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September 8, 2017 **By Email**
File No.: 011313.1016

Guillaume Couillard
Director, Board Secretariat & Communications
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue Weste, Suite 1400
Ottawa, ON K1P 1C1

Dear Mr. Couillard:

Re: In the Matters of Apotex Inc. and the Medicine Apo-Salvent CFC Free

We are counsel to Apotex Inc. ("Apotex"), the respondent in the referenced proceeding. We write in response to the order dated August 28, 2017 of the Panel of the Patented Medicine Prices Review Board (the "Board").

With respect to the "Revised Compliance Status" chart referred to in the order, Apotex does not agree with those numbers and notes that the calculation of alleged excess price would be a contested issue to be determined on the application if it were to proceed. In Apotex's Response to the Board Staff's Statement of Allegations delivered on August 18, 2008 (a copy of which is attached to this letter), Apotex set out a series of reasons as to why these calculations were not correct. Apotex submits that none of those points are resolved by way of the ratio-salbutomal proceeding, as (a) certain of them are unique to Apo-Salvent; and (b) to the extent similar arguments were considered in the Board's decision in the ratio-salbutomal proceeding, with the exception of the jurisdiction arguments none of these points were addressed by way of judicial review.

With respect to the public interest considerations, the motion to discontinue this proceeding was brought by Board Staff. Apotex does not oppose that motion and agrees that it is not in the public interest to continue this proceeding. We have reviewed the letter from David Wilson, counsel to Board Staff, of today's date. While Apotex does not agree that the Federal Court of Appeal decision in the ratio-salbutomal proceeding resolves Apotex's jurisdictional defences, Apotex otherwise supports Mr. Wilson's submissions.

We would be pleased to discuss these issues further during the conference call scheduled for September 13, 2017.

Yours truly,

Original signature redacted

Katherine L. Kay

KLK/sr
cc. Dan Murdoch, *Stikeman Elliott LLP*

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 Apotex Inc. (the "Respondent") and the Medicine "Apo-Salvent CFC Free"

RESPONSE OF APOTEX INC.

INTRODUCTION

1. Apotex Inc. ("Apotex") does not, and has not, sold Apo-Salvent CFC-Free ("Apo-Salvent") at an excessive price. Apotex is Canada's largest generic pharmaceutical company, and sells generic medicines in competitive markets. The price at which Apotex has sold Apo-Salvent has at all times been competitive in the marketplace and significantly below the price of the comparable brand name product, Ventolin®, sold by GlaxoSmithKline ("GSK").

2. The position of Board Staff that Apo-Salvent is and has been sold at an excessive price is incorrect for multiple reasons, including:

   (a) The price charged by Apotex is not excessive when the factors enumerated in subsections 85(1) and (2) of the *Patent Act*, R.S.C. 1985, c. P-4 (the "*Patent Act*") are properly considered and applied;

   (b) The Excessive Price Guidelines (the "Guidelines"), under which Board Staff purports to find that Apotex has sold Apo-Salvent at an excessive price, are not binding on the Board and in any event fail to consider several factors enumerated in subsections 85(1) and (2) of the *Patent Act* despite the clear language of the Act mandating the consideration of those factors;

(c) Additional factors not addressed by the current Guidelines should properly be considered by the Board, including:

(i) Apo-Salvent is sold in a competitive market such that price regulation by the Board is neither required nor appropriate;

(ii) Apotex does not currently break even on the making and marketing of Apo-Salvent; and

(iii) requiring Apotex to sell Apo-Salvent at a lower price is contrary to sound policy, as it may result in a decrease in customer choice and an increase in the market share of the higher priced brand name product Ventolin®[1];

(d) In any event, the Guidelines are currently under review, and eventual revisions will likely impact their application to Apo-Salvent; and

(e) In addition to or in alternative to the above, to the extent the *Patent Act* grants authority to the Board to regulate the prices of generic medicines that are sold in a competitive market, the *Patent Act* is *ultra vires* the Canadian Parliament under the *Constitution Act, 1867*.

3. For these reasons, Apotex therefore asks the Board to conclude that Apo-Salvent is not and has not been sold in Canada at an excessive price, and deny the Board Staff's request for an Order as provided in paragraph 23 of the Statement of Allegations of Board Staff.

ADMISSIONS AND DENIALS

4. With respect to the allegations contained in paragraph 1 of the Statement of Allegations, Apotex has no knowledge of the investigation purportedly conducted by Board Staff.

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[1] The Board has also issued a Notice of Hearing with respect to ratio-Salbutomal, a similarly priced competitor of Apo-Salvent that currently holds a market share of approximately 76%.

