

## 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”)

### RESPONSE

of Baxalta Canada Corporation  
(dated April 29, 2016)

#### Overview

1. The Respondent opposes this Application for an order pursuant to section 81 of the *Patent Act* (the “Act”) requiring the Respondent to provide the information referred to in section 80 of the Act and in sections 3 and 4 of the *Patented Medicines Regulations* (the “Regulations”), in respect of the medicine Oncaspar (pegaspargase).
2. The Respondent is unable, at this time, to address any order of the Patented Medicine Prices Review Board (the “Board”) proposed to be given by the Board because, despite language in the Notice of Application to the effect that draft terms were appended to the Notice of Application (i.e., “the terms set out in the Draft Order at Appendix 1”), no such draft terms or draft Order were appended to the Notice of Application. The Respondent reserves its right to supplement and amend this Response upon receipt of an amended Notice of Application with a proposed Order setting out, with particular detail, the distinct terms with which alleged required compliance is being sought.
3. The Respondent asks for an Order dismissing this Application on the grounds that the Board lacks jurisdiction, as the Respondent is not a “patentee,” for the following reasons:
  - (a) the Respondent does not own, is not entitled to the benefit of, and is not entitled to exercise any rights in relation to Canadian Patent No. 2,283,939 (the ‘939 Patent);

- (b) the '939 Patent is and has always been owned and maintained in good standing by Enzon, Inc.;
- (c) the '939 Patent was not transferred by Enzon, Inc. to any Sigma-Tau entity (as further discussed in paragraphs 11 and 13 below) and was not transferred by any Sigma-Tau entity to Baxalta Incorporated (as further discussed in paragraph 11 below);
- (d) the Respondent is not a "patentee" as it does not own, is not entitled to the benefit of, and is not entitled to exercise any rights in relation to Canadian Patent No. 2,589,975 (the '975 Patent);
- (e) the '975 Patent derived from an application that had always been owned and maintained in good standing by Enzon Pharmaceuticals, Inc.;
- (f) the '975 Patent now stands as an issued patent in the name of its owner, Belrose Pharma Inc., by virtue of an assignment of the patent in 2013 from Enzon Pharmaceuticals, Inc. to Belrose Pharma Inc.;
- (g) the '975 Patent lapsed on December 12, 2015;
- (h) the '975 Patent was not transferred by Enzon Pharmaceuticals, Inc. to any Sigma-Tau entity (as further discussed in paragraphs 11 and 13 below) and was not transferred by any Sigma-Tau entity to Baxalta Incorporated (as further discussed in paragraph 11 below); and lapsed on December 12, 2015;
- (i) neither the '939 Patent nor the '975 Patent pertains to the medicine Oncaspar;
- (j) this Notice of Application has been brought for an improper purpose, namely to satisfy the demands of unnamed complainants, and is thus an abuse of process; and
- (k) the Respondent has been denied procedural fairness and transparency.

**Detailed Response to Notice of Application**

4. The Respondent admits the allegations in paragraphs 4, 6, 7, 11, 12, 14 and 15 of the Notice of Application but otherwise denies the remainder of the allegations.
5. With respect to paragraph 1 of the Notice of Application, the Respondent denies that it has failed to provide the Board with required information and specifically denies that it is in breach of the reporting requirements under the Act and the Regulations.
6. With respect to paragraph 2 of the Notice of Application, the Respondent acknowledges the existence of the '939 Patent but denies that it has owned or presently owns the '939 Patent and, in any event, denies that the '939 Patent pertains to the medicine Oncaspar (pegaspargase).
7. With respect to paragraph 3 of the Notice of Application, the Respondent does not own the '939 Patent and does not own or use the technology covered by the '939 Patent, which is neither relevant to nor used in the making of Oncaspar (pegaspargase).
8. With respect to paragraph 5 of the Notice of Application, the Respondent acknowledges the existence of the '975 Patent but denies that it has owned or presently owns the '975 Patent and, in any event, denies that the '975 Patent pertains to the medicine Oncaspar (pegaspargase). The Respondent does not own or use the technology covered by the '975 Patent, which is neither relevant to nor used in the making of Oncaspar (pegaspargase).
9. With respect to paragraph 7 of the Notice of Application, the Respondent acknowledges that CIPO records the names of the owners of the '939 and '975 Patents, but denies that it has any ownership interest in these patents and further denies that it has any ownership interest in or to Enzon Inc. or Belrose Pharma Inc., the named owners of the '939 Patent and '975 Patent, respectively, which are unrelated to the Respondent.
10. With respect to paragraph 8 of the Notice of Application, the Respondent admits that:
  - (a) it is the Canadian representative of Baxalta Incorporated;
  - (b) Baxalta Incorporated is a corporation registered in Delaware in the United States of America;

