

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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**PETITIONER NALOX-1 PHARMACEUTICALS, LLC's  
REQUEST FOR ORAL ARGUMENT**

***IPR2019-00685 – U.S. Patent No. 9,211,253  
Petitioner’s Request for Oral Argument***

Pursuant to 37 C.F.R. § 42.70(a), the Scheduling Order entered on September 9, 2019 and the Conduct of Proceedings Order entered on November 25, 2019, Petitioner Nalox-1 Pharmaceuticals, LLC (“Petitioner”) respectfully requests oral argument on May 19, 2020. Petitioner proposes (and Patent Owners agree) that the Board conduct a consolidated proceeding in *Inter Partes* Review Nos. IPR2019-00685, -00688, and -00694, as well as any matters joined therewith, as these cases all are scheduled for hearing on the same date, relate to related patents, and the challenge is on identical art.

For these proceedings, the parties have agreed that Petitioner will have a total of forty-five (45) minutes to present its arguments, including time to be reserved for rebuttal, and that Patent Owners will have a total of forty-five (45) minutes to present its responsive arguments, subject to approval by the Board.

The parties will exchange demonstrative exhibits seven (7) business days in advance of the oral hearing in accordance with 37 C.F.R. § 42.70(b). The parties have agreed that any demonstratives will address the issues for all three of IPR2019-00685, -00688, and -00694 per side, and that any references to exhibits and papers will be made to the exhibits and papers filed in IPR2019-00688 for issues common across all IPRs, except that references to other proceedings’ pleadings and exhibits may be made only when necessary to address issues specific to those proceedings.

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Without waiving any issue not specifically listed below, Petitioner identifies the following issues to be argued at the May 19, 2020 hearing:

1) Whether it would have been obvious to a person of ordinary skill in the art (“POSA”) to use benzalkonium chloride (“BAC”) in an intranasal naloxone formulation;

2) Whether the claimed dose of 4 mg of naloxone hydrochloride would have been obvious to a POSA;

3) Whether any evidence of secondary considerations supports patentability, including the following:

- a. Unexpected results;
- b. Skepticism;
- c. Failure of others;
- d. Long-felt but unresolved need; and
- e. Commercial success.

4) Arguments and evidence presented in any motions to exclude evidence or response thereto.

5) Any other issues that the Board deems necessary to issue a final written decision.

Petitioner requests the use of audio/visual equipment to display demonstrative exhibits, including the use of a document camera or “Elmo,” and a

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computer/projector/screen system. In accordance with Trial Practice Guide, 77 Fed. Reg. at 48768, Petitioner will work with the Board Trial Division regarding this request.

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Date: April 6, 2020

Respectfully submitted,

*/s/ Yelee Y. Kim*

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