

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
Petitioner

v.

POZEN INC. and HORIZON PHARMA USA, INC.
Patent Owners

Case No. IPR2017-01995
Patent No. 9,220,698

**DECLARATION OF DAVID A. JOHNSON, M.D. IN SUPPORT OF
PATENT OWNER RESPONSE TO PETITION FOR *INTER PARTES*
REVIEW OF U.S. PATENT NO. 9,220,698**

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I, Dr. David A. Johnson, M.D. declare as follows:

I have been retained by Counsel for Horizon Pharma, Inc., Horizon Pharma USA, Inc., and Pozen, Inc. (collectively “Patent Owner”) in the matter set forth in the caption above. I understand that the Patent Trial and Appeal Board (“PTAB”) has instituted Mylan Pharmaceuticals Inc.’s (“Mylan’s”) petition for *inter partes* review (“IPR”) of claims 1-7 of U.S. Patent No. 9,220,698 (“the ’698 patent”). I submit this expert declaration in support of Patent Owner’s Response to Mylan’s petition.

I. EDUCATIONAL BACKGROUND AND QUALIFICATIONS

1. I am the Chief of Gastroenterology and Professor of Medicine at the Eastern Virginia Medical School in Norfolk, Virginia.

2. I earned a B.A. from University of Virginia in 1976, and an M.D. from the Medical College of Virginia in 1980.

3. I completed my residency in internal medicine at the Naval Regional Medical Center in Portsmouth, Virginia in 1984, and I completed a fellowship in gastroenterology at the National Naval Medical Center in Bethesda, Maryland in 1986.

4. I have been practicing gastroenterology, a branch of medicine that is focused on the digestive system, as a specialist since 1984. As a practicing physician, I see patients nearly every day. In addition to my academic

responsibilities discussed below, my focus is on clinical gastroenterology and I am engaged in patient care daily.

5. In addition to being a practicing physician, I have been a Professor of Medicine at the Eastern Virginia Medical School in Norfolk, Virginia since 1994 and Chief of Gastroenterology there since 2000. As such, I am involved in teaching medical curricula for a variety of programs and am extremely active in clinical research. Both my teaching and research are focused on gastroenterology.

6. In particular, my research interests have included gastroesophageal reflux disease and the use of proton pump inhibitors (PPIs) in the treatment of gastrointestinal disorders. I have published more than 600 articles, reviews, abstracts and book chapters pertinent to gastrointestinal disorders, and I have also served as an editor and reviewer for a number of journals related to medicine and, in particular, gastroenterology.

7. My primary current research interests are esophageal reflux disease, the gut microbiome in health and disease, effects of sleep fragmentation on GI health/disease, colonoscopy quality metrics and colon cancer screening.

8. I serve on numerous editorial boards and reviews for 21 medical journals, including all of the GI journals. I was a member/reviewer of the National

Institutes of Health study section for esophageal/gastric diseases and have provided consultant testimony to the FDA.

9. I am the past co-editor of Reviews in Gastroenterological Disorders, as well as Journal Medicine and section editor for the American Journal of Gastroenterology. I am the founding co-editor of the American College of Gastroenterology GI Universe, and currently continue as the GI section editor for Medscape Gastroenterology, Medscape GI Viewpoints, and Medscape GI Consultant Corner, as well as the esophageal section editor for Journal Watch Gastroenterology (New England Journal of Medicine).

10. I recently edited the book *Gut Microbiome: New Understanding and Potential Translational Applications for Disease Management*, published in December 2015. Additionally, I co-edited the American College of Physicians (ACP) book *Dyspepsia*, edited the 2005 and 2010 GI Clinics of North America series on *Obesity Issues for Gastroenterologists*, and edited the 2012 American College of Physicians module on colorectal cancer (“CRC”) screening.

11. I have also been extensively involved in collaborative efforts regarding NSAID/antiplatelet upper GI mucosal complications and injury as published in three expert consensus documents with the American Heart

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