5. Apotex admits the allegations contained in paragraphs 2, 3, 4, 5, 8 and 17 of the Statement of Allegations.

6. With respect to the allegations in paragraph 6 of the Statement of Allegations, Apotex disputes the authority of the Board to regulate the price of Apo-Salvent and as a result disputes the requirement that Apotex file its price and sales information for this medicine. Nevertheless, following demands from Board Staff Apotex elected to file its price and sales information for Apo-Salvent for all periods as of October 4, 2006.

7. With respect to the allegations in paragraphs 7, 9, 11, 13 and 18 of the Statement of Allegations, Apotex admits that the text of the Guidelines and the *Patent Act* are as set out therein. However, Apotex relies on subsection 96(4) of the *Patent Act* which provides that the Guidelines are not binding on the Board. Furthermore, Apotex states that the Guidelines cannot in any way override the *Patent Act*. Apotex further denies that Board Staff have properly applied the relevant provisions of the Guidelines and/or the *Patent Act* in their assessment of Apo-Salvent.

8. Apotex has no knowledge with respect to the allegations in paragraphs 10, 12, and 15 of the Statement of Allegations.

9. With respect to the allegations in paragraph 16 of the Statement of Allegations, Apotex states that the substance of the referenced

correspondence is best represented by the letter at issue, and denies the conclusions represented by Board Staff in the referenced correspondence.

10. Apotex denies the allegations in paragraphs 14, 19 and 20 of the Statement of Allegations, and denies that there is a basis for the Board to issue an Order as requested in paragraph 23.

11. With respect to paragraph 22 of the Statement of Allegations, Apotex states that certain information that will be filed by Apotex and that may be filed by Board Staff is confidential and that its disclosure may cause harm to Apotex. Apotex will make submissions to the Board with respect to such confidentiality in accordance with the Board's Rules.

THE MEDICINE

12. Apo-Salvent is an inhalation aerosol containing the bronchodilator medicine salbutamol sulphate. Apo-Salvent provides symptomatic relief and prevention of bronchospasm due to brochial asthma and other chronic bronchial disorders. Salbutomol sulphate is "off patent."

13. Apotex has sold Apo-Salvent in Canada since 1989. Prior to 2002, the version of Apo-Salvent sold by Apotex contained a chlorofluorocarbon (CFC) propellant. At this time, there were a number of companies marketing bronchodilator medicines containing salbutomol sulphate, including the

brand name product Ventolin® marketed by GSK and generic companies Novo-Salmol and Kenral (whose product is now marketed by ratiopharm).

14. In 2002, Apotex entered into a licensing agreement with 3M Canada Inc. ("3M") to obtain a non-exclusive licence for Canadian Patent No. 2,004,598, which pertains to the Airomir® product marketed by 3M. Airomir is a CFC-Free inhaler that contained a hydrofluoroalkane propellant, HFA-134a. In 1996, Canada and other developed nations agreed to cease the production and importation of CFCs under a treaty called the Montreal Protocol. On March 13, 2002, Health Canada released a schedule by which CFC-containing pharmaceuticals were to be eliminated. The phase-out process was to be done on a drug-by-drug basis, starting with salbutamol in July 2002.

15. Starting in July 2002, no salbutamol containing CFC products were sold or distributed by manufacturers. However, CFC-containing products remained in the pharmaceutical supply chain (i.e., wholesalers, pharmacies, etc.) for a period of time after July 2002. Today, all inhalers are CFC-Free and there is a competitive market for these salbutomal sulphate medications. The approximate market shares today are approximately 76% for ratiopharm, 15% for Apotex, 8% for Ventolin® and 1% for Airomir®.

APO-SALVENT PRICING

16. Apotex introduced its CFC-Free version of Apo-Salvent at the same price as its prior version which contained a CFC propellant, which was $4.64 per

inhaler. This introductory price was well below the allowable maximum non-excessive (MNE) price at that time. This price was competitive with the other generic anti-asthma inhalers on the market and far below the price for the brand name product Ventolin®. Apotex introduced Apo-Salvent CFC-Free at this price in order to compete against other products in the marketplace.

17. In late 2004 the market conditions for anti-asthma inhalers changed and Apotex increased the price of Apo-Salvent accordingly. On November 1, 2004, ratiopharm increased its price for ratio-Salbutomol to $7.73 per inhaler. Apotex matched that price shortly thereafter. Given the very large market share held by ratio-Salbutomal, in the range of 70%, Apotex would not have been capable of supplying the market if it kept its inhalers at the price of $4.64 per inhaler. In any event, the making and marketing of Apo-Salvent was uneconomic at the price of $4.64 per inhaler. At this time, the price of Ventolin® remained far in excess of $7.73 per inhaler.

