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 the medicine
ONCASPAR (pegaspargase)
sold in Canada by Baxalta Canada Corporation**

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NOTICE OF APPLICATION – Failure to File

TAKE NOTICE THAT Board Staff will bring an application before the Patented Medicine Prices Review Board (the "Board") for hearing on a date to be determined by the Board.

THE APPLICATION IS FOR an Order pursuant to section 81 of the *Patent Act* (the "Act") requiring the Respondent, Baxalta Canada Corporation ("Baxalta") 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) on the terms set out in the Draft Order at Appendix I.

THE GROUNDS FOR THE APPLICATION ARE:

1. Baxalta has failed to provide the Board with certain prescribed information regarding the medicine Oncaspar (pegaspargase) as the patentee of at least Canadian Patent Nos. 2,283,939 ("the '939 Patent") and 2,589,975 ("the '975 Patent") which pertain to Oncaspar. Baxalta ought to have filed certain information upon issuance of the patents for all sales made after the patents were laid open for public inspection. As such, Baxalta is in breach of the reporting requirements under the Act and Regulations, and the Board ought to make an order compelling Baxalta to comply with those requirements.

The Patents and the Patentee

2. The '939 Patent is entitled "Non-Antigenic Branched Polymer Conjugates." The '939 Patent has 40 claims. Claims 1-14 and 24-32 relate to branched non-antigenic polymer compositions. Claims 33-40 relate to methods of preparing branched non-antigenic polymers. Claims 15 and 33 relate to methods of forming biologically active conjugates which comprise branched non-antigenic polymers and biologically active nucleophiles. Claims 16-22 relate to polymer conjugates prepared by reacting branched non-antigenic polymers with

nucleophiles. Claim 23 relates to a method of treatment using the branched polymer conjugate of claim 16. Various claims identify the "non-antigenic polymer" as containing "poly(ethylene glycol) homopolymers". Various claims identify the "nucleophiles" they cover to include, among other things, "antineoplastics", "proteins, peptide and polypeptides", "enzymes" and "chemotherapeutic molecules".

3. The description of the '939 Patent discloses, among other things, that polypeptides that include attached polymers "exhibit reduced immunogenicity/antigenicity and circulate in the bloodstream longer" than the polypeptides that do not. The description further discloses that each attached polymer can be PEG and that the biologically active materials suitable for conjugation include enzymes including asparaginase.

4. The '939 Patent has a PCT publication date of September 24, 1998 and issued on October 28, 2003.

5. Canadian Patent No 2,589,975 is entitled "Releasable Polymeric Conjugates Based on Aliphatic Biodegradable Linkers." The '975 Patent has 27 claims. Claims 1-22 and 24-26 relate to polymer conjugate compounds which comprise polymers that are linked to biologically active agents. Claim 22 also relates to a method of preparing polymer conjugate products. Claim 23 relates to a method of preparing a polymer transport system. Claim 27 relates to the use of a compound of claim 1 for the treatment of a medical condition. According to the claims, the claimed compounds can include polyethylene glycol (PEG). According to the claims, the claim compounds can include biologically active agents.

6. The '975 Patent has a PCT publication date December 13, 2005, issued on December 10, 2013 and lapsed on December 14, 2015.

7. The Canadian Intellectual Property Office lists "Enzon Inc." as the Applicant for both the '939 and '975 Patents and lists "Enzon Inc." as the owner of the '939 Patent and "Belrose Pharma Inc." as the owner of the '975 Patent.

8. Baxalta Canada Corporation is the Canadian representative of Baxalta Incorporated. Baxalta Incorporated is a corporation registered in Delaware in the United States of America. Baxalta Incorporated separated from Baxter International on July 1, 2015. In July 2015, the company acquired the Oncaspar (pegaspargase) product portfolio from Sigma-Tau Finanziaria S.p.A. (Sigma-Tau)

through the acquisition of 100% of the shares of a subsidiary of Sigma-Tau. As of July 2015, the Sigma Tau Oncaspar portfolio included the portfolio of Enzon Pharmaceuticals Inc. for Oncaspar which was acquired by Sigma Tau from Enzon Pharmaceuticals in January of 2010.

9. Baxalta Canada Corporation as such falls within the definition of "patentee" in respect of the '939 and '973 Patents pursuant to subsection 79(1) of the Act.

Oncaspar

10. Baxalta sells Oncaspar (pegaspargase) in Canada under Health Canada's Special Access Programme.

11. Pegaspargase is L-asparaginase (an enzyme) that is isolated from bacteria and is then "PEGylated" – i.e. attached to polyethylene glycol (PEG) (a synthetic chemical polymer like plastic). L-asparaginase that is not attached to PEG is a known antineoplastic (anti-cancer) chemotherapy drug.

12. As per the US Prescribing Information attached herein, Oncaspar (pegaspargase or PEGylated L-asparaginase) is indicated as a component of a multi-agent chemotherapeutic agent for the first line treatment of patients with Acute Lymphoblastic Leukemia (ALL) and ALL and hypersensitivity to asparaginase.

PMPRB Jurisdiction

13. The basis for the PMPRB's jurisdiction with respect to Baxlta's sales of the Oncaspar in Canada, is as follows:

    a. Baxalta is a patentee pursuant to subsection 79(1) of the Act,

    b. in respect of at least one invention pertaining to Oncaspar (pegaspargase), and

    c. Baxalta has sold that medicine in a market in Canada.

Applicable Regulations

14. The Act and the Regulations impose, *inter alia*, the following reporting requirements on patentees of inventions pertaining to a medicine:

    a. Paragraph 80(1)(a) of the Act and subsection 3(1) of the Regulations require the patentee to provide to the PMPRB prescribed information identifying the medicine. Pursuant to subsection 3(2) of the Regulations, the

prescribed information shall be provided if a NOC has been issued with respect to the medicine, or if the medicine is being offered for sale in Canada. Pursuant to subsection 3(3) of the Regulations, the prescribed information shall be provided within the earlier of 30 days after the first NOC is issued, or 30 days after the date on which the medicine is first offered for sale in Canada.

b. Paragraph 80(1)(b) of the Act and subsection 4(1) of the Regulations require the patentee to provide to the PMPRB prescribed information identifying the medicine and concerning the price of the medicine. Pursuant to subsections 4(2) and 4(3), this information shall be provided within 30 days following the date of the first sale in Canada of the medicine, and within 30 days after each six month period commencing on January and July 1of each year.

Failure to Report

15. To date, Baxalta has not filed any information with the PMPRB with respect to Oncaspar.

16. Baxalta has therefore not complied with its obligations and as such, Baxalta is in breach of the reporting requirements under the Act and Regulations.

THE FOLLOWING DOCUMENTARY EVIDENCE will be used at the hearing of the application:

1. One or more affidavits to be sworn;

2. The pleadings and proceedings herein; and

3. Such further and other documentary evidence as counsel may advise and the Board may permit.