

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 IPR2019-00695
Patent 9,629,965 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and
MICHAEL A. VALEK, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

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

INTRODUCTION

Nalox-1 Pharmaceuticals, LLC (“Petitioner”) filed a Petition (Paper 1 (“Pet.”)), seeking an *inter partes* review of claims 1–30 of U.S. Patent No. 9,629,965 B2 (“the ’965 patent,” Ex. 1001). Opiant Pharmaceuticals, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 6 (“Prelim. Resp.”).

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

Related Proceedings

Petitioner challenges claims 1–30 of the ’965 patent in two other concurrently filed petitions. In IPR2019-00694, Petitioner relies on Wyse¹ as the primary reference; and in IPR2019-00696, Petitioner relies on Davies² as the primary reference.

The ’965 patent is one of five patents listed in the Orange Book for intranasal naloxone sold under the brand name NARCAN. Pet. 1; Paper 8, 1. Petitioner also filed petitions for *inter partes* review, challenging the other four patents listed. Pet. 6; Paper 4, 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*

¹ Wyse et al., U.S. Patent No. 9,192,570 B2, issued November 24, 2015 (Ex. 1007).

² Davies et al., PCT Publication WO 00/62757, published October 26, 2000 (Ex. 1009).

Partnership, Case 2:18-cv-15287 (D.N.J.). Pet. 6; Paper 4, 2. Petitioner is not involved in those actions. Pet. 6.

Background of Technology and the '965 Patent

Opioid overdose is a crisis in the United States. Ex. 1001, 6:46. Naloxone is an opioid receptor antagonist that was initially approved for use by injection for the reversal of opioid overdose. *Id.* at 2:15–16. Naloxone hydrochloride injection prevents or reverses the effects of opioids, “including respiratory depression, sedation and hypotension.” Ex. 1044,³ 1300.

According to the '965 patent, administering naloxone via injection requires trained medical personnel and imposes the risk of exposure to blood borne pathogens through needlestick injury. Ex. 1001, 6:17–38. The '965 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 6:45–49.

The '965 patent acknowledges that nasal administration of naloxone was known and used by numerous medical services and health departments. Ex. 1001, 2:32–6:16; *see also id.* at 4:42–45 (“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.”). It points out, however,

³ Physicians’ Desk Reference 2003, entry for NARCAN (Naloxone Hydrochloride Injection, USP).

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 2:50–58.

The ’965 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 6:55–64.

According to the ’965 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 6:66–7:5.

Illustrative Claims

Among the challenged claims, claims 1 and 20 are independent, and are reproduced below:

1. A pharmaceutical formulation for intranasal administration comprising, in an aqueous solution of not more than about 140 μ L:
 - about 4 mg naloxone hydrochloride;
 - about 0.74 mg NaCl;
 - about 0.01 mg benzalkonium chloride;

about 0.2 mg disodium edetate; and
an amount of hydrochloric acid sufficient to achieve a pH
of 3.5–5.5.

20. 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
comprises per 100 μ L of aqueous solution:

- 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
preservative;
- between about 0.1 mg and about 0.5 mg of a stabilizing
agent; and
- an amount of acid sufficient to achieve a pH of 3.5–5.5.

Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claim(s)	Basis	References
1, 2, 9–12, 17, 20–26	§ 103	Wang, ⁴ Djupesland, ⁵ HPE, ⁶ Bahal, ⁷ and Kushwaha ⁸
3–5, 13–16, 18, 19, 29–30	§ 103	Wang, Djupesland, HPE, Bahal, Kushwaha, and Wyse

⁴ Wang et al., Chinese Patent Publication No. CN 1575795 A, published February 9, 2005 (Ex. 1008).

⁵ Djupesland, *Nasal Drug Delivery Device: Characteristics and Performance in a Clinical Perspective - A Review*, 3 DRUG DELIV. & TRANSL. RES. 42–62 (2013) (Ex. 1010).

⁶ 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) (Ex. 1012).

⁷ Bahal et al., U.S. Patent No. 5,866,154, issued February 2, 1999 (Ex. 1014).

⁸ Kushwaha et al., *Advances in Nasal Trans-Mucosal Drug Delivery*, 01(07) J. APPLIED PHARM. Sci. 21–28 (2011) (Ex. 1013).

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