

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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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

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Case IPR2016-01332<sup>1</sup>  
Patent 8,822,438 B2

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

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<sup>1</sup> Case IPR2017-00853 has been joined with this proceeding.

Petitioners respond to Paper 65 pursuant to Paper 64. For each category, Petitioners' citations apply to all items listed by Patent Owner within that category.

## **1. Arguments and Evidence Regarding Aminoglutethimide**

### **a. Prior Disclosure in the Petition**

- i. Petition, p. 25:11-19
- ii. Ex. 1002 (Garnick Declaration) ¶ 32
- iii. Ex. 1003, pp. 2, 7-8, and Ex. 1021, abstract, p. 4

### **b. Material in PO's Response to Which These Arguments Reply**

- i. Response: p. 22:2-21; p. 23:8-15; *see also* p. 15:8-15; p. 17:11-18
- ii. Ex. 2038 (Rettig Decl.) ¶¶ 61, 97-99, 106-109, 121-123, 130
- iii. Ex. 2040 (Auchus Decl.) ¶¶ 30, 36-38

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

### **a. Prior Disclosure in the Petition**

- i. Petition: p. 28:9-19; p. 32:4-18; *see also* p. 5:1-10; pp. 26:11-27:1; pp. 29:21-30:2; p. 40:2-7; pp. 40:20-41:15; p. 45:10-13
- ii. Ex. 1002 ¶¶ 38-40, 58-59, 66-69, 78-80; *see also* ¶¶ 38-40

### **b. Material in PO's Response to Which These Arguments Reply**

- i. Response: pp. 13:18-26:20; *see also* p. 3:4-20; pp. 7:19-8:8; pp. 8:15-9:7; pp. 10:8-12:2; pp. 44:12-47:7
- ii. Ex. 2040 (Auchus Decl.) ¶¶ 11-48

iii. Ex. 2038 (Rettig Decl.) ¶¶ 97-128, 143-53

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

**a. Material in PO's Response to Which These Arguments Reply**

- i. Response: p. 26:5-13
- ii. Ex. 2038 (Rettig Decl.) ¶ 128

**4. Arguments and Evidence Regarding Palliative Effects of Prednisone**

**a. Prior Disclosure in the Petition**

- i. Petition: pp. 13:19-14:6; pp. 58:15-59:2
- ii. Ex. 1002 (Garnick Decl.) ¶¶ 33, 89

**b. Material in PO's Response to Which These Arguments Reply**

- i. Response: pp. 30:7-34:7; p. 47:8-17; *see also* p. 4:1-12; pp. 6:13-7:1; pp. 12:11-13:5; p. 37:19-39:8
- ii. Ex. 2038 (Rettig Decl.) ¶¶ 131-42; *see also* ¶¶ 189-93

**5. Arguments and Evidence Regarding Selection of Prednisone**

**a. Prior Disclosure in the Petition**

- i. Petition: p. 33:15-17; p. 34:4-6, 12-15; pp. 39:15-40:13; pp. 40:20-41:18
- ii. Ex. 1002 (Garnick Decl.) ¶¶ 33, 58-59, 89-90

**b. Material in PO's Response to Which These Arguments Reply**

- i. Response: pp. 41:14-43:16; pp. 44:12-45:11; pp. 45:18-46:4
- ii. Ex. 2038 (Rettig Decl.) ¶¶ 189-193

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that the foregoing Response to Patent Owner's Identification of New Arguments and Evidence in Petitioners' Reply was served electronically via email as follows:

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