

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ASTRAZENECA AB,
Patent Owner.

Case IPR2015-01340
Patent RE44,186 E

DECLARATION OF CHRISTINE S. MEYER, PH.D.

August 2, 2016

CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER

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I, Christine S. Meyer, hereby declare as follows.

I. INTRODUCTION

A. Professional Qualifications and Expertise

1. I am an economist and Senior Vice President at National Economic Research Associates, Inc. (“NERA”). NERA is a firm of consulting economists that was founded in 1961 and provides research and analysis in economics, including analysis in the areas of competition, regulation, and finance. I joined the firm in 2000 and have worked since then mainly in the areas of the economics of intellectual property, antitrust analysis, and the evaluation of commercial damages. I have testified as an expert witness in the United States District Court, the Supreme Court of the State of New York, the Federal Court of Canada, and the High Court of Justice in England.

2. Since joining NERA, I have analyzed economic issues in a wide variety of cases. As part of my work, I have written expert reports and declarations related to commercial success in patent cases for both District Court and Patent Trial and Appeal Board proceedings. I have also analyzed damages arising from patent infringement; irreparable harm as related to potential injunctions in patent cases; and the value of several patents, licenses, and potential business acquisitions. I have written articles and book chapters about patent infringement damages and have been asked to speak about economic issues related to

intellectual property on numerous occasions, including by the U.S. Federal Trade Commission in its hearings entitled “*The Evolving IP Marketplace*.” I have been involved in many cases involving a variety of technologies across a broad range of industries, including pharmaceutical products, medical devices, and consumer products.

3. I received my bachelor’s degree with a concentration in economics from the United States Military Academy at West Point and my Ph.D. in economics from the Massachusetts Institute of Technology. I taught economics and statistics at Bentley College and Colgate University. A list of my prior testimony and publications can be found in my *curriculum vitae*, which is appended to this declaration as Exhibit 2060.

B. Retention and Assignment

4. NERA has been retained by Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, counsel for AstraZeneca AB (“AstraZeneca” or “Patent Owner”) for the above-captioned *inter partes* review (“IPR”) of U.S. Patent Number RE44,186 (“the RE’186 patent” or “the patent at issue”).

5. I understand that the Patent Trial and Appeal Board has granted Mylan Pharmaceuticals Inc.’s (“Mylan” or “Petitioner”) petition to institute this IPR regarding the RE’186 patent on obviousness grounds. I understand that the RE’186 patent, which is titled “Cyclopropyl-Fused Pyrrolidine-Based Inhibitors of

Dipeptidyl Peptidase IV and Method,” claims, among other things, the new chemical entity saxagliptin.¹

6. I understand further that the RE’186 patent is listed in the U.S. Food and Drug Administration’s (“FDA”) Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for the branded pharmaceutical drugs Onglyza[®] and Kombiglyze[™] XR, which were developed by AstraZeneca in a collaboration agreement with Bristol-Myers Squibb Company (“BMS”), and are marketed in the U.S. by AstraZeneca.

7. I provide this declaration in regards to Patent Owner’s arguments concerning objective indicia of non-obviousness. Specifically, I have been asked by counsel for AstraZeneca to evaluate the marketplace performance of Onglyza[®] (saxagliptin) and Kombiglyze[™] XR (saxagliptin and metformin hydrochloride extended-release) and to provide an opinion regarding whether Onglyza[®] and Kombiglyze[™] XR are a commercial success as a result of the patented features of the RE’186 patent.

C. Compensation

8. NERA is being compensated for the time I spend on this assignment at my customary hourly rate of \$675 and is separately reimbursed for reasonable

¹ Ex. 1001, 1, col. 3.

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