

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

U.S. Patent No. 9,220,698 to Ault *et al.*

Inter Partes Review IPR2017-01995

DECLARATION OF DAVID C. METZ, M.D.

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1. I, David C. Metz, M.D., have been retained by counsel for Petitioner Mylan Pharmaceuticals Inc. (“Mylan”). I understand that Mylan is petitioning for *inter partes* review (“IPR”) of U.S. Patent No. 9,220,698 to Ault *et al.* (“the ’698 patent”) (Ex. 1001), which is assigned to Pozen Inc. and Horizon Pharma USA, Inc. (“Patent Owners”), to request that the United States Patent and Trademark Office cancel certain claims of the ’698 patent as unpatentable. I submit this expert declaration in support of Mylan’s IPR petition for the ’698 patent.

I. QUALIFICATIONS AND BACKGROUND

A. Education and Experience

2. I am Professor of Medicine in the Department of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania. I am also Associate Chief for Clinical Affairs in the Division of Gastroenterology, Director of the Acid Peptic Disorders Program, Co-Director of the Gastrointestinal (GI) Physiology Lab, Co-Director of the Penn Program for Swallowing Disorders, and Co-Director of the Penn Neuroendocrine Tumor Program.

3. I have been practicing medicine in the field of gastroenterology for over 30 years with a special emphasis on upper gastrointestinal (GI) tract disease states. I am board certified in gastroenterology and in internal medicine, and listed in Best Doctors in America (Northeast Region). The majority of my clinical activity revolves around the treatment of patients with acid-peptic conditions, and I

have conducted many research protocols involving Proton Pump Inhibitors (PPIs).

As part of my medical practice, I have thousands of patients under my care.

4. I received a Bachelor of Medicine and Bachelor of Surgery from the University of the Witwatersrand Medical School, in Johannesburg, South Africa, in 1982. A Bachelor of Medicine and Bachelor of Surgery is the South African equivalent of a doctor of medicine degree in the United States. In 1983, I interned at the Johannesburg General Hospital in General Medicine and General Surgery. From 1984 to 1985, I was in private practice, first in South Africa, and later in London, England.

5. From 1986 to 1988, I did an internship and residency in internal medicine at the Albert Einstein Medical Center, Philadelphia, Pennsylvania. From 1989 to 1991, I completed a fellowship in gastroenterology in a combined program with Georgetown University, the Washington Veteran's Affairs Medical Center, and the National Institutes of Health. From 1991 to 1993, I was a senior staff fellow in the Digestive Diseases Branch of the National Institutes of Health, Bethesda, Maryland, where I studied Zollinger-Ellison Syndrome, the prototypical acid hypersecretory condition, the management of which requires, amongst other interventions, therapy with PPIs.

6. In 1993, I became an Assistant Professor of Medicine in the Department of Medicine at the University of Pennsylvania, Philadelphia,

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