

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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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,

Petitioners

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

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Case IPR2017-00853  
Patent 8,822,438

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**JANSSEN ONCOLOGY, INC.'S MANDATORY NOTICES**

Janssen Oncology, Inc. submits the following mandatory notices pursuant to 37 C.F.R. §42.8.

### **REAL PARTY-IN-INTEREST**

Janssen Oncology, Inc., a wholly-owned subsidiary of Johnson & Johnson (“J&J”), is a real party-in-interest. J&J, a publicly held company, is also a real party-in-interest. In addition, BTG International Limited, a subsidiary of BTG plc, is a real party-in-interest.

### **RELATED MATTERS**

U.S. Patent 8,822,438 (the “’438 Patent”) issued from U.S. Application No. 13/034,340 (the “’340 Application”). U.S. Patent Application No. 15/019,353, which is now abandoned, claims the benefit of the ’340 Application. U.S. Patent Application No. 15/419,148 filed on January 30, 2017, which is pending, claims the benefit of the ’340 Application.

The ’438 Patent was the subject of *ex parte* reexamination request No. 90/020,096 (the “’096 reexamination”). On June 14, 2016, the Office issued a Notice of Termination of Preprocessing of the ’096 reexamination. As a result, the ’096 reexamination will not be granted a filing date for failure to comply with the requirements of 37 C.F.R. § 1.501(a). *See* Ex. 2001.

The ’438 Patent is the subject of the following *inter partes* reviews:

- IPR2016-00286, which was instituted on May 31, 2016 and was filed by Amerigen Pharmaceuticals Limited;
- IPR2016-01317, which was filed by Argentum Pharmaceuticals LLC on June 29, 2016 (now joined with IPR2016-00286);
- IPR2016-01332, which was filed by Mylan Pharmaceuticals Inc., on June 30, 2016 and instituted on January 10, 2017; and
- IPR2016-01582, which was filed by Wockhardt BIO AG on August 10, 2016 and instituted on January 19, 2017.

The '438 Patent is being asserted in the following patent infringement lawsuits:

- *BTG International Limited, et al. v. Actavis Laboratories FL, Inc., et al.*, C.A. No. 2:15-cv-05909-KM-JBC (D.N.J.) (the “District of New Jersey Action”);
- *Janssen Biotech, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, C.A. No. 1:15-cv-00130-IMK (N.D. W. Va.) (stayed; conditional trial date set for February 2018);
- *BTG International Limited, et al. v. Amerigen Pharmaceuticals, Inc., et al.*, C.A. No. 2:16-cv-02449-KM-JBC (D.N.J.); and
- *BTG International Limited, et al. v. Glenmark Pharmaceuticals Inc., USA et al.*, C.A. No. 2:16-cv-05909 (D.N.J.).

The '438 Patent was asserted in the following patent infringement lawsuits that have now been terminated:

- *Janssen Biotech, Inc., et al. v. Par Pharmaceutical, Inc., et al.*, C.A. No. 1:15-cv-00679-SLR (D. Del.); and
- *BTG International Limited, et al. v. Actavis Laboratories FL, Inc., et al.*, C.A. No. 9:15-cv-81076-DMM (S.D. Fla.).

### **LEAD AND BACKUP COUNSEL**

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Respectfully submitted,

Date: Feb. 21, 2017

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