

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC.,
Petitioner

v.

NOVO NORDISK A/S,
Patent Owner

Case IPR2023-00724
Patent 10,335,462

**EXPERT DECLARATION OF GEORGE L. BAKRIS, M.D.
IN SUPPORT OF PATENT OWNER'S RESPONSE TO
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 10,335,462**

I, George L. Bakris, hereby declare under penalty of perjury:

I. INTRODUCTION

1. I have been retained by Groombridge, Wu, Baughman & Stone LLP, on behalf of Novo Nordisk A/S (“Novo Nordisk”) to provide assistance regarding U.S. Patent No. 10,335,462 (“the ’462 patent”). Specifically, I have been asked to provide my opinions regarding certain objective indicia of non-obviousness for the ’462 patent. Except as otherwise indicated, I have personal knowledge of the facts and opinions set forth in this declaration, and believe them to be true. If called upon to do so, I would testify competently thereto.

2. I am being compensated for my time at a rate of \$700 per hour. I will be reimbursed for any expenses that I incur during the course of this work. My compensation is not contingent upon the results of my study, the substance of my opinions, or the outcome of any proceeding involving the Challenged Claims (claims 1-10). I have no financial interest in the outcome of this matter or in the pending litigations involving Novo Nordisk A/S and Novo Nordisk Inc.

II. BACKGROUND AND QUALIFICATIONS

3. I offer statements and opinions on behalf of Novo Nordisk, generally regarding certain objective indicia of non-obviousness, specifically unexpected results related to the ’462 patent.

4. I am a nephrologist with expertise in treating diabetes-related kidney disease. I am currently a tenured Professor of Medicine at University of Chicago Medicine and the Director of the Comprehensive Hypertension Center at the University of Chicago.

5. I received by BA in Biology and Psychology from Indiana University in 1974, my MA is in Human Development from the University of Chicago in 1975, and my MD from Rosalind Franklin University of Medicine and Science in 1981.

6. From 1981 to 1982 I completed my internship in Internal Medicine at the Mayo Graduate School of Medicine. From 1982 to 1983 I did a residency year in Psychiatry at the Washington University School of Medicine.

7. From 1983 to 1984 I was a research fellow in Renal Physiology and Hypertension at the Mayo Graduate School of Medicine and from 1984 to 1986 I completed my residency in Internal Medicine at the University of Illinois, Chicago.

8. I completed my fellowship in Nephrology at University of Chicago Medicine from 1986 to 1988 and my fellowship in Clinical Pharmacology from 1986 to 1987, also at University of Chicago Medicine.

9. Following my fellowships, from 1988 to 1991 I was a staff nephrologist at the Ochsner Clinic in New Orleans, LA, and Assistant Professor in the Department of Medicine at Tulane University. I was also an Adjunct Assistant Professor in the Departments of Physiology and Pharmacology at Tulane University.

10. From 1991 to 1993 I was an Assistant Professor of Medicine and Pharmacology in the Division of Nephrology and Director of the Renal Fellowship Program at the University of Texas Health Science Center at San Antonio, Texas.

11. From 1993 to 1996 I was an Assistant Professor in the Departments of Preventive Medicine and Internal Medicine at Rush University Medical Center.

12. From 1994 to 2006 I was a Lecturer in the Division of Nephrology at the University of Illinois Medical Center at Chicago.

13. From 1996 to 1998 I was an Associate Professor and from 1999 to 2006 I was a Professor in the Departments of Preventive Medicine and Internal Medicine at Rush University Medical Center.

14. Beginning in 2006, I accepted a position as Professor of Medicine at University of Chicago Medicine, a position I still hold today.

15. I have been a principal investigator or on the steering committees of numerous trials and member of guideline committees involving diabetic kidney disease, I have published over 1000 articles, about 500 in diabetic kidney disease. For example, the ARTS-DN trial (Bakris GL, et.al. *JAMA*, **314**(9):884-894 (2015)) and the FIDELITY program involving two outcome trials (FIDELIO (Bakris GL, et.al. *N Engl J Med.*, **383**(23):2219-2229 (2020)) and FIGARO (Pitt B, Filippatos G, Agarwal R, Anker SD, Bakris GL, et al. *N Engl J Med.*, **385**(24):2252-2263

(2021)) as well as a pooled analysis of these trials (Agarwal R, Filippatos G, Pitt B, et.al.... and **Bakris GL** *Eur Heart J.*, **43**(6):474-484 (2022)).

16. I have also served on many guidelines committees and most recently completed a two year term (2020-2022) on the American Diabetes Association Clinical Practice Guideline Committee. I am also a member of the American Heart Association panel that is working on updating resistant hypertension guidelines. I am the past president of the American College of Clinical Pharmacology and the American Society of Hypertension.

17. I have authored over 1000 peer-reviewed articles and have written over 130 textbook chapters covering diabetic kidney disease, hypertension, and nephropathy progression and editor of 23 books on these topics.

18. I have also received numerous awards, including the Lifetime Achievement Luminary Award in Cardiometabolic Medicine at the 7th Annual Heart in Diabetes Conference in 2023, the National Kidney Foundation of Illinois Lifetime Service Award in 2021, and the Irwin Page and Alma Bradley Lifetime Achievement Award by the American Heart Association Blood Pressure Counsel in 2019. Additionally, in 2021 I was listed as number 76 in Stanford University's list of the top 2% most cited scientists in the world.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.