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Paper 55
Date: August 21, 2020

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 Owner.

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IPR2019-00694
Patent 9,629,965 B2

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

VALEK, *Administrative Patent Judge*.

# JUDGMENT
## Final Written Decision
## Determining No Challenged Claims Unpatentable
*35 U.S.C. § 318(a)*

## INTRODUCTION

Nalox-1 Pharmaceuticals, LLC, ("Petitioner") filed a Petition (Paper 2 ("Pet.")), seeking an *inter partes* review of claims 1–30 of U.S. Patent No. 9,629,965 B2 ("the '965 patent," Ex. 1001). We instituted trial to review the challenged claims. Paper 10 ("Dec."). Thereafter, Adapt Pharma Operations Limited and Opiant Pharmaceuticals, Inc. (collectively, "Patent Owner") filed a Response to the Petition (Paper 32, "PO Resp."), Petitioner filed a Reply (Paper 37, "Reply"), and Patent Owner filed a Sur-Reply (Paper 47, "Sur-Reply"). Petitioner also filed a Motion for Observations (Paper 49). An oral hearing for this proceeding was held on May 19, 2020, and a transcript of that hearing is of record. *See* Paper 51 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6 and issues this final written decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons provided below, and based on the evidence and argument presented in this proceeding, we conclude Petitioner has not established by a preponderance of the evidence that claims 1–30 of the '965 patent are unpatentable.

### *Related Proceedings*

Petitioner filed IPR2019-00695 and IPR2019-00696, challenging the same claims of the '965 patent with additional prior art. We denied those petitions. IPR2019-00695, Paper 10; IPR2019-00696, Paper 10.

The '965 patent is one of the patents listed in the Orange Book for intranasal naloxone sold under the brand name NARCAN. Pet. 1. Petitioner also filed petitions for *inter partes* review, challenging other patents listed in the Orange Book. Pet. 8; Paper 4, 1–2. We denied some of those petitions but also instituted review in IPR2019-00685 (challenging U.S. Patent

No. 9,211,253) and IPR2019-00688 (challenging U.S. Patent 9,468,747). IPR2019-00685, Paper 11; IPR2019-00688, Paper 11. Concurrently with this Decision, we issue a final written decision in each of those cases.

According to the parties, Patent Owner asserted five of its 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. 8; Paper 4, 2. Petitioner is not involved in those actions. Pet. 8.

According to Patent Owner, on March 2, 2020, the Perrigo Case was dismissed with prejudice pursuant to a consent judgment. Paper 54, 3. On June 22, 2020, the district court entered final judgment in the Teva Case, holding claims 21, 24, and 25 of the '965 patent invalid. *Id.* at 4. Patent Owner states that its appeal from this judgment was docketed on August 3, 2020. *Id.* at 4.

*Background of Technology and the '965 Patent*

Naloxone is an opioid receptor antagonist that was initially approved for use by injection for the reversal of opioid overdose. *Id.* at 2:15–17. Naloxone hydrochloride injection prevents or reverses the effects of opioids, "including respiratory depression, sedation and hypotension." Ex. 1044,[1] 1300.[2] The '965 patent explains that "[s]ince the onset of action of naloxone used in opioid overdose cases should be as fast as possible, naloxone is thus

[1] Physicians' Desk Reference 2003, entry for NARCAN (Naloxone Hydrochloride Injection, USP).
[2] Where applicable, we cite to the original page number of the exhibits, and not the pagination added by the parties.

far mainly administered intravenously or intramuscularly by emergency health care personnel." Ex. 1001, 6:17–20.

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, 6:26–38. 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, in fact, had been used by numerous medical services and health departments. *See generally id.* at 2:32–6:54. The patent points out, however, that some studies have "reported that the nasal administration of naloxone is as effective as the intravenous route in opiate addicts," yet 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 2:50–58. 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.

The '965 patent purports to meet this need by providing 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 6:55–7:5.

*Illustrative Claims*

Claims 1 and 20 are independent and reproduced below.

1. A pharmaceutical formulation for intranasal administration comprising, in an aqueous solution of not more than about 140 µL:
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 µL 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.

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