

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 IPR2019-00685
U.S. Patent 9,211,253

SUPPLEMENTAL DECLARATION OF STUART A. JONES, PH.D.

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I, Stuart A. Jones, Ph.D., declare as follows:

I. INTRODUCTION

1. I am an expert in the field of drug development, including the fields of intranasal drug formulation, drug delivery, dosage form design, formulation manufacture, and pharmacokinetics.

2. I understand that this declaration is being submitted in support of Patent Owners Adapt Pharma Operations Limited and Opiant Pharmaceuticals, Inc. (collectively, “Adapt”) in three proceedings before the Patent Trial & Appeal Board—IPR2019-00685, IPR2019-00688, and IPR2019-00694—in which Petitioner Nalox-1 Pharmaceuticals, LLC (“Nalox-1”) has challenged the patentability of certain claims of U.S. Patent Nos. 9,211,253 (“the ’253 patent”), 9,468,747 (“the ’747 patent”), and 9,629,965 (“the ’965 patent”) (collectively, “the Adapt patents” or “the challenged patents”).

3. I am over the age of 18 and otherwise competent to make this declaration. I am being compensated at my customary hourly rate of £320.00, as well as reimbursement of reasonable business expenses. My compensation is not contingent upon the outcome of these proceedings or the opinions I reach.

4. This is my second declaration in these proceedings. I submitted my first declaration on December 23, 2019. *See* Declaration of Stuart A. Jones, Ph.D., Ex. 2201 (“First Jones Decl.”). I have been asked to supplement the opinions set

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forth in my first declaration to respond to certain opinions offered in the Supplemental Declaration of Maureen Donovan, Ph.D. (Nalox1201) (“Supp. Donovan Decl.”). In this declaration, I apply the legal principles of obviousness and the same definition of the the person of ordinary skill in the art (“POSA”) that I set forth in my first declaration. First Jones Decl. (Ex. 2201) ¶¶ 29–44.

5. In preparing this declaration, I have considered the documents cited in my first declaration, the Supplemental Declaration of Dr. Donovan and the documents she cited in it, and the additional documents identified herein. I understand that each of the three IPR proceedings at issue has its own set of exhibit numbers, but that the same exhibit numbers have been maintained for the same exhibits across the three proceedings. I will therefore refer to the exhibits by name; a chart of the relevant exhibit numbers in and the short names I use to refer to different documents is attached to the end of this declaration.

6. Having considered Dr. Donovan’s supplemental declaration, it remains my opinion that none of claims 1–29 of the ’253 patent, claims 1–45 of the ’747 patent, or claims 1–30 of the ’965 patent (“the challenged claims”) would have been obvious to the POSA.

II. BACKGROUND & QUALIFICATIONS

7. In addition to the experience and qualifications described in my previous declaration, *see, e.g.*, First Jones Decl. (Ex. 2201) ¶¶ 1, 10–21, I have the

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following experience and qualifications relevant to my response to Dr. Donovan set forth in this supplemental declaration.

8. My research involves the use of surfactants to design drug delivery systems. I also have studied how surface active excipients influence the formulation characteristics and pharmacokinetics of intranasal medicines. I also have expertise in chemistry, including the physical chemistry of drug-excipient interactions, as well as expertise concerning the ability of metal complexes to influence the physical and chemical stability of formulations. My research and experience in these areas have been the subject of grants I have received and studies published in peer-reviewed scientific journals, as described in my curriculum vitae, previously submitted as Exhibit 2200.

9. In addition to my research, I have been a reviewer for *Langmuir*, a scientific journal published by the American Chemistry Society, including for review articles attempting to understand surfactant behavior in formulations and the use of surfactant micelles to enhance the delivery of drugs.

III. THE POSA WOULD HAVE FOLLOWED WYSE'S TEACH-AWAY CONCERNING BZK AND NALOXONE.

10. In her Supplemental Declaration, Dr. Donovan opines for the first time that BZK “does not act as an oxidizing agent in pharmaceutical formulations” and therefore “could not have been responsible” for the naloxone degradation observed in Wyse. Supp. Donovan Decl. (Nalox1201) ¶¶ 12, 15 & n.7, 16. Dr.

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