

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., and PFIZER INC.,

Petitioners,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

IPR2018-01670: Patent 8,679,069
IPR2018-01678: Patent 8,992,486
IPR2018-01680: Patent 9,526,844
IPR2018-01682: Patent 9,526,844
IPR2018-01684: Patent 9,604,008
IPR2019-00122: Patent 8,992,486

DECLARATION OF DEFOREST MCDUFF, PH.D.

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

I. Introduction

A. Qualifications

1. I am a Partner at Insight Economics 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. 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

DeForest McDuff, Ph.D.

litigation setting and an advisory role, and have published articles and taught continuing legal education on pharmaceutical topics 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 financial economics and applied microeconomics. 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. My curriculum vitae, provided as Attachment A-1, contains more details on my background, education, experience, and expert testimony.

B. Scope of Work

5. In connection with my work on this matter, Insight Economics has been retained by Wilson Sonsini Goodrich & Rosati on behalf of Mylan Pharmaceuticals Inc. (“Mylan”) and by Winston & Strawn on behalf of Pfizer Inc. (“Pfizer”). Insight Economics 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 Insight Economics is not dependent on the substance of my testimony or the outcome of this matter.

6. For this declaration, I was asked to review and respond to the Declaration of Henry G. Grabowski, Ph.D. In Support of Patent Owner’s Response to Petition for

Inter Partes Review of U.S. Patent No. 8,679,069 (“’069 Declaration”), Declaration of Henry G. Grabowski, Ph.D. In Support of Patent Owner’s Response to Petition for Inter Partes Review of U.S. Patent 8,992,486 (“’486 Declaration”), Declaration of Henry G. Grabowski, Ph.D. In Support of Patent Owner’s Response to Petition for Inter Partes Review of U.S. Patent 9,526,844 (“’844 Declaration”), and Declaration of Henry G. Grabowski, Ph.D. In Support of Patent Owner’s Response to Petition for Inter Partes Review of U.S. Patent 9,604,008 (“’008 Declaration”) (collectively, “Grabowski Declarations”), submitted in June 2019 in their respective IPR cases: the ’069 Declaration submitted in IPR2018-01670, the ’486 Declaration submitted in IPR2018-01678 and IPR2019-00122, the ’844 Declaration submitted in IPR2018-01680 and IPR2018-01682, and the ’008 Declaration submitted in IPR2018-01684.¹ The Grabowski Declarations pertain to the alleged commercial success of Lantus SoloStar sold by Sanofi-Aventis Deutschland GmbH (“Sanofi”) and the alleged nexus to U.S. Patent Nos. 8,679,069 (Ex 1001), 8,992,486 (Ex 1003), 9,526,844 (Ex 1004), and 9,604,008 (Ex 1005). The Grabowski Declarations are substantively identical except they

¹ I understand that Dr. Grabowski submitted “corrected” declarations in July 2019, which I have focused on for the purposes of this declaration.

each reference a different one of the four patents.² This declaration addresses all of the Grabowski Declarations collectively for their respective IPR cases. This declaration is a statement of my current opinions in this matter and the basis and reasons for these opinions, which are subject to change based upon additional information, analysis, and/or opinions of other experts.

C. Sources

7. In analyzing the Grabowski Declarations and the alleged commercial success of Lantus SoloStar, I have evaluated the Grabowski Declarations and documents cited therein, the Declaration of Dr. William C. Biggs in Support of Mylan-Pfizer Reply (the “Biggs Declaration”),³ as well as the documents cited throughout my declaration and Attachments. A list of the documents I have relied upon are contained in Attachment A-2.

II. Background

A. Patents-at-issue

8. I understand that the following patents (collectively, “the patents-at-issue”) are at issue in their corresponding IPR proceedings (as noted above, I have been

² Ex 1055: Henry Grabowski, Dep. Tr., 9/5/2019, at 72:3-7.

³ Ex 1048: Expert Declaration of William Curtis Biggs, M.D., FACE, ECNU in Support of Mylan-Pfizer Reply.

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