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Paper 57
Date: August 21, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

ADAPT PHARMA OPERATIONS LIMITED, and
OPIANT PHARMACEUTICALS, INC.,
Patent Owner.

IPR2019-00685
Patent 9,211,253 B2

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

YANG, *Administrative Patent Judge*.

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

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INTRODUCTION

Nalox-1 Pharmaceuticals, LLC ("Petitioner") filed a Petition (Paper 1 ("Pet.")), seeking an *inter partes* review of claims 1–29 of U.S. Patent No. 9,211,253 B2 ("the '253 patent," Ex. 1001). We instituted trial to review the challenged claims. Paper 11 ("Dec."). Thereafter, Adapt Pharma Operations Limited and Opiant Pharmaceuticals, Inc. (collectively, "Patent Owner") filed a Response to the Petition (Paper 34, "PO Resp."), Petitioner filed a Reply (Paper 39), and Patent Owner filed a Sur-Reply (Paper 49). Petitioner also filed a Motion for Observations (Paper 51). An oral hearing for this proceeding was held on May 19, 2020, and a transcript of that hearing is of record. *See* Paper 53 ("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 1–29 of the '253 patent are unpatentable.

Related Proceedings

Petitioner filed IPR2019-00686 and IPR2019-00687, challenging the same claims of the '253 patent with additional prior art. We denied those petitions. IPR2019-00686, Paper 11; IPR2019-00687, Paper 11.

The '253 patent is one of the 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 other patents listed in the Orange Book. Pet. 6; Paper 5, 1–2. We denied some of those petitions but instituted reviews in IPR2019-00688 (challenging U.S.

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Patent No. 9,468,747) and IPR2019-00694 (challenging U.S. Patent No. 9,629,965). IPR2019-00688, Paper 11; IPR2019-00694, Paper 10. Concurrently with this Decision, we issue a final written decision in each of those cases.

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. 5; Paper 5, 2. Petitioner is not involved in those actions. Pet. 5–6.

According to Patent Owner, on March 2, 2020, the Perrigo Case was dismissed with prejudice pursuant to a consent judgment. Paper 56, 3. On June 26, 2020, the district court entered final judgment in the Teva Case, holding invalid certain claims of four patents listed in the Orange Book under NARCAN. *Id.* at 3–4. Patent Owner states that its appeal from that judgment was docketed on August 3, 2020. *Id.* at 4.

Background of Technology and the '253 Patent

Opioid overdose is a crisis in the United States. Ex. 1001, 6:34. Naloxone is an opioid receptor antagonist that was initially approved for use by injection for the reversal of opioid overdose. *Id.* at 2:9–10. Naloxone hydrochloride injection prevents or reverses the effects of opioids,

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"including respiratory depression, sedation and hypotension." Ex. 1044,[1] 1300.[2]

According to the '253 patent, administering naloxone via injection requires trained medical personnel and imposes the risk of exposure to blood borne pathogens through needlestick injury. Ex. 1001, 6:10–22. The '253 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 6:33–37.

The '253 patent acknowledges that nasal administration of naloxone was known and used by numerous medical services and health departments. *Id.* at 2:25–6:3, *see also id.* at 4:32–35 ("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, that some studies "reported that the nasal administration of naloxone is as effective as the intravenous route in opiate addicts," yet 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 2:45–51. The '253 patent states:

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

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> 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 6:43–52.

According to the '253 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 6:54–60.

Illustrative Claims

Among the challenged claims, claims 1 is independent, and is reproduced below:

> 1. 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 preservative;
>
> about 0.2 mg of a stabilizing agent;
>
> an amount of an acid sufficient to achieve a pH o[f] 3.5-5.5.

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