18. The price of Apo-Salvent has remained at or around $7.73 per inhaler since 2004. At this price, Apotex does not presently break even on the making and marketing of Apo-Salvent and has not broken even since approximately July 2007.

THE PRICE OF APO-SALVENT IS NOT EXCESSIVE

Application of the Factors in Subsection 85(1) of the *Patent Act*

19. Subsection 85(1) of the *Patent Act* provides:

> **85(1) Factors to be considered** – 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.

20. The language in subsection 85(1) of the *Patent Act* is clearly mandatory: "the Board *shall* take into consideration the following factors . . . " (emphasis added) As a result, any analysis as to whether Apo-Salvent has been sold at an excessive price must consider all enumerated factors to the extent that information is available.

21. A consideration of these factors clearly establishes that Apo-Salvent has not been sold at an excessive price:

(a) Apo-Salvent's price is currently far less per inhaler than the brand name competitor Ventolin®, and has been since the price increase in 2004. Prior to the price increase in 2004, Apo-Salvent was even further below the price of Ventolin®, as the brand name's price has not changed significantly. With respect to other competitors, Apo-Salvent has generally been sold at the same price as other generics and 1 cent less than the 3M product Airomir®.

(b) As acknowledged in paragraph 15 and shown in Attachment 5 of the Statement of Allegations, Apo-Salvent does not have the highest publicly available ex-factory price when compared to international prices of Airomir® (Apo-Salvent is not sold outside of Canada). At the price of $7.73 per inhaler, the price of Apo-Salvent since 2005 has only been a small amount higher than the international median and over four times cheaper than the cost of Airomir® in the United States.

(c) The price of Apo-Salvent, including the version containing CFCs, did not increase (and in fact went down) over the period 1996 to 2004. The price in 1996 was $4.90 per inhaler and in 1999 it was reduced to $4.65 per inhaler. The Guidelines provide that the price of an existing product will be presumed to be excessive based on a benchmark price for the medicine (its introductory price rather than its introductory MNE), and with a cap on the amount of allowable increase in any one year. Apotex states that, under subsection 85(1) of the *Patent Act*, the CPI must be considered in conjunction with the other enumerated factors, and that a price should – at most – only be considered excessive on the basis of the CPI factor if the price is higher than the *introductory MNE* adjusted for CPI. The price of Apo-Salvent is well excessive, including on that basis.

22. The factors in subsection 85(1) of the *Patent Act* support the position that Apo-Salvent is not sold at an excessive price. These factors far outweigh the significance of a single factor, the CPI, and the fact that in November 2004 Apotex, in response to its market competitors, increased the price of Apo-Salvent in an amount greater than the CPI for that year.

Application of the Factors in Subsection 85(2) of the *Patent Act*

23. Alternatively, if the Board concludes that an application of the factors in subsection 85(1) of the *Patent Act* are inconclusive as to whether Apo-Salvent is sold at an excessive price, reference should be made to subsection 85(2), which provides:

> **85(2) Additional factors** – 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.

24. A consideration of the additional factors in subsection 85(2) of the *Patent Act* further demonstrates that the price of Apo-Salvent is not excessive:

(a) The costs incurred by Apotex in the making and marketing of Apo-Salvent exceed the revenues received on the sale of Apo-Salvent. Apotex's continued participation in the sale of Apotex at the current price is uneconomic, and has been since approximately July 2007. Given that Apotex is not presently making profits on the sale of Apo-Salvent, it is submitted that the Board should certainly not conclude that Apotex is receiving excess revenues;

(b) Although there are no regulations establishing additional factors to be considered under subsection 85(2)(b), Apotex submits that there are other factors that should be considered by the Board because they are relevant in the circumstances, including:

(i) Apotex does not have any monopoly power or competitive benefit because of its non-exclusive licence of the relevant patent. Apo-Salvent is sold in a competitive market which drives the prices of the product. This competitive reality dictates that the Board's exercise of its discretion to regulate prices should not be engaged; and

(ii) Given that the making and marketing of Apo-Salvent is currently uneconomic, an order requiring Apotex to sell Apo-Salvent at a lower price (and a similar order with respect to ratio-Salbutomol) may potentially have the unintended effect of decreasing consumer choice and increasing the market share of

the brand name Ventolin®, which is sold at at a far higher price per inhaler than the current price of Apo-Salvent.

25. These factors support the position that Apotex has not been selling Apo-Salvent at an excessive price. Apotex further submits that there are no other factors properly considered under subsection 85(2) which suggest otherwise. Under both subsections 85(1) and (2) of the *Patent Act*, the only factor that the Board Staff rely on to support their request for an order against Apotex is the factor dealing with CPI. While Apotex disputes the manner in which Board Staff applied the CPI factor, there is no question that all other factors argue against the Board Staff's position.

