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

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

SUPPLEMENTAL DECLARATION OF MAUREEN DONOVAN, Ph.D.

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I, Maureen D. Donovan, Ph.D., 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 as an expert in the field of pharmaceutical formulation, in particular intranasal formulation. I understand that this Declaration is being submitted in support of Petitioner Nalox-1 Pharmaceuticals, LLC's ("Nalox-1") Reply to Patent Owners' Response to the petition for *Inter Partes* Review ("IPR") of certain claims of U.S. Patent No. 9,211,253 ("the '253 patent") (Nalox1001).

2. This is my second Declaration in this proceeding. Previously, I submitted a Declaration (Nalox1002) in support of Nalox-1's petition for IPR challenging the '253 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 Declaration of Stuart A. Jones, Ph.D. (Ex-2201) and the Declarations of Kenneth A. Williams, M.D. (Ex-2001 and Ex-2202).

4. In preparing this Declaration, I have reviewed the '253 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* Nalox1002, ¶5.

Exhibit No.	Description
Nalox1001	U.S. Patent No. 9,211,253 (the ’253 patent)
Nalox1002	Expert Declaration of Maureen Donovan (my first Declaration)
Nalox1007	U.S. Patent No. 9,192,570 (Wyse)
Nalox1010	Djupesland, P., *Nasal Drug Delivery Device: Characteristics and Performance in a Clinical Perspective – A Review*, 3 Drug Deliv. & Transl. Res. 42–62 (2013) (Djupesland)
Nalox1012	Handbook of Pharmaceutical Excipients (Rowe, R. et al. eds., 6th ed. 2009) (HPE)
Nalox1015	U.S. Patent No. 8,198,291 (the ‘291 patent)
Nalox1022	Bitter, C. et al., *Nasal Drug Delivery in Humans*, 40 Curr. Probl. Dermatol. 20–35 (2011) (Bitter)
Nalox1028	FDA, Center for Drug Evaluation and Research, Guidance for Industry, Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products – Chemistry, Manufacturing, and Controls Documentation (2002) (2002 FDA Guidance)
Nalox1031	Glende, O., *Development of non-injectable naloxone for pre-hospital reversal of opioid overdose: A Norwegian project and a review of international status* (May 2016) (unpublished M.A. thesis, Norwegian University of Science and Technology) (on file with Norwegian University of Science and Technology) (Glende)
Nalox1044	Physicians’ Desk Reference, *NARCAN [Naloxone Hydrochloride Injection, USP]*, *IMITREX Nasal Spray [Sumatriptan]*, 1300–02, 1546–50 (57th ed., 2003) (PDR 2003)
Nalox1206	Bureš, F., *Quaternary Ammonium Compounds: Simple in Structure, Complex in Application*, 377(14) Topics in Current Chemistry (2019) (Bureš)

Exhibit No.	Description
Nalox1208	Connors, K. et al., *Oxidation and Photolysis, in* Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists 82–114 (2d ed. 1986) (Connors)
Nalox1210	Ehrick, J. et al., *Considerations for the Development of Nasal Dosage Forms, in* Sterile Product Development: Formulation, Process, Quality and Regulatory Considerations 99–144 (Parag Kolhe, et al., eds., 2013) (Ehrick)
Nalox1213	FDA, Center for Drug Evaluation and Research, Guidance for Industry, *Q8(R2) Pharmaceutical Development* (Revision 2 2009) (2009 FDA Guidance)
Nalox1214	Hiom, S., *Preservation of Medicines and Cosmetics, in* Principles and Practice of Disinfection, Preservation & Sterilization 484–514 (Fraise, A.P. et al., eds., 4th ed. 2004) (Hiom)
Nalox1218	Hsu, H. et al., *Effect of Formulation Variables on the Nasal Permeability and Stability of Naloxone Intranasal Formulations*, 20(232) AAPS PharmaSciTech (2019) (Hsu)
Nalox1219	*Inactive Ingredient Search for Approved Drug Products, Search Names Beginning with B*, U.S. FDA (Mar. 3, 2020, 12:08 PM), https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm?event=browseByLetter.page&Letter=B (FDA B Names)
Nalox1220	*Inactive Ingredient Search for Approved Drug Products: Frequently Asked Questions*, U.S. FDA (Mar. 3, 2020, 12:12 PM), https://www.fda.gov/drugs/drug-approvals-and-databases/inactive-ingredient-search-approved-drug-products-frequently-asked-questions (FDA FAQ)
Nalox1227	Marx, D. et al., *Intranasal Drug Administration – An Attractive Delivery Route for Some Drugs*, InTech Open (2015) (Marx)

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