

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA,
INC. and AKORN INC.,¹
Petitioners,

v.

ALLERGAN, INC.
Patent Owner.

Case IPR2016-01127 (US 8,685,930 B2)
Case IPR2016-01128 (US 8,629,111 B2)
Case IPR2016-01129 (US 8,642,556 B2)
Case IPR2016-01130 (US 8,633,162 B2)
Case IPR2016-01131 (US 8,648,048 B2)
Case IPR2016-01132 (US 9,248,191 B2)

DECLARATION OF DANIEL A. BLOCH, PH.D

¹ Cases IPR2017-00576 and IPR2017-00594, IPR2017-00578 and IPR2017-00596, IPR2017-00579 and IPR2017-00598, IPR2017-00583 and IPR2017-00599, IPR2017-00585 and IPR2017-00600, and IPR2017-00586 and IPR2017-00601, have respectively been joined with the captioned proceedings. The word-for-word identical paper is filed in each proceeding identified in the caption pursuant to the Board's Scheduling Order (Paper 10).

MYLAN - EXHIBIT 1040

Mylan Pharmaceuticals Inc. et al. v. Allergan, Inc.

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I, Daniel A. Bloch, Ph.D., declare as follows:

I. QUALIFICATIONS

1. I am an Emeritus Research Professor in the Department of Health Research and Policy, Division of Biostatistics at Stanford University. I obtained a Ph.D. in mathematical statistics in 1967 from Johns Hopkins University. I began my career in biostatistics as a Research Fellow in the department of biomathematics at Cornell University Medical School in 1967 and as a Research Associate at the Sloan-Kettering Institute for Cancer Research in New York. I became an Assistant Professor of biomathematics at the Cornell University Medical School in 1969 and became an Assistant Professor of Mathematics at California's Sonoma State University in 1970.

2. In 1984 I became the Head Biostatistician for the Arthritis, Rheumatism, and Aging Medical Information System (ARAMIS) and for the Stanford Arthritis Center (SAC) at Stanford University. I was appointed Associate Professor in 1993 and have been a full professor of Health Research and Policy, Division of Biostatistics since 2001. I became Emeritus in 2007.

3. My primary responsibilities include application of mathematical statistics to scientific studies and to advance biostatistical research methodology. Before becoming Emeritus, my salary support at Stanford was fully funded through research grants in various fields of medicine, with grants covering a broad

range of topics, including rheumatic diseases, substance abuse, sleep apnea, basic immunology, juvenile arthritis, vascular structure and stem cell transplantation as immunotherapy.

4. I have published more than 200 original articles in peer-reviewed journals and have additional articles either in press or recently submitted for publication. Approximately 170 of these articles have appeared in medical journals, mostly co-authored with medical faculty at Stanford and at other universities in the United States, Canada and Europe. Often these collaborations have afforded me the opportunity to explore the application of recently developed statistical methods by illustrating their use on real data, and to explore the development of new statistical methods.

5. Among the several dozen articles I have published devoted to statistical methods, topics include efficiency and unbiasedness of estimators, sample size estimation, kappa statistics, non-parametrics, methods of assessing multi-parameter endpoints, and, most recently, designing Phase II and Phase III trials to estimate rare events. I believe that recognition of my expertise as a statistical researcher and at-large applicator to diverse fields of medicine were behind a Nobel Prize committee's invitation to me to provide nominations for the Nobel Prize in Medicine.

6. I have extensive teaching experience, having taught courses offered by both the Mathematical Statistics and the Health Research & Policy departments at Stanford. At Stanford I have supervised the statistical efforts of numerous post-doctoral fellows and medical students. I have also been invited to give dozens of biostatistical presentations, in such diverse settings as Harvard, Johns Hopkins University, the Mayo Clinic, the FDA Center for Biologics Evaluation and Research, the College of Problems for the Drug Dependence annual meetings and at Institute of Mathematical Statistics meetings.

7. Since 1987, I have been a consultant on an *ad hoc* basis to pharmaceutical and biotechnical firms, including both start-up and established companies. Herein I participate in all aspects of applying statistics to implement investigational plans, *e.g.*, for protocol development, design of trials, data base design, analysis of data, and reporting results. I have served on numerous data safety monitoring boards and have been a member of the FDA Statistical Advisors Panel.

8. A significant focus of mine has been the use of statistics to plan, conduct and evaluate experimental research, particularly medical research. I have extensive experience in reviewing published papers. At the request of an editor, my review deals with evaluating all aspects of how the author planned and applied statistics to meet study objectives. Peer-reviewed journals for whom I have

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