

IN THE 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 8,822,438 B2

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

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

In response to Patent Owner's identification of allegedly new arguments and evidence in Petitioners' Reply, Petitioners submit the following reply.

As an initial matter, Petitioner objects to the Patent Owner's end run around the Rules as well as the Board's Scheduling Order. The relief being requested by the Patent Owner, and the basis therefor, are obviously no more than a second Motion to Exclude.

The Patent Owner is attempting to expand the limits of a permitted Motion to Exclude in terms of length and timing. Further, the Patent Owner ignored the Board's Order and provided argument via the incorporation of substantive headings. Petitioners objects to these headings as mischaracterizing the content of the cited passages. Patent Owner's "Request" should be denied on these bases alone. Nonetheless, Petitioners respond that each of the arguments and evidence identified by Patent Owner are proper and respond substantively to Patent Owner's Response and expert declarations, as follows.

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

- a. JSN 2040, ¶¶ 49, 51-58; AMG 1026; AMG 1027; AMG 1025
- b. P.O. Response p. 29, l. 15 - p. 32, l. 4; JSN 2038, ¶¶ 151, 153

- c. P.O. Response p. 20, l. 4-16; JSN 2040, ¶¶28, 52, 58

2. New Arguments and Evidence Regarding Motivation to Combine

Based on Adrenal Insufficiency, Concurrent Stress, or Adrenal Crisis

- a. JSN 2040, ¶¶ 29, 33, 34, 54
- b. P.O. Response p. 18, l. 3 – p. 19, l. 7; JSN 2040, ¶¶ 31, 33, 107-111
- c. P.O. Response p. 43, l. 11- p. 44, l. 12; JSN 2038, ¶¶ 49-50, 154; JSN 2040, ¶¶ 31-35, 59-62
- d. P.O. Response p. 43, l. 11 - p. 44, l. 12; JSN 2040, ¶¶ 31-34; JSN 2038 ¶¶ 105, 107, 111-112
- e. P.O. Response p. 43, l. 11 - p. 44, l. 12; JSN 2040, ¶¶ 31-33

3. New Argument Regarding Prednisone's Safety Profile

- a. P.O. Response p. 30, l. 3 - p. 32, l. 4; JSN 2038 ¶¶ 49-50, 114-115, 124-135, 155-156; JSN 2040 ¶¶ 13-15, 32-33, 43-45, 59-62
- b. JSN 2040 ¶¶ 59-62

4. New Argument Regarding Glucocorticoids as Effective Anti-Cancer

Agents

- a. P.O. Response, p. 55, l. 13 - p. 56, l. 15

- b. Petition, p. 21, l. 10 – p. 22, l. 8
- c. P.O. Response, p. 55, l. 13 - p. 56, l. 15
- d. P.O. Response, p. 55, l. 13 - p. 56, l. 15
- e. P.O. Response, p. 59, ll. 1-6; JSN 2038 ¶188
- f. P.O. Response, p. 48, l. 1 – p. 49, l. 8; p. 55, l. 13 - p. 56, l. 15

Dated: February 3, 2017

Respectfully Submitted,

/William D. Hare/

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the Petitioners' Reply To Patent Owner's Identification of Patent Owner's Identification of New Arguments and Evidence in Petitioners' Reply was served on February 3, 2017 by delivering copies via electronic mail on the following attorneys of record for the Patent Owner:

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