

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 IAN MCKEAGUE, Ph.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, Ian McKeague, Ph.D., do hereby declare:

I. INTRODUCTION

1. I am making this declaration at the request of Petitioners, 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.

II. EDUCATION AND PROFESSIONAL BACKGROUND

2. I received a B.A./M.A. and M.Math in Mathematics from the University of Cambridge in 1975 and 1976, respectively. I received a Ph.D. from the University of North Carolina at Chapel Hill in 1980, authoring a Ph.D. thesis titled *Covariance Operators and Their Applications in Probability and Information Theory*. My *curriculum vitae* is attached as Exhibit A.

3. After completing my Ph.D., I took a position as an Assistant Professor in the Department of Statistics at Florida State University. I held that position from 1980 to 1986, when I was promoted to Associate Professor, a title I held until 1991, when I was promoted to Professor. In 1996, I was promoted to Chairman of the Department of Statistics and I held that position until 1999. From 2000 to 2004, I was the Ralph A. Bradley Professor of Statistics at Florida State University. In 2004, I left that university and took a position as Professor of Biostatistics at Columbia University, a position I hold to this day. In addition, I have been a visiting professor at University of Padua, Italy (1985), University

Joseph Fourier, Grenoble, France (1992, 2001), and the University of California, Berkeley (1991).

4. I have received numerous professional honors, served as an editor on various journals, and have served on a number of professional committees. For example, I am a Fellow of the Institute of Mathematical Studies and a Fellow of the American Statistical Association. I am also an Associate Editor of the Journal of the American Statistical Association (1993–96, 2011–present), the International Journal of Biostatistics (2005–present), and Statistical Inference for Stochastic Processes (1998–present), and a former Associate Editor of the Annals of Statistics (1989–1995) and ESAIM: Probability and Statistics (2000–2005). At Florida State University, I received the Named Professorship Award (2000), the Graduate Teaching Award (1998), and the Professorial Excellence Program Award (1999). I have served on the Institute of Mathematical Statistics Fellows Committee (2008–2010); the ASA Section on Nonparametric Statistics Awards Committee (2010–2011); the NSF Statistics and Probability Program Panel (1997, 1999, 2000, 2002, 2003, 2007, 2009, 2010, 2016), Special Meetings Panel (2005), Biocomplexity in the Environment Panel (2004), and Knowledge and Distributed Intelligence Program Panel (1998).

5. As a biostatistician, I have more than twenty years of experience in clinical trial design and statistical analysis. I have consulted for a variety of

entities regarding clinical trial design and analysis, including biopharmaceutical companies and nonprofit research centers. In particular, I have been involved in the design and analysis of numerous clinical trials, with special expertise in designing cohort studies. I have published dozens of papers analyzing clinical trial data, often including analysis regarding study methodology. I have also spoken widely at conferences, symposia, and seminars on clinical trials. For example, I was the Keynote Speaker at the Fourth Annual International Symposium on the Evaluation of Clinical Trial Methodologies and Applications in Beijing, China in 2011, and I also was an invited speaker on clinical trials at the ICSA Applied Statistics Symposium in 2011.

6. My research interests include functional data analysis, empirical likelihood, and non-standard asymptotics, to name a few. I am a named author on 111 peer-reviewed articles, I have supervised eighteen doctoral students, and I have received grants from a number of organizations including the NIH and the NSF.

7. In the past four years, I have testified in the following cases:

- *Casas v. Consolidated Edison Co. of New York, Inc.*, Index No. 115106/04 (N.Y. Sup. Ct.);
- *In re Copaxone 40 mg Consolidated Cases*, No. 1:14-cv-01171-GMS (consolidated) (D. Del.);

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