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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 IPR2019-00688
Patent 9,468,747 B2

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

YANG, *Administrative Patent Judge*.

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

INTRODUCTION

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

Under the statute, an *inter partes* review may not be instituted unless the information presented in the petition and the preliminary response shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). On April 24, 2018, the Supreme Court held that a decision under § 314 may not institute review on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355–56 (2018).

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Thus, based on the information presented, and under *SAS*, we institute an *inter partes* review of claims 1–45 of the '747 patent.

Related Proceedings

Petitioner concurrently filed IPR2019-00689 and IPR2019-00690, challenging the same claims of the '747 patent with additional prior art.

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 also filed petitions for *inter partes* review, challenging the other four patents listed. Pet. 7; Paper 5, 1–2.

According to the parties, Patent Owner asserted all five Orange-Book-listed patents in *Adapt Pharma Operations Ltd. v. Teva Pharmaceuticals*

USA, Inc., Case 2:16-cv-07721 (D.N.J.) (consolidated, "the Teva Case"), and *Adapt Pharma Operations Ltd. v. Perrigo UK FINCO Limited Partnership*, Case 2:18-cv-15287 (D.N.J.) ("the Perrigo Case"). Pet. 7; Paper 5, 2. Petitioner is not involved in those actions. Pet. 7.

Background of Technology and 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 by injection for the reversal of opioid overdose. *Id.* at 2:13–14. Naloxone hydrochloride injection prevents or reverses the effects of opioids, "including respiratory depression, sedation and hypotension." Ex. 1044,[1] 1300.

According to the '747 patent, 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

[1] Physicians' Desk Reference 2003, entry for NARCAN (Naloxone Hydrochloride Injection, USP).

that educate people at risk for overdose and potential bystanders on how to prevent, recognize and respond to an overdose."). It points out, however, although some studies "reported that the nasal administration of naloxone is as effective as the intravenous route in opiate addicts," others "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 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 '747 patent, its 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.

Illustrative Claims

Among the challenged claims, claims 1 and 30 are independent, and are reproduced below:

> 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.

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.

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