

IN THE 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.

BOEHRINGER INGELHEIM INTERNATIONAL GMBH,  
Patent Owner

U.S. Patent No. 8,846,695 to Dugi  
Issue Date: Sept. 30, 2014  
Title: Treatment for Diabetes in Patients  
with Inadequate Glycemic Control  
Despite Metformin Therapy Comprising a DPP-IV Inhibitor

*Inter Partes* Review No.: IPR2016-01564

**DECLARATION OF MAYER B. DAVIDSON, M.D.**

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## ***I. Introduction***

1. I am over the age of eighteen (18) and otherwise competent to make this Declaration.

2. I have been retained as an expert witness on behalf of Mylan Pharmaceuticals Inc. (“Mylan”) for the above captioned *inter partes* review (“IPR”). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$500 per hour for non-testifying work. My compensation is in no way dependent on the outcome of this IPR.

3. I understand that the petition for *inter partes* review involves U.S. Patent No. 8,846,695 (the “695 patent”), Ex. 1001. I have considered references published prior to January 7, 2009. I have been informed that such references are referred to as “prior art.” And I will refer to these references as such in my Declaration. I can confirm that the opinions expressed herein comport with my own understandings based on an independent review of the prior art cited herein.

## ***II. List of Documents Considered***

4. In formulating my opinion, I have considered all documents cited in this Declaration and all documents cited in the Petition for *Inter Partes* Review of U.S. Patent No. 8,846,695. I refer herein to the prior art references and other documents cited herein using the defined terms presented in the Petition.

## ***III. My Background and Qualifications***

5. I am an expert in the field of medicine, specifically diagnosing and treating type II diabetes mellitus,<sup>1</sup> and I have been an expert in this field since well before 2009. Throughout the remainder of this Declaration, I will refer to the field of diagnosing and treating type II diabetes as the relevant field or the relevant art. In formulating my opinions, I have relied upon my training, knowledge, and experience in the relevant art. A copy of my current curriculum vitae is provided as Ex. 1009, and it provides a comprehensive and current description of my academic and employment history.

6. I received a M.D. from Harvard Medical School in 1961. I completed my residency at Cornell Medical School, Bellevue Hospital in Internal Medicine in 1963. I then completed my research fellowship at the University of Washington King County Hospital in Endocrinology and Metabolism.

7. I am currently a Professor of Medicine at both the David Geffen School of Medicine at UCLA and Charles Drew University. I am board certified in Internal Medicine and also board certified in the subspecialty of Diabetes, Endocrinology, and Metabolism. I have been practicing in the field of diabetes, endocrinology, and metabolism for 50 years.

8. During my career, I have focused my practice on the diagnosis and treatment of diabetes.

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<sup>1</sup> I refer to “type II diabetes mellitus” as “type II diabetes.”

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