Trials@uspto.gov
571-272-7822

Paper No. 14
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

ADAPT PHARMA LIMITED, and
OPIANT PHARMACEUTICALS, INC.,
Patent Owners.

Case IPR2019-00693
Patent 9,561,177 B2

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

HARLOW, *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 requesting *inter partes* review of claims 1–30 of U.S. Patent No. 9,561,177 B2 (Ex. 1001, "the '177 patent"). Paper 1 ("Pet."). Adapt Pharma Limited and Opiant Pharmaceuticals, Inc. (collectively, "Patent Owner") timely filed a Preliminary Response. Paper 9 ("Prelim. Resp."). Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the information presented in the petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Having considered the evidence and arguments of record, we agree with Patent Owner that the prior art teaches away from the claimed invention, and, therefore, decline to institute *inter partes* review.

A. Related Matters

Claims 1–30 of the '177 patent are also the subject of IPR2019-00691 and IPR2019-00692, initiated by Petitioner contemporaneously with the instant proceeding. Paper 8, 2–3. We issue our decisions declining to institute *inter partes* review in IPR2019-00691 and IPR2019-00692 concurrently with this Decision.

In addition to the three petitions challenging the '177 patent, Petitioner has filed 12 petitions against four patents related to the '177 patent. *Id.*; Pet. 7–8. Each of the five patents for which Petitioner seeks *inter partes* review is listed in the Orange Book for intranasal naloxone sold under the brand name NARCAN. Pet. 1, 8. These five patents are also the subject of pending district court litigation in *Adapt*

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Pharma Operations Ltd. v. Teva Pharmaceuticals USA, Inc., Case 2:16-cv-07721 (D.N.J.) (consolidated, "the Teva Case"),[1] and *Adapt Pharma Operations Ltd. v. Perrigo UK FINCO Limited Partnership*, Case 2:18-cv-15287 (D.N.J.). Pet. 8; Paper 8, 3. Petitioner is not party to the district court actions. Pet. 8.

B. The '177 Patent

The '177 patent, titled "Nasal Drug Products and Methods of Their Use" (Ex. 1001, (54)), describes "[d]rug products adapted for nasal delivery, comprising a pre-primed device filled with a pharmaceutical composition comprising an opioid receptor antagonist" (*id.* at Abstract), as well as "[m]ethods of treating opioid overdose or its symptoms with the inventive drug products" (*id.*).

Opioid overdose is a growing public health challenge in the United States. Ex. 1001, 1:57–2:4. According to the '177 patent, in 2014 alone, more than 28,000 people in the United States died from overdoses of heroin or prescription opioids, representing a nearly four-fold increase since 1999. *Id.* at 1:63–65. The patent further explains that "the increase in the rate of drug overdose in recent years has been driven mainly by overdoses of prescription [opioid] analgesics." *Id.* at 2:2–4.

The '177 patent identifies naloxone as "an opioid receptor antagonist that is approved for use by injection for the reversal of opioid overdose and for adjunct use in the treatment of septic shock." Ex. 1001, 2:5–7. The

[1] Patent Owner informs us that bench trial in the Teva Case is set for August 26, 2019. Paper 10, 1.

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patent states that intranasal ("IN") delivery of naloxone is "considered an attractive route for needle-free, systemic drug delivery, especially when rapid absorption and effect are desired. In addition, nasal delivery may help address issues related to poor bioavailability, slow absorption, drug degradation, and adverse events (AEs) in the gastrointestinal tract and avoids the first-pass metabolism in the liver." Ex. 1001, 10:50–56. The patent also notes that several intranasal naloxone formulations of have been elsewhere described. *Id.* at 2:15–49. For example, the '177 patent states that

> WO 00/62757 to Davies[2] reports pharmaceutical compositions for IN or oral (PO) administration which comprise an opioid antagonist, such as naloxone for application by spray in the reversal of opioid depression for treatment of patients suffering from opioid over-dosage, wherein the spray applicator is capable of delivering single or multiple doses and suitable dosage units are in the range of 0.2 to 5 mg.

Ex. 1001, 2:28–34. The patent goes on to explain, however, that "[t]he use of nasal naloxone is not without controversy." *Id.* at 2:35. In this regard, the '177 patent represents that a study by Dowling[3] "reported that naloxone administered intranasally displays a relative bioavailability of 4% only and concluded that the IN absorption is rapid but does not maintain measurable

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[2] Davies *et al.*, PCT Publication No. WO 00/62757, published Oct. 26, 2000 (Ex. 1009).

[3] Dowling *et al.*, Population Pharmacokinetics of Intravenous, Intramuscular, and Intranasal Naloxone in Human Volunteers, 30(4) THER. DRUG. MONIT. 490–96 (2008) (Ex. 1027).

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concentrations for more than an hour." *Id.* at 2:37–41. Moreover, and of particular relevance here, the '177 patent observes that

> U.S. Pat. No. 9,192,570 to Wyse[4] reports naloxone formulations for intranasal administration. Wyse reports (column 27, lines 29–37) that benzalkonium chloride [("BAC") or ("BZE")] is not suitable in such formulations, because it facilitates unacceptable degradation of the naloxone. Wyse recommends (lines 41–43) benzyl alcohol and paraben preservatives in place of benzalkonium chloride.

Id. at 2:42–48.

According to the '177 patent, therefore, "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." Ex. 1001, 2:49–53. The patent goes on to explain that "[t]he therapeutically effective dose should be sufficient to obviate the need for the untrained individual to administer an alternative medical intervention to the patient, and to stabilize the patient until professional medical care becomes available." *Id.*at 2:53–57.

To meet these needs, the '177 patent discloses devices adapted for nasal delivery of "a therapeutically effective amount of an opioid antagonist selected from naloxone and pharmaceutically acceptable salts thereof, wherein said device is pre-primed, and wherein said therapeutically effective amount, is equivalent to about 2 mg to about 12 mg of naloxone

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[4] Wyse *et al.*, U.S. Patent No. 9,192,570 B2, issued Nov. 24, 2015 (Ex. 1007).

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