

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
and PFIZER INC.,

Petitioners,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,

Patent Owner.

Case No. IPR2018-01670 - Patent No. 8,679,069

Case No. IPR2018-01678 - Patent No. 8,992,486

Case No. IPR2018-01680 - Patent No. 9,526,844

Case No. IPR2018-01682 - Patent No. 9,526,844

Case No. IPR2018-01684 - Patent No. 9,604,008

Case No. IPR2019-00122 - Patent No. 8,992,486

**DECLARATION OF DR. WILLIAM C. BIGGS
IN SUPPORT OF MYLAN-PFIZER REPLY**

I. INTRODUCTION

1. My name is Dr. William Curtis Biggs. I am a Medical Doctor specializing in the treatment of metabolic diseases, and have extensive experience treating patients with diabetes.

2. Counsel for Mylan Pharmaceuticals, Inc. (“Mylan”) and Pfizer Inc (“Pfizer”) approached me for expert assistance in inter partes review of involved U.S. Patent Nos. 8,679,069 (EX1001), 8,992,486 (EX1003), 9,526,844 (EX1004), and 9,604,008 (EX1005). Specifically, Mylan and Pfizer requested my views on considerations in prescribing insulin for patients.

A. Education and Experience

3. I received my bachelor’s degree in chemistry from the University of California, San Diego (magna cum laude) in 1978. I then attended medical school at the University of Texas, Southwestern Medical School at Dallas, and graduated in 1982 with a medical doctorate degree. I have been Board Certified by the American Board of Internal Medicine in Internal Medicine since 1985, and by the American Board of Preventative Medicine in Clinical Informatics in 2014.

4. I have extensive post-doctoral experience, starting as an Intern in Medicine at the University of California, San Diego from 1982-83. I served as a Junior Assistant Resident at the New England Deaconess Hospital in Boston from 1983-84, and then as a Senior Assistant Resident from 1984-85. From 1985-86, I was

a Fellow in Endocrinology/Diabetes at the Joslin Diabetes Center, Harvard Medical School, and New England Deaconess Hospital in Boston. The Joslin Diabetes Center is the largest diabetes research center and clinic in the world, and a preeminent research institution for endocrinology and metabolic diseases, providing cutting-edge care for patients afflicted with diabetes.

5. I currently hold academic and clinical appointments in Amarillo, Texas, including as a Clinical Assistant Professor in the Department of Internal Medicine at Texas Tech School of Medicine in Amarillo. I am the Medical Director of the Diabetes Center at Northwest Texas Hospital in Amarillo, Texas, the only American Diabetes Association recognized education program in our region. I have active staff privileges with the Baptist St. Anthony's Hospital in Amarillo, Texas for hospital inpatient consultation.

6. I am a Founder and Chief Executive Officer of the Amarillo Legacy Medical Accountable Care Organization (ACO) since 2012. As the director of an Accountable Care Organization, I am responsible for ensuring the quality of healthcare delivery under a Medicare Shared Savings Program contract. I supervise 300 healthcare providers who are working to improve healthcare delivery, improve patient outcomes, and reduce costs.

7. I am the Managing Partner and Chief Medical Information Officer for Amarillo Medical Specialists LLP since 1995. Amarillo Medical Specialists LLP currently manages 43 medical providers in the Amarillo, Texas area.

8. I also currently hold committee positions with the American Association of Clinical Endocrinologists and serve as the Current Procedural Terminology (CPT) Advisor representing the American Association of Clinical Endocrinologists (AAACE) at the American Medical Association CPT Editorial Panel.

9. I am the Vice Chairman of the Amarillo Hospital District, which is a governmental agency with ability to levy taxes, which provides healthcare for impoverished persons living within the City of Amarillo.

10. I have held various leadership positions in local and national medical profession organizations, including serving as President of the Texas Chapter of the American Association of Clinical Endocrinologists, as well as serving on the Board of Directors for various diabetes organizations, including the Juvenile Diabetes Foundation in Amarillo, and the Amarillo Chapter of the American Diabetes Association. I also served on the Board of Governors for the Northwest Texas Healthcare System in Amarillo, and the Board of Directors for the Texas Chapter of the American Association for Clinical Endocrinologists.

11. I have been recognized for my past work in endocrinology and medicine, including in Who's Who in Medicine and Healthcare (1998-2008), Who's Who in

America (2001-2008), in Who's Who in Science and Engineering (2002-2006), as a Fellow of the American College of Endocrinology (2005), as a Promise Honoree from the Juvenile Diabetes Research Foundation (Amarillo, June 2005), and as a Texas Monthly Magazine "SuperDoctor" in Endocrinology (2005-2019).

12. I have published articles and delivered oral presentations specifically on diabetes care and prevention throughout the United States, including as a Program Speaker and Co-Director for Texas AACE Diabetes Management for Primary Care Physicians, and an invited speaker at the HIMSS¹ National and Texas Annual Meetings.

13. I continue to work as the Principal Investigator for numerous clinical research trials involving diabetes for type 1 and type 2 diabetes, including trials that look specifically at the effect of insulins, devices, patient education, and healthcare costs.

14. A copy of my curriculum vitae detailing my education and work experience is included as exhibit EX1049 in support of my declaration.

¹ Healthcare Information and Management Systems Society.

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