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

REPLY DECLARATION OF JOHN BANTLE, M.D. IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,822,438



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

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I. Qualifications and Background

1. My name is John Bantle, M.D. I have been retained by Petitioner in the matter of the *Inter Partes* Review (IPR) of U.S. Patent No. 8,822,438 (the "'438 Patent"), as set forth in the above caption.

A. Education and Experience

- 2. I am a medical endocrinologist and Professor Emeritus of Medicine in the Division of Diabetes, Endocrinology, and Metabolism, Department of Medicine, at the University of Minnesota. I have substantial experience in clinical research, treatment of patients, and academic publication in the field of endocrinology.
- 3. I received a Bachelor of Science degree in 1970 from the University of Minnesota and a Doctor of Medicine degree in 1972 from the University of Minnesota Medical School. I completed an internship at Cleveland Metropolitan General Hospital in 1973; residencies in internal medicine at the Mayo Clinic in Minnesota and Dunedin Public Hospital in Dunedin, New Zealand in 1975 and 1976, respectively; and a fellowship in endocrinology and metabolism at the University of Minnesota in 1978.
- 4. In addition to my teaching positions, I have held multiple clinical research positions throughout my career. I was the Associate Director of the General Clinical Research Center at the University of Minnesota Medical School from 1983–2009, the Medical Staff Clinical Service Chief for Internal Medicine at



Fairview-University Medical Center from 2001–2007, and the Clinical Research Implementation Services Leader of the Clinical and Translational Science Institute at the University of Minnesota from 2011–2013. In addition, I have participated in numerous clinical trials, both as principal investigator and co-investigator. I have authored approximately 150 publications, book chapters, and presentations on the topics of endocrinology and metabolism.

- 5. I have received numerous honors and awards for teaching, clinical excellence, and treatment of patients. For example, I was named by the Best Doctors Organization as one of the Best Doctors in America for twenty consecutive years from 1996–2015; I was named a Top Doctor by Minneapolis/St. Paul Magazine in 1992, 1994, 1996, 1999–2002, 2004, and 2006–2017; and I received the University of Minnesota Department of Medicine Clinical Excellence Award in 2002, 2004, and 2011.
 - 6. My *curriculum vitae* is attached as Exhibit A to this declaration.
- 7. Based upon my education, training and experience, as summarized above, I believe I am qualified to provide opinion testimony as an expert in endocrinology.

B. Bases for Opinions

8. The opinions to which I testify are based on the education, experience, training and skill that I have accumulated in the course of my career as a practicing



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