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September 8, 2017

VIA EMAIL

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

Dear Mr. Couillard:

RE: THE APOTEX AND APO-SALVENT MATTERS
OUR MATTER ID: 1360-003 & 1360-004

On August 28, 2017, the Panel of the Patented Medicine Prices Review Board (the "Board") issued an order seeking additional details in respect of Board Staff's request to discontinue these proceedings as requested in Board Staff's motions.

Set out below are additional submissions by Board Staff in respect of the issues raised by the Board. We will be available to address these points and answer any questions the Board may have at the case conference scheduled for September 13, 2017 (please note, I will be out of the country at the time, but I can join by telephone).

As a preliminary matter, notwithstanding Apotex's disagreement concerning the implications of *Attorney General) v. Sandoz Inc; Canada (Attorney General) v. Ratiopharm Inc, 2015 FCA 249*, the law in this regard is settled. The *Sandoz/Ratiopharm* ruling by the Federal Court of Appeal has resolved the jurisdictional issues raised by Apotex. Indeed, the settled state of the law is one of the reasons why Board Staff is of the view that it is no longer in the public interest to further pursue this litigation.

The Board seeks additional information concerning the revised compliance status chart in Attachment 8 of the Board Staff Statement of Allegations in respect of Apo-Salvent. While Board Staff is not aware of any inaccuracies, the request for a discontinuance must be considered in light of the considerations set out below.

First, the regulatory environment for generic medicines in Canada, and related industry practices in connection with "trade-spend", have changed dramatically since the time period covered by proceedings. Provincial governments have developed new regulatory frameworks to address certain market practices by generic manufacturers and pharmacies, as upheld by the Supreme Court of Canada in *Katz Group Canada Inc. v. Ontario (Health and Long -Term Care)* 2013 SCC 64. The price of many generic medicines, including Apo-Salvent, have decreased in recent years, and are unlikely to rise significantly again given the existence of the pan-Canadian Pharmaceutical Alliance ("pCPA"), which seeks to capitalize on the combined negotiating power of drug plans across multiple provinces and territories.

Additionally, when the Statement of Allegations was prepared, some nine years ago, Board Staff (and similarly the Board) did not have the benefit of guidance from the Federal Court as to the accounting treatment of trade-spend which serves to reduce the net selling price by a generic manufacturer. Trade-spend, in this context, refers to after-sales amounts paid by generic drug manufacturers to purchasers, typically pharmacies, in the form of rebates/free goods, purchasing incentives, educational subsidies, trade allowances, returns, early payment discounts, etc.

In calculating losses under section 8[1] of the Patented Medicines (Notice of Compliance) Regulations, the Federal Court has repeatedly accepted that the trade-spend for generic manufacturers is considerably higher where there are multiple generic manufacturers in the market place. For instance, in Apotex Inc. v. Takeda Canada Inc., the Federal Court considered both single generic circumstances, multi-source generic environments, as well as the impact of the identity of the purchase on trade-spend. Ultimately, while noting that the evidence was diverse and dispersed, the Federal Court found a 44.7% rebate rate in a multi-source market in relation to chains (55% of the market). This is relevant because, in the relevant historic period, Apo-Salvent was being sold in a market with multiple generic manufacturers, supporting the proposition that its trade-spend would be, accordingly, on the higher end of the spectrum.

Furthermore, the Federal Court has been fairly liberal in accounting for "trade-spend". For example, in *Eli Lilly Canada Inc. et. al. v. Teva Canada Limited*, the Federal Court considered a variety of rate ranges proposed by the parties, as well as trade-spend rates from other drug products. The Federal Court also considered evidence with respect to average trade-spend rates across all of a party's products, the impact of licensing agreements with other parties on trade-spend rates, as well as summary trade-spend documents prepared by the defendant in the course of its business, and thus admissible as a business record for the proof of its contents. This approach to accounting for trade-spend can be contrasted with the stricter approach adopted by the Board in the decision concerning Ratio-Salbutamol in which another panel of the Board

[1] Section 8 provides for liability by an innovator to a generic manufacturer for the generic manufacturer's damages if an application for a Prohibition Order preventing the generic manufacturer from obtaining a Notice of Compliance is unsuccessful. A manufacturer's trade-spend is applied as against the lost sales of then generic manufacturer in the context of proceedings under the Patented Medicines (Notice of Compliance) Regulations.

rejected evidence put forward by the patentee as failing to show the "trade-spend" was "clearly, directly and verifiably related to the medicine involved"[2].

Second, it is also relevant to address the reason why these proceedings have been in abeyance for so long, as well as the challenges stemming from the lengthy abeyance. At a case conference in September 26, 2011, at a time when there was a different Board Panel, Board Staff spoke in favour of moving forward with the Apotex and Apo-Salvent Matters. No ruling was issued, leaving Board Staff to conclude that the Board Panel preferred to allow the Ratiopharm/Sandoz matters to be decided before considering reactivating these proceedings. Similarly, on December 2, 2015, following the issuance of the *Sandoz/Ratiopharm* ruling, Board Staff wrote to the Board to inquire as to the status of the Apotex and Apo-Salvent matters. In a December 7, 2015 letter in response, the Board informed the parties that both the Apotex and Apo-Salvent matters would be held in abeyance until the expiry of all available appeal routes. The application for leave to appeal the Sandoz/Ratiopharm FCA decision to the Supreme Court of Canada was discontinued on September 8, 2016; the Apotex and Apo-Salvent Matters, however, remained in abeyance.

There are significant evidentiary complications stemming from the length of time that has passed since these proceedings began, and related turnover at Board Staff, and potentially at Apotex. None of the Board Staff legal and regulatory employees who worked on this file are still with the PMPRB, and outside legal counsel did not have carriage of the file when the preparatory work was done. In addition, these proceedings were previously dealt with by a different Panel of the Board having different outside legal counsel. These realities will make it much more difficult, as a practical matter, to further pursue these proceedings.

The above factors have further attenuated the public interest in further pursuing these proceedings. Accordingly, given the factors set out above, Board Staff submits that it would not be in the public interest, and would not be an appropriate use of the Board's time and resources, to further pursue the Apotex and Apo-Salvent Matters.

Yours very truly,

Original signature redacted

David K. Wilson

/mt

cc Katherine Kay & Dan Murdoch, Stikeman Elliot LLP
Isabel Jean Raasch & Livia Aumand, PMPRB

[2] Ratio-Salbutamol Order, May 2011, para 111