

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 MICHAEL J. BLAHA
IN SUPPORT OF PATENT OWNER'S RESPONSE TO
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT No. 10,335,462**

TABLE OF CONTENTS

I.	INTRODUCTION	2
II.	BACKGROUND AND QUALIFICATIONS.....	2
III.	PRIORITY DATE	6
IV.	LEGAL STANDARDS.....	6
V.	MATERIALS RELIED UPON	8
VI.	BACKGROUND ON TYPE 2 DIABETES AND CARDIOVASCULAR DISEASE	9
VII.	THE '462 PATENT AND OZEMPIC®	11
VIII.	OBJECTIVE INDICIA.....	13
	A. Unexpected Results of Ozempic®: The SUSTAIN-6 Trial and Published Cardiovascular Benefits of Once-Weekly 1.0 mg Semaglutide in Patients with Type 2 Diabetes.....	14
	B. Industry Praise and Acceptance of Ozempic®: Clinical Guidelines and Paradigm Shift in Treatment and Management of T2D.....	20
IX.	CONCLUSION	25

I, Michael J. Blaha, M.D. M.P.H., 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. All statements herein made of my own knowledge are true and all statements made on information and belief are believed 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 \$500 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 and praise, related to the ’462 patent.