UNITED STATES PATENT AND TRADEMARK OFFICE
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BEFORE THE PATENT TRIAL AND APPEAL BOARD
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WATSON LABORATORIES, INC.

Petitioner,

v.

UNITED THERAPEUTICS CORPORATION
Patent Owner.

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Case IPR2017-01622
Patent 9,339,507

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<u>DECLARATION OF DEFOREST MCDUFF, Ph.D.</u>

Mail Stop Patent Board
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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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

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 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 as Attachment A, contains more details on my background, education, experience, and expert testimony.

B. Scope of Work

6.   In connection with my work on this matter, Insight Economics has been retained by Winston & Strawn LLP on behalf of Watson Laboratories, Inc. ("Watson"). 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.

7.   For this declaration, I was asked to evaluate aspects of commercial success relating to U.S. Patent No. 9,339,507 (Ex. 1001) as it relates to Tyvaso (treprostinil). This declaration is a statement of my opinions in this matter and the

basis and reasons for those opinions.[1] In forming the opinions expressed in this declaration, I have relied upon my education, experience, and knowledge of the subjects discussed.

II. Background

A. Patent-at-issue

8.   I understand that the following patent is at issue in this IPR proceeding: 9,339,507 ("the '507 patent" or "the patent-at-issue").

9.   The '507 patent, entitled "Treprostinil Administration by Inhalation," was filed on May 11, 2012 and issued on May 17, 2016. I understand that the '507 patent has the following abstract:

> Treprostinil can be administered using a metered dose inhaler. Such administration provides a greater degree of autonomy to patients. Also disclosed are kits that include a metered dose inhaler containing a pharmaceutical formulation containing treprostinil.

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[1]   This declaration reflects only my current opinions, which are subject to change based upon additional information, analysis, and/or opinions of other experts.

B. Pulmonary hypertension

10.   Pulmonary hypertension ("PH") is generally defined by high blood pressure in the lungs and the right side of the heart. This can occur when blood is not able to flow freely through arterioles in the lungs. Over time, the heart muscle weakens from the increased effort required to pump blood and may fail. Pulmonary arterial hypertension ("PAH") is known as Group 1 PH, classified by the World Health Organization ("WHO"), and includes PH that is inherited, has no known cause, or is caused by certain drugs or conditions.[2]

11.   Patients diagnosed with PH have several treatment options, including medications and surgery. Treatment for PH includes anticoagulants, digoxin, diuretics, and calcium channel blockers ("CCB"), among others.   Heart or lung transplants or open heart surgery may be warranted if drug therapy is not successful.   For the treatment of PAH, in particular, approved pharmaceuticals

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[2]   Ex. 1120: Mayo Clinic Website, Pulmonary hypertension, Overview, http://www.mayoclinic.org/diseases-conditions/pulmonary-hypertension/home/ovc-20197480 (accessed 3/22/2017).

Ex. 1122: NIH Website; National Heart, Lung, and Blood Institute; Types of Pulmonary Hypertension, https://www.nhlbi.nih.gov/health/health-topics/topics/pah/types (accessed 5/16/2017).

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