

**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 Baxalta Canada Corporation  
(the “Respondent”)**

**REPLY OF BOARD STAFF**

1. The same defined terms indicated in Board Staff’s Notice of Application apply to this Reply.
2. With respect to the allegation at paragraph 2 of Baxalta Canada Corporation’s Response (the “Response”), Board Staff admits that no order was attached to the Notice of Application, and that the reference therein to a draft order was made in error. No such draft order currently exists.
3. Board Staff further admits the following facts:
  - a) that the Director, Regulatory Affairs & Outreach Branch of the Patented Medicine Prices Review Board (“PMPRB”) Staff communicated with Baxalta Canada Corporation (“Baxalta”) on January 12, 2016 with respect to complaints it had received in respect of the price of Oncaspar;
  - b) that the correspondence of January 12, 2006 identified two patents pertaining to Oncaspar, and identified Baxalta as a patentee in respect of those patents under the Act;
  - c) that the correspondence of January 12, 2006 advised Baxalta that it was required to file a Form 1 for Oncaspar and Form 2 information for Oncaspar for all six-month reporting periods from the date of first sale in Canada;
  - d) that the Notice of Application was referred to the Board by the Board Chair on March 1, 2016;

- e) that Baxalta sent Board Staff a very brief email on March 4, 2016, which stated that “The patents referenced in this letter related to ONCASPAR product are no longer active and were not owned by Baxalta at the time of acquisition.”
  - f) that, to date, no information has ever been filed with the PMPRB with respect to Oncaspar; and
  - g) that, prior to January 12, 2016, no steps had been taken to require any party to file information with the PMPRB with respect to Oncaspar.
4. Board Staff denies the remainder of the allegations in the Response.
  5. Board Staff maintains that it has jurisdiction with respect to Oncaspar (pegaspargase). Baxalta is a patentee as contemplated under the Act as it relates to the ‘939 and ‘973 Patents, and these patents pertain to Oncaspar.
  6. Board Staff denies that the Notice of Application was brought for an improper purpose or that it constitutes abuse of process.
  7. Board Staff further denies that there has been any breach of procedural fairness in connection with this proceeding.
  8. Board Staff reserves its right to amend this Reply prior to the Hearing.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 19<sup>th</sup> day of May, 2016.

Original signature redacted

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