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 ERIC KARAS

I, Eric Karas, 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 No. 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 currently Vice President and General Manager of U.S. Commercial at Emergent BioSolutions, Inc. ("Emergent"), a pharmaceutical life sciences company. In that role, I am responsible for sales, marketing, and distribution of Narcan® Nasal Spray in the United States.

3. Narcan® Nasal Spray was originally developed by Patent Owner Adapt Pharma Operations Limited and its affiliates (which I refer to herein collectively as "Adapt Pharma"). It is Adapt Pharma's only commercial product.

4. The FDA approved Narcan® Nasal Spray in November 2015, and Adapt Pharma began marketing Narcan® Nasal Spray in the United States in

February 2016. Adapt Pharma has marketed Narcan® Nasal Spray in the United States continuously since that time.

5. I joined Adapt Pharma in December 2016 as Executive Director of Marketing. In that role, I was responsible for marketing Narcan® Nasal Spray to healthcare providers and patients. After approximately six to nine months, I was promoted to Vice President of Marketing. In that role, I remained responsible for marketing Narcan® Nasal Spray to healthcare providers and patients, but also assumed responsibility for working with third-party payors, such as insurance companies, to address coverage issues regarding Narcan® Nasal Spray.

6. In 2018, Emergent acquired Adapt Pharma. After the acquisition, Emergent promoted me to my current role. For ease of reference in this declaration, I refer to Emergent and Adapt Pharma collectively as "Adapt."

7. I have an undergraduate degree in accounting from Rutgers University, a Master of Business Administration from Michigan State University, and 23 years' experience in sales and marketing in the pharmaceutical industry. Over the course of my career, I have been involved in sales and marketing of approximately 50 pharmaceutical products.

III. BACKGROUND ON NALOXONE AND NARCAN® NASAL SPRAY

8. Adapt sells cartons of Narcan® Nasal Spray in the United States and Canada. Each carton of Narcan® Nasal Spray contains two devices. Each device contains a 4 mg dose of naloxone.

9. Adapt sells Narcan® Nasal Spray in packs of two devices for several reasons. For example, the second device serves as a backup in the rare instance that one of the devices is damaged or defective. Also, the second device serves as a backup if a caregiver fails to administer correctly the first device, for example, by attempting to "prime" it. Third, the second device provides a backup dose of naloxone for "re-dosing" a patient who does respond adequately to the first dose.

10. After the FDA approved Narcan® Nasal Spray with a 4 mg dose in November 2015, Adapt submitted to the FDA a new drug application for a version of Narcan® Nasal Spray with a 2 mg dose. Adapt went forward with submitting the 2 mg product to the FDA for approval in March 2016 because Adapt had received feedback, including from healthcare providers, pharmacists, addiction specialists, and opioid-use disorder advocates, expressing concern that a 4 mg intranasal dose may be too high for many patients. These people were concerned that Adapt's 4 mg product could cause unnecessary opioid withdrawal symptoms and other dangerous side effects.

11. Although Adapt's 2 mg product was approved by the FDA in January 2017, Adapt ultimately decided not to market the 2 mg version because of the low incidence of reported adverse events experienced by patients treated with the 4 mg version of the product. Adapt's pharmacovigilance team drew this conclusion from its review of adverse event reports regarding the product. Accordingly, Adapt has never marketed the 2 mg version of the Narcan® Nasal Spray. The only version of Narcan® Nasal Spray that Adapt has marketed contains 4 mg naloxone per device.

12. Adapt sells Narcan® Nasal Spray in two distinct market segments: The "retail" market segment and the "public interest" market segment. The retail market segment refers to sales of Narcan® Nasal Spray to patients through retail pharmacies. The public interest market segment refers to sales of Narcan® Nasal Spray to "public interest" organizations, such as government departments (e.g., federal and state departments of health), first responders (e.g., police officers, firefighters, and emergency medical services personnel), prisons, hospitals, addiction treatment centers, and various community-based organizations.

13. There are three types of naloxone products that compete with Narcan® Nasal Spray in the markets I have just described: traditional injectable naloxone, the Mucosal Atomizer Device improvised naloxone kit ("MAD kit"), and the Evzio® auto-injector.

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