The Excessive Price Guidelines

26. The Statement of Allegations relies entirely upon a strict application of the Guidelines in its attempt to establish that Apo-Salvent has been sold at an excessive price. Such a strict application should not be adopted by the Board for the following reasons:

(a) The Guidelines are not binding on the Board;

(b) The Guidelines are contrary to the clear language of the *Patent Act* to the extent they provide that the price of an existing drug product can be found to be excessive solely by considering the CPI factor in a vacuum, and without considering the factors enumerated in subsection 85(1)(a), (b) and (c);

(c) The Guidelines are currently under review, with a discussion paper being released for comment. The eventual revisions to the Guidelines will likely impact their application to the pricing of Apo-Salvent, and the current timetable provides that an amended Compendium of

Policies, Guidelines and Procedures will be released November 17, 2008, prior to the scheduled hearing of this matter.

27. The Guidelines acknowledge that the *Patent Act* stipulates the factors the Board "must take into consideration" when determining whether a medicine is sold at an excessive price. They further acknowledge that they "are not a rigid set of decision-making rules and are not binding on the Board or on any patentee." Board Staff ignores these limitations of the Guidelines and instead asks the Board to apply them strictly and make a finding against Apotex based solely on the application of one factor, the CPI.

28. The Guidelines differentiate between "new" and "existing" drug products. There is no such distinction in the *Patent Act*. The general structure of the Guidelines, whereby the prices of new drug products are considered in relation to comparators, and the prices of existing drug products are considered solely in relation to the CPI, is not grounded in any provision of the *Patent Act*.

29. Apotex submits that the Guidelines are contrary to the *Patent Act* to the extent they provide that the price of an existing drug can be "presumed to be excessive" solely on the basis of a price increase in a given year exceeding CPI, in particular when the price of that drug was previously well below the introductory MNE. The introductory MNE is determined on the basis of a consideration of all other factors enumerated in subsection 85(1), and Apotex

should not be punished for choosing to introduce Apo-Salvent at a price below the introductory MNE. Such an approach discourages competitive pricing when medicines are introduced and is contrary to sound policy.

30. In any event, however, with respect to Apo-Salvent, the so-called presumption of excess pricing on the basis of CPI is clearly rebutted by the other factors that support the position that Apo-Salvent is not sold at an excessive price, as outlined above.

31. Apotex further submits that the Guidelines are contrary to the *Patent Act* to the extent they provide that a one-year price increase "may not exceed 1.5 times the forecast change in the annual CPI" without any consideration of the other factors in subsection 85(1).

32. In the July 2008 PMPRB Newsletter, Volume 12, Issue No. 3, the Board Staff announced that a Stakeholder Communique will be issued August 18, 2008, with respect to draft revised Guidelines, and that the draft revised Guidelines will be posted to the Board website on August 20, 2008. The Newsletter further provides that stakeholders have until October 6, 2008, to make submissions with respect to the draft revised Guidelines, and an amended Compendium of Policies, Guidelines and Procedures will be released November 17, 2008. In light of the expected revisions to the Guidelines and the likely possibility that the revised Guidelines will impact the

determination of this hearing, further stages in this hearing should not occur until the revised Guidelines are released.

THE BOARD DOES NOT HAVE THE POWER TO FIX PRICES OF APO-SALVENT

33. Apotex submits that the Board's powers, as granted by Parliament pursuant to the *Patent Act*, are limited to those powers that Parliament can grant under section 91(22) of the *Constitution Act, 1867* relating to "patents of invention and discovery." The regulation of the prices of medicines sold in a competitive market, where the participant does not have a monopoly power with respect to that medicine, does not fall under this power, but is in fact an intrusion on the provinces' powers to make laws with respect to "property and civil rights" under section 92(13) of the *Constitution Act, 1867*.

34. Four provinces, Alberta, Ontario, Quebec and Newfoundland, restrict the medicines that can be listed on their Provincial Drug Formulary based on the prices charged for those medicines. The Provincial Drug Formulary controls the medicines whose costs can be claimed under public plans. All four provinces have approved Apo-Salvent for inclusion on their respective Provincial Drug Formularies and all four provinces provide full benefit coverage for Apo-Salvent.

35. Apotex submits that the Board lacks the authority to grant the relief sought by the Board Staff.

SERVICE

36. Service of any document in this proceeding may be effected on the following individuals:

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DOCUMENTS

37. The following documents may be used in evidence to support the grounds and material facts on which Apotex is relying:

(a) the documents set out in the Notice of Hearing;

(b) affidavit evidence from a representative of Apotex and any documents attached thereto; and

(c) such further and other documents as counsel may advise and the Board may permit.

Dated at Toronto, the 18th day of August, 2008

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