UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and MYLAN LABORATORIES LIMITED, Petitioner,

v.

UCB PHARMA GMBH, Patent Owner.

Case No. IPR2016-00510 Patent No. 6,858,650 B1

DECLARATION OF WILLIAM R. ROUSH, PH.D.



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I. INTRODUCTION

- 1. I, William R. Roush, Ph.D., have been retained by White & Case LLP, counsel for Patent Owner UCB Pharma GmbH ("UCB"), as an expert witness in the above-captioned *inter partes* review of United States Patent No. 6,858,650 (the "650 patent"). I understand that Mylan Pharmaceuticals Inc. and Mylan Laboratories Limited (collectively with Mylan Pharmaceuticals Inc., "Petitioner") have petitioned for *inter partes* review of the '650 patent, and request that the United States Patent and Trademark Office ("PTO") cancel as unpatentable certain claims of the '650 patent.
- 2. This declaration sets forth my analyses and opinions based on the materials I have considered thus far, as well as the bases for my opinions.

A. Background and Qualifications

3. I am a chemist with more than 35 years of professional experience in organic chemistry and medicinal chemistry. I am Professor of Chemistry and Executive Director of Medicinal Chemistry of the Scripps Research Institute in Jupiter, Florida ("Scripps Florida"). I am also the Associate Dean of the Graduate Program at Scripps Florida. A copy of my curriculum vitae is attached as Exhibit 2003. My educational background and my professional experience are summarized below.



- 4. I obtained a Bachelor of Science degree in Chemistry from the University of California, Los Angeles in 1974, graduating summa cum laude. I obtained my Ph.D. in Chemistry from Harvard University in 1977.
- 5. After a year of post-doctoral work at Harvard (1977-78), I joined the faculty at the Massachusetts Institute of Technology (MIT) as an Assistant Professor of Chemistry. I taught chemistry courses and performed research at MIT from 1978 to 1987. My research interests included the total synthesis of natural products and the development of new synthetic methods.
- 6. In 1987, I moved to Indiana University, where I ultimately became Distinguished Professor of Chemistry. At Indiana University, I initiated a research program on the design and synthesis of inhibitors of cysteine proteases. These inhibitors, designed to combat certain tropical parasitic diseases, are chemical compounds which prevent (i.e., inhibit) an enzyme, specifically a cysteine protease, from performing an essential chemical reaction in the parasite, resulting in the death of the microorganism.
- 7. In 1997, I was appointed the Warner-Lambert/Parke-Davis Professor of Chemistry at the University of Michigan. This is an endowed chair established by a gift from Parke-Davis to the University of Michigan. I subsequently served as the Chairman of the Department of Chemistry at the University of Michigan from 2002-2004. While at the University of Michigan, I served as Co-Director of the



Life Sciences Initiative Commission, which conceived the Life Sciences Institute (LSI), and laid out the blueprint for its creation and development to stimulate interdisciplinary research in the biomedical sciences. I also continued to develop my research program focusing on the synthesis of biologically active natural products, the development of new synthetic methodology, and the design and development of inhibitors of cysteine proteases.

- 8. In 2004, I was recruited to join the Scripps Research Institute at its new campus in Florida. I assumed my current positions Executive Director of Medicinal Chemistry, Professor of Chemistry, and Associate Dean of the Graduate Program in 2005. Scripps Florida is an expansion of the well-known Scripps Research Institute, which is headquartered in La Jolla, California. The Scripps Research Institute is one of the leading biomedical research institutes in the world and is internationally recognized for its commitment to, and its basic research in, the fields of immunology, biology, chemistry, neurosciences, virology, autoimmune and cardiovascular diseases, and synthetic vaccine development. Particularly significant is the Scripps Research Institute's study of the basic structure and design of biological molecules.
- 9. As Associate Dean of the Graduate Program at Scripps Florida, I am developing and leading the graduate program on the Jupiter campus.



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