

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 THOMAS J. BEGRES

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I, Thomas J. Begres, declare as follows:

I. OVERVIEW

1. I am over the age of 18 and otherwise competent to make this declaration. This declaration is based on my personal knowledge and experience. I understand that this declaration is being submitted in support of the Response of Patent Owners Adapt Pharma Operations Limited and Opiant Pharmaceuticals, Inc., to petitions for *inter partes* review filed by Nalox-1 Pharmaceuticals, LLC challenging claims 1–29 of U.S. Patent Nos. 9,211,253, claims 1–45 of U.S. Patent No. 9,468,747, and claims 1–30 of U.S. Patent No. 9,629,965.

II. BACKGROUND

2. I am the Senior Director of Clinical and Medical Affairs at Emergent BioSolutions, Inc. (“Emergent”), which is now the parent company of Adapt Pharma.¹ Previously, I worked as the head of Clinical Affairs for Adapt Pharma. I started in that role at Adapt Pharma in early 2015, before the launch of Adapt Pharma’s only commercial product, Narcan® Nasal Spray. I remained in that role until after Emergent acquired Adapt Pharma in 2018, when Emergent promoted me to my current title. I refer to Adapt Pharma and Emergent collectively in this declaration as “Adapt.”

¹ By “Adapt Pharma,” I mean Patent Owner Adapt Pharma Operations Limited and its affiliates.

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3. In my role as Senior Director of Clinical and Medical Affairs at Adapt, I am the “clinical face” of Narcan® Nasal Spray in the United States and Canada. Among other things, I provide clinical information to healthcare providers and others regarding naloxone, including Narcan® Nasal Spray. I regularly interact with numerous medical professionals around North America, including medical directors of fire and emergency medical services (“EMS”) agencies and medical directors of state or local programs that provide direction on the use of medications (including naloxone) by pre-hospital providers. During these interactions, medical professionals often share with me their experiences with treating opioid overdoses with naloxone, including Narcan® Nasal Spray. I am in a noncommercial unit at Adapt, meaning I am not responsible for any marketing or direct sales.

4. In addition to my full-time job at Adapt, I am also a full-time firefighter-paramedic for the Scio Township Fire Department, which operates near Detroit, Michigan. I have been trained to provide—and do provide—both fire suppression services and EMS. I am also a licensed firefighter instructor and a licensed paramedic instructor, and I regularly teach firefighting and EMS courses, which include instruction on the administration of naloxone to treat opioid overdose. It took me approximately 2,500 hours of training to obtain these

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licenses. Throughout my 21-year career as a firefighter-paramedic, I have treated hundreds of persons suffering from opioid overdose.

5. As a firefighter-paramedic, I am an “advanced life support” provider. In the United States, there are essentially two types of EMS providers: “advanced” life support providers (often called “paramedics”), and “basic life support” providers (often called “EMTs”). Advanced life support providers receive extensive medical training and are authorized to administer a variety of medications. Basic life support providers receive limited training and are generally not authorized to administer medications.

6. In addition to my firefighter-paramedic training, I also have a Bachelor of Science in nursing and a Master of Science in Family Nurse Practitioning. I am a licensed registered nurse practitioner in Michigan, and I have over a decade of experience working as a registered nurse in hospital emergency departments. I started my nursing career at Detroit Receiving Hospital Emergency Department in the late 1990s, which is a Level 1 Trauma Center, meaning it is equipped to treat the most serious emergencies. While working as a nurse, I treated hundreds of persons suffering from opioid overdose.

7. As a result of the training and experience I have described above, I am knowledgeable about the administration of opioid antagonists to treat opioid overdoses by medically trained personnel, first responders, and in the community.

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I have clinical experience with administering opioid antagonists to overdose patients. I am also familiar with recommended practices and procedures for the treatment of opioid overdoses in hospital and pre-hospital settings, and with potential adverse effects associated with the administration of opioid antagonists and withdrawal from opioid intoxication.

8. In addition to the experience I have just described, from 1990 to 1995, I served as a police officer in South Central Los Angeles. In that role, I regularly encountered individuals who had overdosed on opioids. At that time (which was before I began my medical career), police officers in my area were not equipped to treat opioid overdoses. If we encountered a person experiencing an opioid overdose, we would radio dispatch and request EMS, then wait for EMS to arrive. Today, in contrast, officers of the Los Angeles Police Department carry Narcan® Nasal Spray to treat opioid overdose.

III. PRACTICE OF ADMINISTERING NALOXONE TO TREAT OPIOID OVERDOSE AS OF MARCH 16, 2015

9. As of March 16, 2015, I had administered naloxone hundreds of times to treat opioid overdose. The following paragraphs describe my practice when administering naloxone to treat opioid overdose, which has not changed materially since I first received training to administer naloxone over twenty years ago.

10. I have been trained to administer naloxone via a variety of routes, including intravenously, intraosseously (i.e., into the bone marrow), by

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