

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NALOX-1 PHARMACEUTICALS, LLC,

Petitioner

v.

ADAPT PHARMA OPERATIONS LIMITED, AND  
OPIANT PHARMACEUTICALS, INC.

Patent Owners

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IPR2019-00694

U.S. Patent No. 9,629,965

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**SUPPLEMENTAL DECLARATION OF GÜNTHER HOCHHAUS, Ph.D.**

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*Inter Partes Review of U.S. Patent No. 9,629,965  
Supplemental Declaration of Günther Hochhaus, Ph.D. (Nalox1202)*

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*Inter Partes Review of U.S. Patent No. 9,629,965  
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. 9,629,965 ("the 965 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 '965 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 '965 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. 9,629,965  
Supplemental Declaration of Günther Hochhaus, Ph.D. (Nalox1202)*

| Exhibit No.      | Description   |
|------------------|---|
| <b>Nalox1001</b> | U.S. Patent No. 9,629,965 (the '965 patent)   |
| <b>Nalox1002</b> | Expert Declaration of Maureen Donovan   |
| <b>Nalox1003</b> | Expert Declaration of Günther Hochhaus (my first Declaration)   |
| <b>Nalox1007</b> | U.S. Patent No. 9,192,570 (Wyse)  |
| <b>Nalox1008</b> | Chinese Patent No. 1,575,795 (Wang)   |
| <b>Nalox1009</b> | PCT International App. Pub. No. WO00/62757 (Davies)   |
| <b>Nalox1016</b> | Wermeling, D., <i>A Response to the Opioid Overdose Epidemic: Naloxone Nasal Spray</i> , 3 Drug Deliv. & Transl. Res. 63–74 (2013) (Wermeling 2013)   |
| <b>Nalox1017</b> | Alabama Department of Public Health, <i>Alabama EMS Patient Care Protocols</i> (7th ed., Oct. 2013) (Alabama EMS Protocols)   |
| <b>Nalox1020</b> | Barton, E. et al., <i>Intranasal Administration of Naloxone by Paramedics</i> , 6 Prehosp. Em. Care 54–58 (Barton 2002)   |
| <b>Nalox1023</b> | Boyer, E., <i>Management of Opioid Analgesic Overdose</i> , 367(2) N. Engl. J. Med. 146–55 (2012) (Boyer)   |
| <b>Nalox1025</b> | Excerpt of Commonwealth of Kentucky, <i>Kentucky Patient Care Protocols</i> (Mar. 13, 2015) (Kentucky Patient Care Protocols)   |
| <b>Nalox1027</b> | 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)        |
| <b>Nalox1034</b> | 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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