests if it were granted intervener status, does not disentitle GSK from being an intervener in this proceeding. Indeed, the intervention of Janssen-Ortho in the ongoing proceeding before the Board concerning Shire BioChem's medicine Adderall XR is an example of a direct competitor demonstrating an interest in a proceeding that warranted intervener status. The maximum non-excessive prices of the two companies' competing medicines were arguably logically linked. However, in the case of GSK, the Board sees no similar or analogous interest in the instant proceeding.

Conclusion

22. For the foregoing reasons, the application of GSK to intervene in this proceeding is dismissed.

Board Members: Dr. Brien G. Benoit
Anne Warner La Forest
Anthony Boardman

Board Counsel: Gordon Cameron

Original signed by

Sylvie Dupont
Secretary of the Board

July 26, 2007

TAB 8

Regulatory Process

The PMPRB (Patented Medicine Prices Review Board) monitors the prices charged by patentees for patented drugs on an ongoing basis. Under the *Patent Act*, patentees are required to file price and sales information about their patented drug products at introduction and twice a year thereafter for each strength of each dosage form of each patented drug product sold in Canada. However, patentees are welcome to consult with the PMPRB (Patented Medicine Prices Review Board) on the application of the Guidelines at any time. The Board may, on request, pre-approve a price under certain conditions by issuing an Advance Ruling Certificate (view.asp?ccid=480). Patentees are not required to obtain approval of the price before a drug is sold.

If you are a patentee, please visit Are You a Patentee? (view.asp?ccid=525) for more information about your reporting obligations.

Scientific Review

The first step in the PMPRB (Patented Medicine Prices Review Board)'s regulatory process is a scientific review, which assesses the level of therapeutic improvement of a new patented drug product. A committee of experts known as the Human Drug Advisory Panel (view.asp?ccid=478) also recommends appropriate drug products to be used for comparison. The level of therapeutic improvement of a patented drug is used to determine a ceiling price, known as the Maximum Average Potential Price, at introduction.

- More information on the scientific review (view.asp?ccid=474) process
- More information on the HDAP (Human Drug Advisory Panel) meeting schedule and filing requirements (view.asp?ccid=479)

Price Review

Board Staff reviews pricing information for all patented drug products sold in Canada on an ongoing basis to ensure that the prices charged by patentees comply with the Guidelines (view.asp?ccid=355) established by the Board. The Guidelines, which are based on the price

determination factors in Section 85 of the Act, were developed by the Board in consultation with stakeholders, including the provincial and territorial Ministers of Health, consumer groups, and the pharmaceutical industry.

- More information on the price review (view.asp?ccid=475) process

New Patented Medicines Reported to the PMPRB (Patented Medicine Prices Review Board)

The PMPRB (Patented Medicine Prices Review Board) publishes information on the price review of all new patented drug products in a searchable table format. This format was introduced in January 2012 as part of the ongoing implementation of the 2010 Guidelines. The table is updated as the review of each new patented drug product is completed.

Each new patented drug product from 2010 onward that has a status classified as “Within the Guidelines” or “Does Not Trigger an Investigation” has a link from the brand name to an individual Price Review Record. Price Review Records include information such as the level of therapeutic improvement; the price test used to establish the maximum average potential price (MAPP); comparable drug products and countries used for price comparisons; and the MAPP (maximum average potential price).

Price Review Records are currently available for almost all new drug products reported in 2010 and will be gradually populated for 2011. Summary Reports (view.asp?ccid=573) are available for new drug products reported prior to 2010.

- Listing of New Patented Medicines Reported to the PMPRB (Patented Medicine Prices Review Board) (pmpMedicines.asp?x=611)

Investigations

If Board Staff finds that a price appears to exceed the Guidelines, and the circumstances meet the criteria for commencing an investigation, Board Staff will open an investigation to determine whether the price of the patented drug product in fact exceeds the Guidelines.

An investigation could result in:

- closure of the file if the price is found to be within the Guidelines
- a Voluntary Compliance Undertaking by the patentee to reduce the price and offset excess revenues through a payment and/or a reduction in the price of another patented drug
- a public hearing to determine whether the price is excessive.

Voluntary Compliance Undertakings

A Voluntary Compliance Undertaking (VCU) is a written commitment by a patentee to comply with the Board's Guidelines, including adjusting the price of the patented drug in question to a non-excessive level and offsetting any excess revenues that may have been received as the result of having sold the patented drug at an excessive price in Canada. Patentees are given the opportunity to submit a VCU (Voluntary Compliance Undertaking) when Board Staff concludes, following an investigation, that the price of a patented drug product sold in Canada appears to have exceeded the Guidelines. A VCU (Voluntary Compliance Undertaking) can also be submitted following the issuance of a Notice of Hearing, but must then be approved by the Hearing Panel. VCU (Voluntary Compliance Undertaking)s represent a compromise between the PMPRB (Patented Medicine Prices Review Board) and the patentee as a result of negotiations between the parties in view of the specific facts and underlying context of a particular case. As such, VCU (Voluntary Compliance Undertaking)s are not intended to have precedential value.

- More information on Voluntary Compliance Undertakings (view.asp?ccid=465)

Hearings

If the price of a patented medicine appears to be excessive, the Board can hold a public hearing. If it finds that the price is excessive, it may issue an order to reduce the price and to offset revenues received as a result of the excessive price.

Board decisions are subject to judicial review in the Federal Court of Canada.

- More information on Hearings and Decisions (view.asp?ccid=482)

Date modified:

2016-01-29