

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., ACTAVIS LABORATORIES FL, INC.,
AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF
NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S
LABORATORIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, LTD.,
SUN PHARMACEUTICALS INDUSTRIES, INC., TEVA
PHARMACEUTICALS USA, INC., WEST-WARD PHARMACEUTICAL
CORP., and HIKMA PHARMACEUTICALS, LLC,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-01332¹
Patent 8,822,438 B2

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

¹ Case IPR2017-00853 has been joined with this proceeding.

Pursuant to the Board's April 28, 2017 Order (Paper 64), 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 (Paper 55), including paragraphs of the declarations of Drs. Garnick (Ex. 1104) and Bantle (Ex. 1097), as specifically identified below.

1. New Arguments and Evidence Regarding Aminoglutethimide

- a. Pet. Reply, p. 2, ll. 3-6, 7-10, 12-15
- b. Pet. Reply, p. 4, l. 20 – p. 5, l. 4
- c. Pet. Reply, p. 6, ll. 5-9
- d. Pet. Reply, p. 10, l. 8 – p. 11, l. 5
- e. Ex. 1104, ¶¶ 5, 16-17, 22-23, 26-27, 48, 52, 68
- f. Ex. 1097, ¶¶ 46, 49, 50, 67, 94

2. New Arguments and Evidence Regarding Motivation to Combine Based on Adrenal Insufficiency and/or Low Adrenal Reserve

- a. Pet. Reply, p. 1, ll. 5-6
- b. Pet. Reply, p. 3, ll. 2-4
- c. Pet. Reply, p. 5, ll. 5-9
- d. Pet. Reply, p. 10, l. 6 – p. 11, l. 5
- e. Pet. Reply, p. 11, l. 9 - p. 12, l. 2
- f. Pet. Reply, p. 13, ll. 4-11
- g. Pet. Reply, footnote 7, ll. 3-6
- h. Ex. 1097, ¶¶ 12-13, 15, 32-40, 43-44, 48-54, 58-60, 63-67, 69-82, 84, 88, 93, 99

i. Ex. 1104, ¶¶ 18, 33, 42-48, 51, 68

3. New Arguments and Evidence Regarding COU-AA-BE Study

a. Pet. Reply, p. 14, ll. 5-9

b. Ex. 1104, ¶¶ 56-58

4. New Arguments and Evidence Regarding Purported Palliative Effects of Prednisone

a. Pet. Reply, p. 1, ll. 8-9, 14-16

b. Pet. Reply, p. 3, ll. 7-9

c. Pet. Reply, p. 8, ll. 7-9

d. Pet. Reply, p. 18, ll. 16-19

e. Pet. Reply, p. 20, ll. 7-8

f. Ex. 1104, ¶¶ 24, 60, 70, 80-87

g. Ex. 1097, ¶ 96

5. New Arguments and Evidence Regarding Selection of Prednisone from Among Glucocorticoids

a. Pet. Reply, p. 8, ll. 3-13

b. Ex. 1104, ¶¶ 5, 24

Respectfully submitted,

Dated: May 3, 2017

/Dianne B. Elderkin/

Dianne B. Elderkin (Reg. No. 28,598)

delderkin@akingump.com

Barbara L. Mullin (Reg. No. 38,250)

bmullin@akingump.com

IPR2016-01332
U.S. Patent 8,822,438

Ruben H. Munoz (Reg. No. 66,998)
rmunoz@akingump.com
AKIN GUMP STRAUSS HAUER &
FELD LLP
Two Commerce Square
2001 Market Street, Suite 4100
Philadelphia, PA 19103
Tel: (215) 965-1200
Fax: (215) 965-1210

David T. Pritikin (*pro hac vice*)
Bindu Donovan (*pro hac vice*)
Paul J. Zegger (Reg. No. 33,821)
Todd L. Krause (Reg. No. 48,860)
Alyssa B. Monsen (*pro hac vice*)
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
Tel.: (212) 839-5300
Fax: (212) 839-5599
ZytigaIPRTeam@sidley.com

Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Patent Owner's Identification of New Arguments and Evidence in Petitioners' Reply was served on counsel of record on May 3, 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 Petitioners at the following addresses:

Brandon M. White – bmwhite@perkinscoie.com
Crystal R. Canterbury – ccanterbury@perkinscoie.com
Bryan D. Beel – bbeel@perkinscoie.com
Shannon Bloodworth – sbloodworth@perkinscoie.com
Emily J. Greb – egreb@perkinscoie.com
Robert D. Swanson – rswanson@perkinscoie.com

Samuel S. Park – spark@winston.com
Ryan B. Hauer – rhauer@winston.com
Jovial Wong – jwong@winston.com

Respectfully submitted,

Date: May 3, 2017

/Dianne B. Elderkin/
Dianne B. Elderkin
Registration No. 28,598
Counsel for Patent Owner