

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

IPR2019-00688

U.S. Patent No. 9,468,747

SUPPLEMENTAL DECLARATION OF GÜNTHER HOCHHAUS, Ph.D.

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*Inter Partes Review of U.S. Patent No. 9,468,747
Supplemental Declaration of Günther Hochhaus, Ph.D. (Nalox1202)*

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*Inter Partes Review of U.S. Patent No. 9,468,747
Supplemental Declaration of Günther Hochhaus, Ph.D. (Nalox1202)*

I, Günther Hochhaus, 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 and experience in the field of clinical pharmacology, in particular with respect to nasal spray dosage forms. I understand that this Declaration is being submitted in support of Petitioner Nalox-1 Pharmaceuticals, LLC's ("Nalox-1") Reply to Patent Owner's Response to the petition for *Inter Partes* Review ("IPR") of certain claims of U.S. Patent No. 9,468,747 ("the 747 patent") (Nalox1001).

2. This is my second Declaration in this proceeding. Previously, I submitted a Declaration (Nalox1003) in support of Nalox-1's petition for IPR challenging the '747 patent. I refer to that Declaration hereinafter as "my first Declaration."

3. I have now been asked to supplement the opinions I expressed in my first Declaration. I have also been asked to respond to certain opinions contained in the Declarations of Kenneth A. Williams, M.D. (Ex-2001; Ex-2202) and Stuart A. Jones, Ph.D. (Ex-2201).

4. In preparing this Declaration, I have reviewed the '747 patent and its file history. I have also considered each of the documents listed in the table below, in addition to the exhibits disclosed in my first Declaration. *See* Nalox1003, ¶5.

***Inter Partes Review of U.S. Patent No. 9,468,747
Supplemental Declaration of Günther Hochhaus, Ph.D. (Nalox1202)***

Exhibit No.	Description
Nalox1001	U.S. Patent No. 9,468,747 (the '747 patent)
Nalox1002	Expert Declaration of Maureen Donovan
Nalox1003	Expert Declaration of Günther Hochhaus (my first Declaration)
Nalox1007	U.S. Patent No. 9,192,570 (Wyse)
Nalox1008	Chinese Patent No. 1,575,795 (Wang)
Nalox1009	PCT International App. Pub. No. WO00/62757 (Davies)
Nalox1016	Wermeling, D., <i>A Response to the Opioid Overdose Epidemic: Naloxone Nasal Spray</i> , 3 Drug Deliv. & Transl. Res. 63–74 (2013) (Wermeling 2013)
Nalox1017	Alabama Department of Public Health, <i>Alabama EMS Patient Care Protocols</i> (7th ed., Oct. 2013) (Alabama EMS Protocols)
Nalox1020	Barton, E. et al., <i>Intranasal Administration of Naloxone by Paramedics</i> , 6 Prehosp. Em. Care 54–58 (Barton 2002)
Nalox1023	Boyer, E., <i>Management of Opioid Analgesic Overdose</i> , 367(2) N. Engl. J. Med. 146–55 (2012) (Boyer)
Nalox1025	Excerpt of Commonwealth of Kentucky, <i>Kentucky Patient Care Protocols</i> (Mar. 13, 2015) (Kentucky Patient Care Protocols)
Nalox1027	Dowling, J. et al., <i>Population Pharmacokinetics of Intravenous, Intramuscular, and Intranasal Naloxone in Human Volunteers</i> , 30(4) Ther. Drug. Monit. 490–96 (2008) (Dowling)
Nalox1034	Kelly, A-M. et al., <i>Randomised Trial of Intranasal Versus Intramuscular Naloxone in Prehospital Treatment for Suspected Opioid Overdose</i> , 182(1) Med. J. Austl. 24–27 (2005) (Kelly)

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