UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.

Petitioner,

v.

UNITED THERAPEUTICS CORPORATION
Patent Owner.

Case IPR2017-01621
Patents 9,358,240

EXPERT DECLARATION OF MAUREEN D. DONOVAN, PH.D.

I. INTRODUCTION

1. I, Maureen D. Donovan, Ph.D., hereby submit my expert declaration on behalf of Defendant Watson Laboratories, Inc. ("Watson").

2. I have been retained by Watson to provide technical expertise and expert opinions regarding U.S. Patent No. 9,358,240 ("the '240 patent").

3. The opinions to which I will testify at trial, if asked, are set forth in this report. My opinions in this report are based upon the information that I have received to date. They may be supplemented or modified if additional information is received. They also may be supplemented to reply to additional information or opinions provided by the parties (or witnesses retained by the parties) and issues that may arise at trial.

4. I may rely on demonstrative exhibits at trial to assist in explaining my trial testimony.

II. PERSONAL BACKGROUND AND EXPERT QUALIFICATIONS

5. I am a Professor in the Division of Pharmaceutics and Translational Therapeutics at the University of Iowa College of Pharmacy. I have more than 25 years of experience working and consulting in the field of pharmaceutics. My *curriculum vitae* is attached to this report as Exhibit A.

6. I am an expert in pharmaceutics. I received my Bachelor of Science in Pharmacy from the University of Minnesota College of Pharmacy in 1983 and my Ph.D. in Pharmaceutics from the University of Michigan in 1989.

7. My professional experience includes working as a Staff Pharmacist for Clark Professional Pharmacy from 1986 until 1989 and as a Visiting Scholar for SmithKline Beecham Pharmaceuticals in 1991. From 1989 through the present, I have held various positions at the University of Iowa College of Pharmacy. Specifically, in the Division of Pharmaceutics, I was an Assistant Professor from 1989 until 1996, and an Associate Professor from 1996 until 2008. I was promoted to the rank of Professor in 2008 in the College of Pharmacy, and I currently hold this position. From 2008 until 2013, I was the Division Head for the Division of Pharmaceutics. In 2013, I became the Associate Dean for Undergraduate Programs at the College of Pharmacy, and I currently hold this position.

8. I have over 25 years of experience in pharmaceutical research and development including actively teaching drug delivery, pharmaceutical preformulation, and compounding to pharmacy students and graduate students, and directing research programs focused on drug absorption, nasal drug delivery, and alternative routes of drug delivery and delivery systems.

9. I have published numerous articles, book chapters, and abstracts in the area of pharmaceutics, drug absorption, drug delivery, and materials

characterization. I also belong to several professional societies for pharmaceutical science and technology, including the American Association of Pharmaceutical Scientists and the Controlled Release Society.

10. I am being compensated for my work at $250 per hour for general document and background review; $400 per hour spent preparing reports; and a daily rate of $5,000 when testifying. No part of this compensation due or received is contingent upon the outcome of this matter or the pending litigation.

11. In addition to my knowledge, education, and experience in the field of pharmaceutical formulation, in forming the opinions I express in this report, I reviewed the full list of materials cited herein.

III. SUMMARY OF OPINIONS

12. As explained in detail in section VII.C., each of the asserted claims of the ’240 patent would have been obvious in light of the prior art as of May 15, 2006, which collectively teach and motivate a person of ordinary skill in the art to make a kit comprising a therapeutically effective amount of treprostinil by inhalation in an aerosol form in a pulsed ultrasonic nebulizer utilizing an opto-acoustical trigger, with instructions for use.

IV. LEGAL STANDARDS

13. While I am neither a patent lawyer nor an expert in patent law, I have been informed of the applicable legal standards for patent invalidity. I have relied

upon these legal principles, as explained to me by counsel, in forming my opinions set forth in my report.

14. I understand that clear and convincing evidence must be presented to render a patent claim invalid. I understand that evidence is sufficiently clear and convincing if it leaves the fact-finder with a definite and firm belief in the truth of a fact.

15. I understand that, even if a single prior art reference does not disclose each and every limitation of the claim, a patent claim may still be invalid as obvious. I have been informed that the standard for obviousness for the patent-in-suit, which was filed prior to the effective date of the AIA, is set out in pre-AIA version of 35 U.S.C. §103(a), which is quoted below:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. I have been informed that in order for a patent claim to be considered obvious, at the time the invention was made, each and every limitation of the claim must be present within the prior art, or within the prior art in combination with the

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.