

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC and AMNEAL
PHARMACEUTICALS OF NEW YORK, LLC,
Petitioners

v.

ALMIRALL, LLC,
Patent Owner

Case IPR2019-00207
Patent 9,517,219

SUPPLEMENTAL DECLARATON OF DAVID W. OSBORNE, PH.D.

I, David W. Osborne, do hereby declare as follows:

1. I am over the age of 18 and otherwise competent to make this declaration. I have been retained as an expert on behalf of patent owner Almirall, LLC (“Almirall”). I understand this declaration is being submitted to supplement my first declaration, which was submitted in connection with Almirall’s Patent Owner Response to the Petition for *Inter Partes* Review (“IPR”) of claims 1-8 of U.S. Patent No. 9,517,219 (“the ’219 patent”) (Ex. 1001).

2. I am being compensated for my time in connection with this IPR at my standard legal consultant rate of \$500/hr. My compensation is not contingent on the outcome of this case.

Exhibit 2049 (Poulsen)

3. Exhibit 2049, Boyd Poulsen, *Development Process in Topical Dosage Forms*, AAPS/FDA Joint Workshop on Topical Product Development: Principles and Criteria for the Development and Optimization of Topical Therapeutic Products, Arlington, VA (Mar. 26, 1990) (“Poulsen”), is a copy of the program for an AAPS/FDA Joint Workshop on Topical Product Development titled Principles and Criteria for the Development and Optimization of Topical Therapeutic Products, which took place March 26–28, 1990, at the Hyatt Regency Crystal City in Arlington, Virginia, and the printed presentation of Boyd J. Poulsen, Ph.D.,

titled “Development Process in Topical Dosage Forms,” presented at 10:50 a.m. on Monday, March 26, 1990, as part of that Joint Workshop.

4. The program was printed and distributed in advance of the Joint Workshop. The Joint Workshop was put on jointly by the AAPS, which is the American Association of Pharmaceutical Scientists, a professional scientific organization with thousands of members, and the FDA. The Joint Workshop was open to the public, provided they paid a fee for attendance.

5. Dr. Poulsen’s presentation was printed and distributed to all attendees of the Joint Workshop.

6. I personally attended the Joint Workshop and Dr. Poulsen’s presentation. I estimate there were 300–500 people in attendance.

7. In advance of the Joint Workshop, I, like other attendees, received in the mail a printed copy of the program for the Joint Workshop, setting forth the schedule of the workshop, topics of presentations to be given at the workshop, and various other items relating to the workshop.

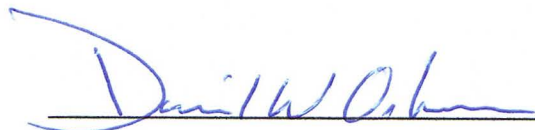
8. I confirm that Pages 1–4 of Exhibit 2049 are true and accurate copies of the printed program in advance of the Joint Workshop.

9. At Dr. Poulsen’s presentation at the Joint Workshop, I, like other attendees, received a printed copy of Dr. Poulsen’s presentation.

10. I confirm that Pages 5–50 of Exhibit 2049 are true and accurate copies of the printed presentation of Dr. Poulsen distributed at the Joint Workshop, with my handwritten notes taken during the presentation. My handwritten notes appear on Pages 5 (my name), 8, 11, 16, 21–24, 46 and 49.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine, imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

EXECUTED at Fort Collins, Colorado this 30th day of August, 2019.



David W. Osborne, Ph.D.