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Paper No. 13
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

ADAPT PHARMA LIMITED, and
OPIANT PHARMACEUTICALS, INC.,
Patent Owners.

IPR2019-00697
Patent 9,775,838 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and JACQUELINE T. HARLOW, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Nalox-1 Pharmaceuticals, LLC ("Petitioner"), filed a Petition requesting *inter partes* review of claims 1–46 ("the challenged claims") of U.S. Patent No. 9,775,838 B2 (Ex. 1001, "the '838 patent"). Paper 1 ("Pet."). Adapt Pharma Limited and Opiant Pharmaceuticals, Inc. (collectively, "Patent Owner") timely filed a Preliminary Response. Paper 9 ("Prelim. Resp.").

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the information presented in the petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Having considered the evidence and arguments of record, we agree with Patent Owner that the prior art teaches away from the claimed invention, and, therefore, decline to institute *inter partes* review.

A. Related Matters

The parties identify the following district court cases involving the '838 patent: *Adapt Pharma Operations Ltd. v. Teva Pharmaceuticals USA*, No. 2:16-cv-07721 (D.N.J.); *Adapt Pharma Operations Ltd. v. Perrigo UK FINCO Limited Partnership*, No. 2:18-cv-15287 (D.N.J.). Pet. 8; Paper 6, 2. Petitioner is not a party in either of those cases. Petitioner additionally challenges claims 1–46 of the '838 patent in two other petitions concurrently filed in IPR2019-00698 and IPR2019-00699.

The ’838 patent is one of five patents listed in the Orange Book for intranasal naloxone sold under the brand name NARCAN. Pet. 1; Paper 9, 1. Petitioner has also filed petitions for *inter partes* review of claims of each of those other four patents. Paper 6, 1–2.

B. The ’838 Patent

The ’838 patent is directed to “pharmaceutical compositions comprising an opioid receptor antagonist, medical devices for delivery of the pharmaceutical compositions, and methods of using the compositions and the medical devices.” Ex. 1001, 1:35–39. In particular, the Specification discloses what is described as an “improved single-use, pre-primed device adapted for nasal delivery of a pharmaceutical solution to a patient” comprising naloxone hydrochloride or a hydrate thereof. *Id.* at 2:66–3:2. Naloxone is an opioid receptor antagonist approved for use by injection for the reversal of opioid overdose. *Id.* at 2:9. According to the Specification, the improvement derives from administering naloxone nasally with a device being adapted to spray a round plume with an ovality ratio less than about two. *Id.* at 3:3–5. Additionally, the Specification explains that nasal delivery of naloxone is “considered an attractive route for needle-free, systemic drug delivery, especially when rapid absorption and effect are desired. In addition, nasal delivery may help address issues related to poor bioavailability, slow absorption, drug degradation, and adverse events (AEs) in the gastrointestinal tract and avoids the first-pass metabolism in the liver.” Ex. 1001, 10:52–58.

The disclosed compositions comprise benzalkonium chloride ("BAC"). *Id.* at 13:67–14:16. The Specification explains that BAC "can function as a preservative (even in low amounts), a permeation/penetration enhancer, and/or a cationic surfactant (typically at a higher amount for these latter two)." *Id.* at 14:16–19.

C. Illustrative Claim

Claims 1 and 41 are the only independent claims of the '838 patent. Claim 1, reproduced below, is illustrative of the claimed subject matter.

> 1. A method of treating opioid overdose, the method comprising:
> delivering a 25–200 μL spray of a pharmaceutical solution from a pre-primed device into a nostril of a patient,
> wherein the device is adapted for nasal delivery,
> wherein the spray delivers between about 4 mg and about 10 mg naloxone, an isotonicity agent, and *between about 0.005% and about 0.015% (w/v) of benzalkonium chloride*.

Ex. 1001, 63:5–13 (emphasis added).

Independent claim 41 recites a method of treating narcotic-induced respiratory depression, wherein the method similarly requires the spray of a pharmaceutical solution from a pre-primed device into a nostril of a patient to deliver between about 4 mg and about 10 mg naloxone, an isotonicity agent, and "between about 0.005% and about 0.015% (w/v) of benzalkonium chloride." *Id.* at 65:16–19.

D. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–46 under 35 U.S.C. § 103 on the following grounds:

Claim(s)	References
1–4, 18–23, 25–29, 30–34, 36, 39–40	Wyse[1] and HPE[2]
5–12	Wyse, HPE, and Wang[3]
13–17, 41–46	Wyse, HPE, and the '291 patent[4]
24, 35, 37	Wyse, HPE, and Djupesland[5]
38	Wyse, HPE, Djupesland, and Zomig Review[6]

Petitioner also relies on the Declarations of Maureen D. Donovan, Ph.D. (Ex. 1002) and Günther Hochhaus, Ph.D. (Ex. 1003) to support its challenge.

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[1] Wyse et al., U.S. Patent No. 9,192,570 B2, issued Nov. 24, 2015 ("Wyse") (Ex. 1007).
[2] Handbook of Pharmaceutical Excipients, 56–60, 64–66, 78–81, 220–22, 242–44, 270–72, 441–45, 517–22, 596–98 (Rowe et al. eds., 6th ed. 2009) ("HPE") (Ex. 1012).
[3] Wang et al., Chinese Patent Publication No. CN 1575795 A, published February 9, 2005 ("Wang") (Ex. 1008).
[4] Wermeling, U.S. Patent No. 8,198,291 B2, issued June 12, 2012 ("the '291 patent") (Ex. 1015).
[5] Djupesland, *Nasal Drug Delivery Device: Characteristics and Performance in a Clinical Perspective - A Review*, 3 DRUG DELIV. & TRANSL. RES. 42–62 (2013) ("Djupesland") (Ex. 1010).
[6] CDC, NDA No. 21-450 Clinical Pharmacology & Biopharmaceutics Review (2002) ("Zomig Review") (Ex. 1024).

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