

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

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

Case IPR2019-00691
U.S. Patent No. 9,561,177

DECLARATION OF KENNETH A. WILLIAMS, M.D

I, Kenneth A. Williams, M.D., do hereby 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 as an expert in the fields of emergency and pre-hospital medicine. I understand that this Declaration is being submitted in support of the Preliminary Response of Patent Owners Adapt Pharma Limited and Opiant Pharmaceuticals, Inc. to a petition for *inter partes* review (“IPR”) filed by Nalox-1 Pharmaceuticals, LLC (“Nalox-1”), challenging certain claims of U.S. Patent No. 9,561,177 (“the ’177 patent”).

II. BACKGROUND AND QUALIFICATIONS

2. I am a practicing physician and am licensed in the State of Rhode Island and the Commonwealth of Massachusetts. I am a Professor of Emergency Medicine at The Warren Alpert Medical School of Brown University. I also serve as Director of Brown’s Division of Emergency Medical Services (EMS) and Program Director for Brown’s EMS Fellowships within the Brown Department of Emergency Medicine. I am also Medical Director for the LifePACT Critical Care Transport Team at Rhode Island Hospital and for Rhode Island Hospital’s Ambulance Services, which provide the only comprehensive critical care transport capability in Rhode Island and the only physician-staffed critical care transport service in New England. I also serve as the Medical Director for the Rhode Island

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Department of Health, Center for Emergency Medical Services, Division of Preparedness, Response, Infectious Disease & EMS and immediate past Chair of the Medical Director's Council for the National Association of State EMS Officials.

3. I am board-certified in both emergency medicine and emergency medical services, and have current certifications as an instructor in advanced cardiac life support and advanced trauma life support. I have been actively engaged in the practice of emergency medicine since 1984. Over the course of my career, I have treated thousands of patients experiencing opioid overdoses, and I have administered or ordered administration of naloxone to such patients on hundreds of occasions.

4. In my role as Medical Director for the Rhode Island Department of Health Center for EMS, I am responsible for the protocols that govern the scope of practice for the over 4,000 EMS practitioners working in Rhode Island. Those protocols specify, among many other things, the standard of care for pre-hospital treatment of known or suspected opioid overdose, including (when appropriate) the administration of naloxone. The protocols and standing orders I am responsible for are the product of evidence-based literature review, incorporation of input from several committees, and review of other state and national EMS guidelines and protocols.

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5. I received my undergraduate degree from Hampshire College in 1977, continued my education with Postgraduate Science Studies at the University of Massachusetts, Amherst, and received my medical degree from the University of Massachusetts Medical School in 1984. I also participated in additional training from the University of Massachusetts, Amherst in Medical Informatics, Artificial Intelligence and Knowledge Engineering, during the mid-1990s.

6. I began my residency in Emergency Medicine at the University of Pittsburgh in 1984, served as Chief Resident between 1986 and 1987, and graduated in 1987. I received a resident research award from the Emergency Medicine Foundation in 1986.

7. During my 30-plus year career in emergency medicine, I have served in numerous leadership and committee positions for various national, regional, state, and local organizations focused on the provision of emergency medicine and emergency medical services, including the Air Medical Physician Association, the Association of Air Medical Services, the Alliance for Critical Care Transport, the National Association of EMS Physicians, the American College of Emergency Physicians, the National Association of State EMS Officials, the Society for Academic Emergency Medicine, the National Registry of EMTs, the Prehospital Guidelines Consortium, and The New England Council for Emergency Medical Services, to name a few. Among other things, I am a member of the Board of

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Directors of the Rhode Island Medical Society, and I have served as President of the Air Medical Physician Association and as President of the Rhode Island chapter of the American College of Emergency Physicians.

8. I have received numerous honors and awards for my work in emergency medicine, including an Exemplary Service Award from the University Emergency Medicine Foundation, a President's Award and a Distinguished Physician Award from the Air Medical Physician Association, and the Rhode Island ACEP¹ Exceptional Service Award. I am also a fellow of the Academy of Emergency Medical Services. I have received multiple awards for my teaching of emergency medicine at Brown's Alpert Medical School.

9. I have published dozens of articles, books, and book chapters on the practice of emergency medicine. My articles have appeared in peer-reviewed journals such as the Annals of Emergency Medicine, the Air Medical Journal, Resuscitation, The American Journal of Emergency Medicine, the Rhode Island Medical Journal, and Prehospital Emergency Care. In addition, I have given hundreds of presentations on emergency medicine to local, national, and international audiences. A complete list of my publications and presentations is contained in my CV, attached as Exhibit A.

¹ ACEP stands for the American College of Emergency Physicians.

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