UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
WOCKHARDT BIO AG, TEVA PHARMACEUTICALS USA, INC.
and AUROBINDO PHARMA U.S.A. INC.,
Petitioners,

v.

ASTRAZENECA AB,
Patent Owner.

Case IPR2015-01340
Patent RE44,186 E[1]

DECLARATION OF DEFOREST MCDUFF, Ph.D.

[1] Petitioners Wockhardt (IPR2016-01209), Teva (IPR2016-01122), and Aurobindo (IPR2016-01117) have each been joined as Petitioner to this proceeding.

I, DeForest McDuff, Ph.D., declare as follows:

I. Introduction

A. Qualifications

1. I am a Vice President of Intensity Corporation ("Intensity") and an expert in applied business economics, with more than ten years of experience in consulting, finance, and economic research. I provide expert witness testimony and consulting in a variety of areas, including lost profits, reasonable royalties, unjust enrichment, commercial success, irreparable harm, finance, statistics, valuation, and business optimization.

2. My expertise and experience span a variety of topics, including intellectual property, competition, business, antitrust, finance, labor, employment, and class action. I am an expert in the economics of technology and intellectual property. My work spans the life sciences (including pharmaceuticals, biotechnology, diagnostics, and medical devices), electronics (including consumer electronics, semiconductors, computers, and telecommunications), and has included projects on a diverse range of other industries.

3. I have significant experience evaluating the economics of the pharmaceuticals industry. I have provided expert analysis and consulting in over 50 cases involving pharmaceuticals and related products, including evaluations of economic damages, competition, commercial success, irreparable harm, and other

issues. I have evaluated a number of pharmaceutical product launches, both in a litigation setting and an advisory role, and have published articles and taught continuing legal education on pharmaceutical products as well.

4. I earned my Ph.D. in economics from Princeton University. At Princeton, I received a National Science Foundation Graduate Research Fellowship for academic research studying economic and statistical properties of housing markets and financial derivatives. I have published research in several peer-reviewed academic journals. I graduated *summa cum laude* with undergraduate degrees in economics and mathematics from the University of Maryland.

5. My curriculum vitae, provided in EX1061, Attachment A, contains more details on my background, experience, publications, and prior expert testimony.

B. Scope of Work

6. Intensity has been retained by Wilson Sonsini Goodrich & Rosati on behalf of Mylan Pharmaceuticals, Inc. ("Mylan") in connection with my work in this matter. Intensity is being compensated at a rate of $700 per hour for my work and at lower rates for time spent by others on my team. The compensation of Intensity is not dependent on the substance of my testimony or the outcome of this matter.

7. For this declaration, I was asked to review and discuss the declaration of Dr. Christine Meyer relating to the alleged commercial success of Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin HCl extended-release; together, the "products-at-issue") and U.S. Patent No. RE44,186 E ("the '186 patent" or "patent-at-issue," EX1001) submitted on August 2, 2016 ("Meyer Declaration").[2] This declaration is a statement of my opinions in this matter and the basis and reasons for those opinions. In forming the opinions expressed in this declaration, I have relied upon my education, experience, and knowledge of the subjects discussed.

8. This declaration summarizes only my current opinions, which are subject to change depending upon additional information and/or analysis. The entirety of my declaration, including exhibits EX1061 (CV) & EX1062 (attachments) and referenced materials, supplies the basis for my analysis and conclusions. The organizational structure of the declaration is for convenience. To the extent that facts, economic analysis, and other considerations overlap, I generally discuss such issues only once for the sake of brevity. Neither the specific order in which each issue is addressed nor the organization of my declaration or attachments affects the ultimate outcome of my analysis.

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[2] EX2059A: Meyer Declaration.

II. Background

A. Type 2 diabetes

9. Type 2 diabetes is a disease related to improper function of how the body utilizes insulin and metabolizes sugar. (*see* EX2057 (Declaration of M. James Lenhard, M.D.) for sources and references) Type 2 diabetes results in a build-up of sugar in the bloodstream and can cause heart disease, stroke, vision loss, kidney failure, sensory loss, amputation, and premature death. *Id* at ¶ 21. Treatment for Type 2 diabetes includes healthy eating, regular exercise, blood sugar monitoring, and a variety of prescription drug options: sulfonylureas, meglitinides, biguanides, alpha-glucose inhibitors, and thiazolidinediones. *Id* at ¶¶ 25, 34.

B. Products at issue

10. Onglyza (saxagliptin) is a prescription drug product sold by AstraZeneca that is used to lower blood sugar in adults with type 2 diabetes.[3] Onglyza is a once-daily oral tablet that was approved in the United States in July 2009.[4] I understand that Onglyza was co-promoted and sold together between

[3] EX2121.

[4] EX2118, EX2120.

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