

Paper No. ____

Date Filed: Jan. 31, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED and
ARGENTUM PHARMACEUTICALS LLC

Petitioners

v.

JANSSEN ONCOLOGY, INC.
Patent Owner

Case IPR2016-00286¹
Patent No. 8,822,438 B2

**PATENT OWNER'S IDENTIFICATION OF NEW ARGUMENTS AND
EVIDENCE IN PETITIONERS' REPLY**

¹ Case IPR2016-01317 has been joined with this proceeding.

Pursuant to the Board's January 26, 2017 Order (Paper 68), Patent Owner Janssen Oncology, Inc. hereby submits an itemized list of what Patent Owner considers to be *new* arguments and evidence raised in Petitioners' Reply, including paragraphs of the declarations of Drs. Ratain (Ex. 1091) and Dorin (Ex. 1093), as specifically identified below.

1. New Argument and Evidence Regarding Motivation to Combine based on "Combined Congenital CYP 17 Deficiency"

- a. Pet. Reply, p. 4, l. 13 - p. 5, l. 3
- b. Pet. Reply, p. 10, l. 20 - p. 11, l. 5
- c. Ex. 1093 ¶¶ 15-19, 34-35, 61, 66

2. New Arguments and Evidence Regarding Motivation to Combine Based on Adrenal Insufficiency, Concurrent Stress, or Adrenal Crisis

- a. Pet. Reply, p. 3, l. 20 - p. 4, l. 3
- b. Pet. Reply, p. 7, ll. 12-16
- c. Pet. Reply, p. 8, l. 7 - p. 9, l. 9
- d. Pet. Reply, p. 12, ll. 4-8
- e. Ex. 1091 ¶¶ 30, 35, 39; Ex. 1093 ¶¶ 20-24, 31-32, 36, 47-49, 53-54, 56, 59-60, 62, 69

3. New Argument Regarding Prednisone's Safety Profile

- a. Pet. Reply, p. 10, ll. 5-13
- b. Ex. 1093 ¶ 30

4. New Argument Regarding Glucocorticoids as Effective Anti-Cancer Agents

- a. Pet. Reply, p. 12, ll. 15-17
- b. Pet. Reply, p. 14, FN4
- c. Pet. Reply, p. 15, ll. 1-10
- d. Pet. Reply, p. 16, ll. 1-8
- e. Pet. Reply, p. 17, l. 5 - p. 18, l. 17
- f. Ex. 1091 ¶¶ 42-47, 54, 59-61, 63

Dated: January 31, 2017

Respectfully submitted,

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IPR2016-00286
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Patent Owner's Identification of New Arguments and Evidence in Petitioner's Reply was served on counsel of record on January 31, 2017 by filing this document through the End-to-End System, as well as delivering a copy via electronic mail to counsel of record for the Petitioner and Patent Co-Owner at the following addresses:

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