- (c) Baxalta Incorporated was a planned separation (or “spin-off”), as of July 1, 2015, of the biopharmaceuticals business of Baxter International Inc.;
- (d) in July 2015, Baxalta Incorporated acquired the business relating to the product Oncaspar (pegaspargase) from Sigma-Tau Finanziaria S.p.A., an Italian joint stock corporation, as provided for in a Purchase Agreement dated as of May 11, 2015 (the “Purchase Agreement,” the terms of which are confidential) between Sigma-Tau Finanziaria S.p.A. (“Seller”) and Baxalta UK Investments Ltd., a private company limited by shares incorporated in England and Wales (“Buyer”);
- (e) by virtue of the Purchase Agreement, the Buyer acquired from the Seller:
  - (i) the issued shares of Sigma-Tau Pharma Limited, an English private company limited by shares (“Sigma-Tau Pharma UK”); and
  - (ii) assets required to run the business relating to the product Oncaspar (“Business Assets”).

Sigma-Tau Pharma UK did not own at the time of the acquisition, and the Business Assets do not include, the ‘939 Patent, the ‘975 Patent or any other related application, patent or foreign counterpart.

11. Further, with respect to paragraph 8 of the Notice of Application, the Respondent denies that:

- (a) as of July 2015, the Sigma-Tau Oncaspar “portfolio” included the ‘939 Patent or the ‘975 Patent;
- (b) the Sigma-Tau Oncaspar “portfolio” included the ‘939 Patent or the ‘975 Patent, by virtue of some prior acquisition of the “portfolio” from “Enzon Pharmaceuticals”;
- (c) “Enzon Pharmaceuticals” transferred the ‘939 Patent or ‘975 Patent to any Sigma-Tau entity; and
- (d) the Respondent owns or has, by license, direct or indirect share ownership or otherwise, any right, license or benefit in and to the ‘939 Patent or the ‘975 Patent.

12. Further still, with respect to paragraph 8 of the Notice of Application, the Respondent acknowledges that at some point prior to the Purchase Agreement, there were dealings in the 2009-2010 timeframe between a Sigma-Tau entity and an Enzon entity, but the Respondent denies that, by virtue of those dealings, the '939 Patent or the '975 Patent (or related applications, patents or foreign counterparts) were transferred from any Enzon entity to any Sigma-Tau entity. As stated below, in paragraphs 18 and 25, the '939 Patent continues to be owned by Enzon Inc. and the '975 Patent was transferred in 2013 from Enzon Pharmaceuticals, Inc. to Belrose Pharma Inc.

13. With respect to paragraph 9 of the Notice of Application, the Respondent denies that it is or has been a patentee, owner, licensee or one entitled to the benefit of, or to exercise any rights in respect of, the '939 Patent or the '975 Patent (misidentified in paragraph 9 of the Notice of Application as the '973 Patent).

14. With respect to paragraph 10 of the Notice of Application, the Respondent admits that Oncaspar (pegaspargase) has been made available in Canada under the Special Access Program ("SAP").

15. With respect to paragraph 11 of the Notice of Application, the Respondent acknowledges that pegaspargase is an L-asparaginase enzyme that is isolated from bacteria and then pegylated with a number of polyethylene glycol synthetic polymers. More specifically, pegaspargase is a pegylated version of type II L-asparaginase that is isolated from bacteria and then pegylated with a number of straight-chained polyethylene glycol synthetic polymers. The Respondent denies that pegaspargase is pegylated with branched chain synthetic polymers, a different technology to which the '939 and '975 Patents are directed, the application of which would result in a different medicine. The Respondent denies that the '939 and '975 Patents relate to straight chain synthetic polymer technology or to the medicine Oncaspar (pegaspargase).

