

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

ADAPT PHARMA OPERATIONS LIMITED, and
OPIANT PHARMACEUTICALS, INC.,
Patent Owners.

Case IPR2019-00688
U.S. Patent No. 9,468,747

DECLARATION OF ROBERT L. VIGIL, PH.D.



TABLE OF CONTENTS

I. INTRODUCTION4

 A. Assignment.....4

 B. Summary of Conclusions5

 C. Qualifications6

 D. Compensation.....8

 E. Evidence Considered.....8

II. BACKGROUND17

 A. The Challenged Patents17

 B. The Naloxone Marketplace18

 C. Naloxone Products20

 1. Vials and Pre-Filled Syringes for Injection21

 2. Unapproved and Off-Label Intranasal “Kits”22

 3. Evzio® Auto-Injector23

 4. Narcan® Nasal Spray.....27

 D. Naloxone Distribution and Reimbursement.....30

 1. Retail Segment30

 2. Public Interest Segment34

III. LEGAL FRAMEWORK35

IV. MARKETPLACE SUCCESS OF NARCAN® NASAL SPRAY36

 A. Sales Revenue and Units37

 B. Market Expansion.....40

 C. Market Share43

 1. Retail Segment43

 2. Public Interest Segment45

 D. Contribution to Acquisition of Adapt46

 E. Generic Entry47

DECLARATION OF ROBERT L. VIGIL PH.D.



V. CAUSAL NEXUS49

 A. Overview of Patented Features49

 B. Contribution of Patented Features to Consumer Demand50

 1. Patented Features Emphasized in Marketing Materials.....50

 2. Patented Features Praised by Third Parties.....54

 C. Non-Patented Features61

 1. Adapt’s Sales and Marketing Efforts.....62

 2. FDA Approval.....72

 3. Pricing.....78

I, Robert L. Vigil, Ph.D., hereby declare as follows:

I. INTRODUCTION

A. Assignment

1. This declaration is being submitted on behalf of Adapt Pharma Operations Limited (“Adapt”) and Opiant Pharmaceuticals, Inc. (“Opiant”) (collectively, “Patent Owners”) in three *inter partes* review (“IPR”) proceedings filed by Nalox-1 Pharmaceuticals, LLC (“Nalox-1”), Case Nos. IPR2019-00685, IPR2019-00688, and IPR2019-00694. Because there are a number of common issues in these IPR proceedings, I am providing a single declaration across all three IPR proceedings.

2. I have been retained to provide expert analysis and testimony regarding the commercial success of the invention described and claimed in U.S. Patent Nos. 9,211,253 (“the ’253 patent”); 9,468,747 (“the ’747 patent”); and 9,629,965 (“the ’965 patent”) (collectively, “the Adapt patents” or “the challenged patents”). I understand that Nalox-1 has challenged claims 1–29 of the ’253 patent, claims 1–45 of the ’747 patent, and claims 1–30 of the ’965 patent (“the challenged claims”) as being unpatentable as obvious.

3. Specifically, I have been asked to evaluate whether Narcan® Nasal Spray is a success in the marketplace, and whether there is a nexus between that product’s success, if any, and the invention described in the challenged patents. As

part of this assignment, I have been asked to consider whether Narcan® Nasal Spray's marketplace success reflects the product's fulfillment of long-felt need, as well as third-party praise for the invention described in the challenged patents.

4. I understand that each of the three IPR proceedings at issue has its own set of exhibit numbers. I will therefore refer to the exhibits by name; a chart of the relevant exhibit numbers in each proceeding and the short names I use to refer to different documents is attached to the end of this declaration.

5. For the purpose of my analysis, I have relied on the opinions of Dr. Stuart Jones expressed in his declaration ("Jones Decl.") that Narcan® Nasal Spray and/or the use of the Narcan® Nasal Spray embodies the challenged claims of the Adapt patents. I have not conducted an independent analysis of whether Narcan® Nasal Spray embodies every element of those claims.

B. Summary of Conclusions

6. Based upon my review and analysis of the evidence, it is my opinion that the commercial embodiment of the challenged patents and claims, Narcan® Nasal Spray, has been a marketplace success in the United States. Moreover, the challenged patents and claims have enabled key features and benefits of Narcan® Nasal Spray that have contributed to its success in the marketplace. As a result, I conclude that the invention described in the challenged patents and claims has been a commercial success. I also conclude that these features and benefits of Narcan®

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.