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Paper No. 11
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

OPIANT PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2019-00689
Patent 9,468,747 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)

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I. INTRODUCTION

Nalox-1 Pharmaceuticals, LLC ("Petitioner") filed a Petition seeking an *inter partes* review of claims 1–45 ("the challenged claims") of U.S. Patent No. 9,468,747 B2 ("the '747 patent," Ex. 1001). Paper 1 ("Pet."). Opiant Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314. For the reasons provided below, we exercise our discretion under 35 U.S.C. § 314 to deny institution of an *inter partes* review.

A. Related Proceedings

The parties identify the following district court cases involving the '747 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. 6; Paper 5, 2. Petitioner is not a party in either of those cases.

In addition to the instant Petition, Petitioner challenges claims 1–45 of the '747 patent in two other petitions concurrently filed in IPR2019-00688 and IPR2019-00690. The '747 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 5, 1–2.

B. The '747 Patent

Opioid overdose is a crisis in the United States. Ex. 1001, 6:43. Naloxone is an opioid receptor antagonist that was initially approved for use

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by injection for the reversal of opioid overdose. *Id.* at 2:13–14. According to the Specification, administering naloxone via injection requires trained medical personnel and imposes the risk of exposure to blood borne pathogens through needlestick injury. Ex. 1001, 6:20–32. The '747 patent discloses that "it ha[d] been suggested that in view of the growing opioid overdose crisis in the US, naloxone should be made available over-the-counter (OTC), which would require a device, such as a nasal spray device, that untrained consumers are able to use safely." *Id.* at 6:42–46.

The '747 patent acknowledges that nasal administration of naloxone was known and used by numerous medical services and health departments. Ex. 1001, 2:29–6:13, *see also id.* at 4:39–42 ("Overdose education and nasal naloxone distribution (OEND) programs are community-based interventions that educate people at risk for overdose and potential bystanders on how to prevent, recognize and respond to an overdose."). The Specification explains, however, that although some studies "reported that the nasal administration of naloxone is as effective as the intravenous route in opiate addicts," other studies have "reported that naloxone administered intranasally displays a relative bioavailability of 4% only and concluded that the IN [intranasal] absorption is rapid but does not maintain measurable concentrations for more than an hour." *Id.* at 2:47–55. The '747 patent states

> Thus, there remains a need for durable, easy-to-use, needleless devices with storage-stable formulations, that can enable untrained individuals to quickly deliver a therapeutically effective dose of a rapid-acting opioid antagonist to an opioid overdose patient. The therapeutically effective dose should be sufficient to obviate the need for the untrained individual to

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> administer either a second dose of opioid antagonist or an alternative medical intervention to the patient, and to stabilize the patient until professional medical care becomes available.

Id. at 6:52–61.

According to the Specification, the disclosed invention relates to devices adapted for nasal delivery of "a therapeutically effective amount of an opioid antagonist selected from naloxone and pharmaceutically acceptable salts thereof, wherein the device is pre-primed, and wherein the therapeutically effective amount, is equivalent to about 2 mg to about 12 mg of naloxone hydrochloride." *Id.* at 6:63–7:2.

C. Illustrative Claims

Claims 1 and 30 of the '747 patent, reproduced below, are the only independent claims challenged, and are illustrative of the claimed subject matter.

> 1. A method of treatment of opioid overdose or a symptom thereof, comprising nasally administering to a patient in need thereof a dose of naloxone hydrochloride using a single-use, pre-primed device adapted for nasal delivery of a pharmaceutical composition to a patient by one actuation of said device into one nostril of said patient, having a single reservoir comprising a pharmaceutical composition which is an aqueous solution of about 100 μL comprising:
>
> about 4 mg naloxone hydrochloride or a hydrate thereof;
>
> between about 0.2 mg and about 1.2 mg of an isotonicity agent;
>
> between about 0.005 mg and about 0.015 mg of a compound which is at least one of a preservative, a cationic surfactant, and a permeation enhancer;
>
> between about 0.1 mg and about 0.5 mg of a stabilizing agent; and
>
> an amount of an acid sufficient to achieve a pH of 3.5-5.5.

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30. A pharmaceutical formulation for intranasal administration comprising, in an aqueous solution of not more than about 140 μL:
about 4 mg naloxone hydrochloride or a hydrate thereof;
between about 0.2 mg and about 1.2 mg of an isotonicity agent;
between about 0.005 mg and about 0.015 mg of a compound which is at least one of a preservative, a cationic surfactant, and a permeation enhancer;
between about 0.1 mg and about 0.5 mg of a stabilizing agent;
an amount of an acid sufficient to achieve a pH of 3.5-5.5.

D. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–45 under 35 U.S.C. § 103 on the following grounds:

Claims	References
1–7, 16, 30–33	Wang,[1] Djupesland,[2] HPE,[3] Bahal,[4] and Kushwaha[5]
10–15, 17–29, 34–39	Wang, Djupesland, HPE, Bahal, Kushwaha, and Wyse[6]

[1] Wang et al., Chinese Patent Publication No. CN 1575795 A, published February 9, 2005 ("Wang") (Ex. 1008).
[2] Djupesland, *Nasal Drug Delivery Devices: Characteristics and Performance in a Clinical Perspective - A Review*, 3 DRUG DELIV. & TRANSL. RES. 42–62 (2013) ("Djupesland") (Ex. 1010).
[3] 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).
[4] Bahal et al., U.S. Patent No. 5,866,154, issued February 2, 1999 ("Bahal") (Ex. 1014).
[5] Kushwaha et al., *Advances in Nasal Trans-Mucosal Drug Delivery*, 01(07) J. APPLIED PHARM. Sci. 21–28 (2011) ("Kushawaha") (Ex. 1013).
[6] U.S. Patent No. 9,192,570, issued November 24, 2015 ("Wyse") (Ex. 1007).

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