

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BAYER INTELLECTUAL PROPERTY GMBH,
Patent Owner.

Patent No. 9,539,218

DECLARATION OF LESLIE Z. BENET, PH.D.

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I, Leslie Z. Benet, declare as follows:

I. QUALIFICATIONS

1. I am currently a Professor of Bioengineering and Therapeutic Sciences, Schools of Pharmacy and Medicine, at the University of California, San Francisco (“UCSF”).

2. I received my Bachelor of Arts in English in 1959 and my Bachelors of Science in Pharmacy in 1960 from the University of Michigan. In 1962, I received a Master’s Degree in Pharmaceutical Chemistry, also from the University of Michigan. Three years later, in 1965, I was awarded a doctorate degree from UCSF in Pharmaceutical Chemistry. Since obtaining that degree, I have received nine honorary doctorate degrees, five from European universities and four from US institutions, the last in June, 2016 from the University of Lisbon. I held a licentiate in Pharmacy and am a credentialed Applied Pharmacologists with the American Board of Clinical Pharmacology.

3. In 1965, I joined the faculty of the School of Pharmacy at Washington State University, in Pullman, Washington. In 1969, I joined the Departments of Pharmacy and Pharmaceutical Chemistry within the School of Pharmacy at UCSF as an Assistant Professor. From 1969 to 1976, I progressed first from Assistant

Professor to Associate Professor, and then to Professor. I served as chairman of the department at UCSF from 1978-1998.

4. My areas of specialization over the course of my career include pharmacokinetics/pharmacodynamics, biopharmaceutics, drug delivery and dosage forms, drug metabolism, drug transporters, bioequivalence, animal and human drug pharmacology and other scientific aspects of drug regulatory issues.

5. In addition to my teaching responsibilities, I have held leadership positions in a number of organizations in my field of study, including:

a) From 1985 to 1986, I served as President of the Academy of Pharmaceutical Research and Science (formerly the Academy of Pharmaceutical Sciences).

b) In 1986, I founded and served as the first President of the American Association of Pharmaceutical Scientists (AAPS). From 1986 to 1993, I variously held the positions of Treasurer, Member, and Chair of the Board of Directors of AAPS.

c) From 1988 to 2004, I served as a Specialist Member, Chairman, Past Chair and Member of the Executive Committee of the Board of Pharmaceutical Sciences for the International Pharmaceutical

Federation (FIP). From 2007 through 2012, I served as Chair of the FIP Foundation for Education and Research.

d) From 1992 to 1995 I served as a Member, President, and Chair of the Board of Directors of the American Association of Colleges of Pharmacy (AACCP).

6. I have been awarded numerous awards, prizes and honors for work I have conducted in my field, including:

a) In 1982, I received the American Pharmacists Association (APhA) Academy of Pharmaceutical Sciences Research Achievement Award in Pharmaceutics and the University of Michigan, College of Pharmacy Distinguished Alumnus Award.

b) In 1987, I was elected to membership in the National Academy of Medicine (NAM) of the U.S. National Academy of Sciences.

c) In 1988, I received the Distinguished Service Award of the American College of Clinical Pharmacology (ACCP), and in 1989 I was chosen to receive the first AAPS Distinguished Pharmaceutical Scientist Award.

d) In 1990, I was the recipient of the Rho Chi Lecture Award, and the UCSF School of Pharmacy Long Teaching Award.

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