16. With respect to paragraph 13 of the Notice of Application, the Respondent denies that the PMPRB has jurisdiction with respect to Baxalta's (misidentified as "Baxlta" in paragraph 16 of the Notice of Application) sales of Oncaspar in Canada.

17. Further, with respect to paragraph 13, of the Notice of Application, the Respondent denies that the Notice of Application identifies “at least one invention pertaining to Oncaspar.” The Respondent relies on the following material facts:

- (a) Enzon Inc. is listed as the owner of the ‘939 Patent, was not transferred in the 2009-2010 timeframe to Sigma-Tau and thus could not have been transferred to Baxalta Incorporated by virtue of the 2015 Purchase Agreement; and
- (b) Belrose Pharma Inc., a party with no connection to the Respondent, is listed as the owner of the ‘975 Patent, having received it from Enzon Pharmaceuticals, Inc. in a 2013 transaction.

18. With respect to paragraph 15 of the Notice of Application, the Respondent admits that it has not filed any information with the PMPRB with respect to Oncaspar but denies that it is obligated to do so.

19. With respect to paragraph 16 of the Notice of Application, the Respondent denies that it has, or has had, any obligation to file any information with the PMPRB with respect to Oncaspar. The Respondent further denies that it is in breach of any reporting requirements of the Act or Regulations.

#### **The ‘939 Patent**

20. The patent application that ultimately issued as the ‘939 Patent was filed by the Applicant, Enzon, Inc., through its agents, Bereskin & Parr. The patent application was prosecuted to issuance by Enzon, Inc., through its agents Bereskin & Parr.

21. No assignment of the patent application, or the ‘939 Patent, has ever been recorded with CIPO. This is because Enzon, Inc. has never actually been assigned the ‘939 Patent.

22. A maintenance fee was paid to CIPO on March 7, 2016, to maintain the ‘939 Patent in good standing by Enzon, Inc., through its agents Bereskin & Parr, neither of which has any connection with the Respondent. The payment was processed through an annuity service known as Computer Packages Inc. of Rockland, Maryland, an agent acting under the instructions of an entity other than the Respondent, which has no connection with this annuity service.

**The '975 Patent**

23. The patent application that ultimately issued as the '975 Patent was filed by the Applicant, Enzon Pharmaceuticals, Inc., through its agents, Bereskin & Parr. The patent application was prosecuted to issuance by Enzon Pharmaceuticals, Inc., through its agents Bereskin & Parr.

24. The '975 Patent issued on December 10, 2013 after the final fee was paid by Enzon Pharmaceuticals, Inc. through its agent, Bereskin & Parr. The change of ownership from Enzon Pharmaceuticals, Inc. to Belrose Pharma Inc. was recorded with CIPO by virtue of an assignment document dated as of April 30, 2013 and filed with CIPO on August 29, 2013 by Bereskin & Parr. The '975 Patent lapsed on December 14, 2015.

**The History leading to this Proceeding**

25. On January 12, 2016, the Director, Regulatory Affairs & Outreach Branch of the PMPRB's Staff ("Director") wrote to the Respondent to advise the Respondent that the PMPRB had received complaints from a cancer agency and hospitals in British Columbia, Saskatchewan and Ontario regarding the price of Oncaspar. However, the Director refrained from providing any particulars as to the timing or nature of the complaints or the identity of the complainants.

26. The Director also advised that the Board Staff conducted a patent search in light of the fact that Baxalta was not reporting information for Oncaspar. However, the Director refrained from providing any particulars as to the nature of the search or the particulars to support the conclusion of the Board Staff that there were "at least" two patents that pertained to Oncaspar.

27. The Director indicated that it was the Board Staff's "understanding" that Baxalta is entitled to the benefit of these two patents "in view" of corporate arrangements involving Baxter, Sigma-Tau Pharmaceuticals and Enzon Pharmaceuticals. However, the Director refrained from providing any particulars as to the "corporate arrangements" that supported the Board Staff's understanding.

