Paper No. ____ Date Filed: June 28, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED, Petitioner

v.

JANSSEN ONCOLOGY, INC., Patent Owner

> Case IPR2016-00286 Patent 8,822,438 B2

JANSSEN ONCOLOGY, INC.'S UPDATED MANDATORY NOTICES

Janssen Oncology, Inc. submits the following updated mandatory notices pursuant to 37 C.F.R. §42.8 to apprise the Board of the status of related proceedings and litigations involving U.S. Patent 8,822,438 (the "'438 Patent"). Specifically, the Office has issued a Notice of Termination of Preprocessing of *ex parte* reexamination request No. 90/020,096 (the "'096 reexamination") and the '438 Patent is at issue in two additional district court litigations.

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

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 currently pending before the Office, claims the benefit of the '340 Application.

The '438 Patent was the subject of 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. 2026.

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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SERVICE INFORMATION

Janssen consents to electronic service at the following email address:

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Janssen may be served courtesy copies by postal mailing or hand-delivery as

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Respectfully submitted,

Date: June 28, 2016

<u>/Dianne B. Elderkin/</u>

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