

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
MSN LABORATORIES PRIVATE LTD.,
and MSN PHARMACEUTICALS INC.
Petitioners,

v.

BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

IPR2022-00722¹
Patent No. 7,041,786

DECLARATION OF MICHAEL S. EPSTEIN, M.D.

¹ IPR2023-00016 has been joined with this proceeding.

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I, Michael S. Epstein, declare as follows:

I. QUALIFICATIONS

1. I am Founder and President of Investigative Clinical Research, Founder and President of Maryland Diagnostic & Therapeutic Endo Center (MDTEC), and Principal Physician at Gastro Health (formerly, Digestive Disorders Associates), all based in Annapolis, Maryland. I am currently licensed to practice medicine in the state of Maryland and I am Board-certified with the American Board of Internal Medicine, with a subspecialty in Gastroenterology.

2. I obtained by Doctor of Medicine in 1981 at the Robert Wood Johnson School of Medicine of the New Jersey College of Medicine and Dentistry (which later merged with Rutgers University). I joined the Internship and Residency Program at George Washington University Hospital and School of Medicine and then a Fellowship in Gastroenterology and Hepatology at the Veterans Administration Medical Center in Washington, D.C. Since then, I have been a practicing gastroenterologist in the state of Maryland for more than thirty years.

3. I am experienced as both a practicing physician and a clinical researcher in the treatment of gastrointestinal (GI) disorders and diseases. For instance, as a physician at Gastro Health, I regularly see patients who are experiencing symptoms associated with chronic constipation, including those

diagnosed with chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C). I am familiar with ordinarily-prescribed treatments used to alleviate symptoms associated with chronic constipation and I often prescribe such treatments to my patient. This includes, in some cases, prescription-based treatments intended to relieve chronic constipation, including guanylate cyclase-C (GCC) activators, such as plecanatide (Trulance®) and linaclotide (Linzess®).

4. Through my research facility, Investigative Clinical Research, I am also experienced in the clinical development of treatments for those with CIC or IBS-C, including study protocols testing the safety and efficacy of drugs like plecanatide and linaclotide. I have also published several journal articles discussing treatments for chronic constipation and irritable bowel syndrome.

5. For a more detailed listing of my credentials and publications, please see my curriculum vitae, EX1071.

II. SCOPE OF WORK

6. I understand that Mylan Pharmaceuticals Inc. (“Mylan”) filed a petition with the United States Patent and Trademark Office for *Inter Partes* Review of claims 1-6 of U.S. Patent No. 7,041,786 to Shailubhai (“Shailubhai,” EX1001). I also understand that the Patent Trial and Appeal Board instituted *inter partes* review of the claims of Shailubhai. I understand that Patent Owner Bausch

Health Ireland Ltd. (“Bausch”) filed a Patent Owner Response to the petition. In support of that response, I have been informed that Bausch has submitted, among other things, the declaration of Dr. Scott A. Waldman (EX2025).

7. I have been asked to review the declaration of Dr. Waldman and provide my opinions regarding the testimony Dr. Waldman provides. In particular, I have been asked to opine on Dr. Waldman’s testimony “regarding the state of the art as of January 17, 2002,” including “information about the gastrointestinal (‘GI’) tract; constipation, including chronic idiopathic constipation (‘CIC’) and irritable bowel syndrome with constipation (‘IBS-C’); and guanylate cyclase C (‘GCC’) receptors and ligands.” EX2025 (Waldman Declaration), ¶3. I have also been asked to opine on Dr. Waldman’s testimony “regarding the activity of plecanatide versus the activity of human uroguanylin.” *Id.*, ¶4. In connection with this, I have also reviewed the transcript of the deposition of Dr. Waldman (EX1062). I understand that Dr. Waldman is “a clinical pharmacologist, physician, and biomedical scientist,” but he is not Board-certified in internal medicine or certified in the subspecialty of gastroenterology. EX2025 (Waldman Declaration), ¶6; EX1062 (Waldman Deposition Transcript), 10:11-11:10.

8. My opinions are based on my skills, knowledge, training, education, and experience in matters of this nature, and my examination of the materials used in preparing this testimony. For convenience, documents cited in this declaration

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