UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,

Patent Owner.

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Case IPR2022-00722
U.S. Patent No. 7,041,786

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DECLARATION OF SCOTT A. WALDMAN, M.D., PHD, FDP, FAHA, FNAI, FASPET

Table of Contents

I. Introduction

1. I have been retained by counsel for Patent Owner Bausch Health Ireland Limited ("Bausch")[1] as an expert in connection with the above-captioned *inter partes* review proceeding.

2. I understand that Petitioner Mylan Pharmaceuticals Inc.'s ("Mylan") has asserted that claims 1-6 of U.S. Patent No. 7,041,786 (Ex. 1001 ("the '786 patent"))[2] would have been obvious and that the Patent Trial and Appeal Board ("Board") has instituted *inter partes* review of claims 1-6 of the '786 patent based on four grounds of unpatentability.

3. I have been asked to provide information regarding the state of the art as of January 17, 2002. In particular, I have been asked to provide 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.

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[1] I understand that Bausch acquired the '786 patent from Synergy Pharmaceuticals, Inc. In my declaration, I use Bausch to also refer to Synergy Pharmaceuticals, Inc.

[2] U.S. Patent No. 7,041,786, titled "Guanylate Cyclase Receptor Agonist for the Treatment of Tissue inflammation and Carcinogenesis" (Ex. 1001 ("the '786 patent")).

4.   I have also been asked to provide my opinions regarding the activity of plecanatide versus the activity of human uroguanylin.

II.   Qualifications and Experience

5.   My qualifications and experience are reflected in my *curriculum vitae*, attached as Exhibit 2030[3] and incorporated herein by reference. Also included in my *curriculum vitae* is a list of publications that I have authored to date.

6.   I am a clinical pharmacologist, physician, and biomedical scientist with over 30 years of experience with GCC and gastrointestinal disorders, including CIC and IBS-C. For example, I have presented on CIC and IBS-C. I have also published peer-reviewed journal articles that discuss chronic constipation, including: Bharucha, A.E. et al., Taking a lesson from microbial diarrheagenesis in the management of chronic constipation. Gastroenterology 138(3):813-7 (2010); Waldman, S.A., et al., Blunted evoked prouroguanylin endocrine secretion in chronic constipation. Clin Trans Gastroenterol. 00:e-00016 (2019); Sayuk, G.S., et al., Mechanisms of action of current treatment options for chronic idiopathic constipation and irritable bowel syndrome with constipation. Am. J. Gastro. 117:S6-S13 (2022); Brenner, D.M., et al. Real-world treatment strategies to improve

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[3] Scott Arthur Waldman, MD, PhD, FCP, FAHA, FNAI, FASPET Curriculum Vitae (Ex. 2030).

outcomes in patients with chronic idiopathic constipation and irritable bowel syndrome with constipation. Am. J. Gastro. 117:S21-S26 (2022).

7.   I am currently Chair of the Department of Pharmacology, Physiology and Cancer Biology at Thomas Jefferson University. I am also the MD/PhD Program Director and the Samuel M.V. Hamilton Professor of Medicine at Thomas Jefferson University.

8.   My research focuses on GCC, GCC agonists, cyclic guanosine monophosphate ("cGMP"), and their therapeutic implications. In 2021, I ranked among the top 30 most cited authors in cell signaling per Google Scholar and among the top 0.01% (top 50) of authors in Translational Medicine per Expertscape.

9.   I received a B.S. in Biology from State University of New York at Albany in 1975, followed by a Ph.D. in Human Anatomy from Thomas Jefferson University in 1980, where I worked at the Daniel Baugh Institute of Anatomy. I completed postdoctoral fellowships in pharmacology at the University of Virginia in 1981 and at Stanford University in 1983. I then attended medical school and graduated with an M.D. from Stanford University in 1987. I completed my internship (1987–1988) and clinical residency (1988–1990) in the department of medicine at the Stanford University Hospital.

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