28. The Director refrained from providing any analysis supporting the Board Staff's conclusion other than baldly pointing to its 2006 Guidelines:

*In understanding how Board Staff reviews a patent to see whether it pertains to a particular medicine, you may wish to consult the July 2006 issue of the NEWSletter which contains an article entitled, "The Scope of the PMPRB's Jurisdiction: When Does a Patent Pertain to a Medicine?"*

29. The Director took the position that Baxalta is a patentee by virtue of the two patents it referenced, and directed it 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, up to and including the July to December 2015 reporting period.

30. The Respondent investigated the letter from the Director and concluded that the patents referenced in the Board Staff's letter were not owned by Baxalta. This information was communicated to Board Staff on March 4, 2016.

**The Notice of Application was a foregone conclusion**

31. Without waiting for any response from the Respondent, and without any prior notice to the Respondent, the Board Staff submitted the Notice of Application to the Board on March 1, 2016. Upon receiving a response from the Respondent on March 4, 2016, the Board Staff took no steps to:

- (a) amend its Notice of Application or otherwise inform the Board of the Respondent's response that it did not own the '939 Patent or the '979 Patent; or
- (b) investigate the Respondent's response that it did not own the '939 Patent or the '979 Patent.

32. The Board Staff took these steps knowing that if and when a Notice of Hearing would be issued, a public Press Release would soon follow – as happened on March 24, 2016.



**Improper purpose, abuse of process and lack of procedural fairness**

33. The Respondent alleges that this Application has been brought for an improper purpose. In particular, the Respondent alleges that the Application was brought to respond to the unidentified complaints referred to in paragraph 25 above.

34. To the knowledge of the Respondent, at no time has any party ever filed any information with the PMPRB with respect to Oncaspar, and at no time has the Board Staff taken steps to require any party to file information with the PMPRB. Yet, Oncaspar has been made available in Canada:

- (a) according to the Health Canada Notice of Compliance database, pursuant to a Notice of Compliance dated November 19, 1997 (DIN 02236849) to Rhone-Poulenc Rorer Canada Inc.;
- (b) according to the Health Canada Notice of Compliance database, pursuant to a Notice of Compliance dated October 24, 2000 (and under the same DIN 02236849) to Aventis Pharma Inc., which DIN was cancelled on 2004-01-02;
- (c) through the SAP.

The full details, including when and how Oncaspar has been made available in Canada, are not known to the Respondent.

35. The within Notice of Application is an abuse of process, insofar as it was commenced without any consideration of the Respondent's response and without regard to the merits.

36. The Respondent has been denied procedural fairness. In particular:

- (a) Board Staff failed to give the Respondent an opportunity to know or respond to the Board Staff's "understanding", "views", conclusions and application of the Guidelines (as set out in paragraphs 26 to 29 above);
- (b) Board Staff failed to give the Respondent an opportunity to respond fully to its initial letter;
- (c) Board Staff formed its understanding, views, recommendations and conclusions without input from the Respondent;

- (d) without advising the Respondent of its intentions, Board Staff have driven the process to a predetermined conclusion as demonstrated by:
  - (i) the lack of consideration by the Board Staff of the Respondent's response that it does not own the patents in question;
  - (ii) the fact that a Notice of Application had been drafted prior to receiving a response from the Respondent;
  - (iii) the fact that a Notice of Application had been referred to the Board on March 1, 2016, without notice to the Respondent;
- (e) The Respondent has been denied the right to be heard and respond to not only the substantive issue but also to the complaints referred to above in paragraph 26.

**Guidelines Cannot be Construed or Applied in a Manner Inconsistent with the Act**

37. The determination of whether prescribed information has to be filed with the Board must be made in accordance with sections 79, 80 and 81 of the Act. The Board cannot fetter its discretion by relying solely on an interpretation of non-binding Guidelines. Rather, it is the Guidelines and their application that must be consistent with the Act.

**Procedural Relief**

38. The Respondent will seek disclosure, by motion if necessary, of the Board Staff's investigative file so as to better understand the position of the Board Staff that ought to have been transmitted to the Respondent, and challenge the "understanding", "views" and conclusions of the Board Staff as set out in paragraphs 26 to 29 above and the Board Staff's application of the Guidelines.

39. The Respondent reserves the right to file documents with the Board marked "CONFIDENTIAL/CONFIDENTIEL" in accordance with Rule 14(6).

**Relief Requested**

40. The Respondent requests that this application be dismissed.

April 29, 2016

Original signature redacted

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