

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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Case IPR2019-00685  
U.S. Patent No. 9,211,253

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**SECOND DECLARATION OF KENNETH A. WILLIAMS, M.D.**

**DECLARATION OF KENNETH A. WILLIAMS**

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I, Kenneth A. Williams, M.D., declare as follows:

## **I. OVERVIEW**

1. I am over the age of 18 and 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 Response of Patent Owners Opiant Pharmaceuticals, Inc. (“Opiant”) and Adapt Pharma Operations Limited (“Adapt”) to petitions for *inter partes* review (“IPR”) filed by Nalox-1 Pharmaceuticals, LLC (“Nalox-1”), challenging U.S. Patent Nos. 9,211,253 (“the ’253 patent”), 9,468,747 (“the ’747 patent”), and 9,629,965 (“the ’965 patent”).

2. This is my second declaration in this proceeding. Earlier this year, I submitted a declaration in support of Opiant’s preliminary responses to Nalox-1’s petitions challenging the ’253, ’747, and ’965 patents. *See* IPR2019-00685, Exhibit 2001; IPR201900688, Exhibit 2001; IPR201900694, Exhibit 2001. I refer to that declaration hereinafter as “my first declaration.”

3. In preparing this declaration, I have reviewed the ’253, ’747, and ’965 patents and their file histories; the petitions for *inter partes* review filed by Nalox-1 challenging those patents; the exhibits submitted in support of Nalox-1’s petitions, including the declarations and deposition transcripts of Maureen Donovan, Ph.D. and Günther Hochhaus, Ph.D; Patent Owner Opiant Pharmaceuticals, Inc.’s

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preliminary responses to Nalox-1's petitions and the exhibits submitted in support thereof; and the Board's orders instituting trial on the petitions. I have considered the materials cited herein, as well as in my first declaration. I have also relied on my professional judgment and expertise.

4. I understand that each of the three IPR proceedings at issue has its own set of exhibit numbers. I will therefore refer to the exhibits by name; a chart of the relevant exhibit numbers in each proceeding and the short names I use to refer to different documents is attached to the end of this declaration.

5. I am being compensated at the rate of \$500 per hour for my time spent working on this matter. My compensation is not contingent on my findings, testimony rendered, or on the outcome of this proceeding.

## **II. LEGAL STANDARDS**

### **A. Obviousness**

6. I understand that a patent claim is "obvious," and thus invalid, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill ("POSA") in the art to which said subject matter pertains. I understand that factual determinations relevant to the obviousness inquiry include (a) the scope and content of the prior art, (b) the differences between the claimed invention and the prior art, (c) the level of

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