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Paper 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 IPR2019-00687
Patent 9,211,253 B2

Before ZHENYU YANG, JACQUELINE T. HARLOW, and MICHAEL A. VALEK, *Administrative Patent Judges.*

VALEK, *Administrative Patent Judge.*

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

I. INTRODUCTION

Nalox-1 Pharmaceuticals, LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–29 of U.S. Patent 9,211,253 B2 (Ex. 1001, "the '253 patent"). Paper 1 ("Pet."). Opiant Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp."). We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314, which provides that 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."

For the reasons set forth below, upon consideration of the papers filed by both parties, we exercise our discretion under 35 U.S.C. § 314 and deny institution of *inter partes* review in this case.

II. BACKGROUND

A. Related Matters

The parties inform us that the '253 patent is asserted in *Adapt Pharma Operations Ltd. v. Teva Pharmaceuticals USA*, No. 2:16-cv-07721 (D.N.J.) and *Adapt Pharma Operations Ltd. v. Perrigo UK FINCO Limited Partnership*, No. 2:18-cv-15287 (D.N.J.). Pet. 6; Paper 5, 2. Petitioner is not a party to either of these litigations.

Petitioner informs us that it is "concurrently filing *inter partes* review petitions on related U.S. Patent Nos. 9,468,747; 9,562,177; 9,629,965; and 9,775,838, which are listed in The Orange Book [along with the '253 patent] as covering Narcan® nasal spray (naloxone)." Pet. 6. What Petitioner does

not clearly indicate is that it has, in fact, filed three IPR petitions on each of these five patents for a total of fifteen petitions.

Petitioner's other two petitions on the '253 patent are docketed as IPR2019-00685 and IPR2019-00686. The petitions in those proceedings challenge the same claims (claims 1–29) of the same patent under the same statutory provision (35 U.S.C. § 103(a)) as the Petition here, but purport to focus on a different primary reference. As do the parties, we refer to Petitioner's petitions on the '253 patent by the name of the primary reference asserted in each, e.g., the "Wyse Petition" (IPR2019-00685, Paper 1) and the "Davies Petition" (IPR2019-00687, Paper 1).

B. The '253 Patent

The '253 patent discloses "devices adapted for nasal delivery of a pharmaceutical composition to a patient, comprising . . . naloxone and pharmaceutically acceptable salts thereof." Ex. 1001, 6:54–57. The '253 patent describes 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." *Id.* at 2:9–11. "Since the onset of action of naloxone used in opioid overdose cases should be as fast as possible, naloxone is thus far mainly administered intravenously or intramuscularly by emergency health care personnel." *Id.* at 6:4–7. According to the '253 patent, it can be difficult to "find access into a vein of the addict's body for administering naloxone intravenously" and the use of a needle to inject it carries the "risk of exposure to blood borne pathogens." *Id.* at 6:14–23. Thus, "[t]he administration of naloxone via injection . . . requires . . . trained

medical personnel (for intravenous injection) or a trained carer (for intramuscular injection)." *Id.* at 6:10–23.

According to the '253 patent, "it has 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 explains that such devices should be capable of delivering a "therapeutically effective dose. . . 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 6:47–54. The '253 patent purports to describe devices that meet the need for an easy-to-use and effective intranasal dosage form of naloxone. *See id.*

C. Representative Claim

Claim 1 is the sole independent claim and 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 or 3.5–5.5.

Ex. 1001, 50:36–47. Claim 2 additionally specifies that the "preservative is benzalkonium chloride" and the "stabilizing agent is disodium edetate."

Ex. 1001, 50:50–51. Claims 3–15 and 24–29 depend from claim 2 and are likewise limited to those excipients. Claims 1 and 16–23 are not limited to a particular preservative or stabilizing agent in the recited pharmaceutical composition.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–29 under 35 U.S.C. § 103(3) on the following grounds (Pet. 3):

Claim(s)	References
1–4, 16–24	Davies[1] in view of HPE,[2] Bahal,[3] and Kushwaha[4]
28–29	Davies in view of HPE, Bahal, Kushwaha, and Wyse[5]
5–7, 10–14	Davies in view of HPE, Bahal, Kushwaha, and Djupesland[6]
8–9	Davies in view of HPE, Bahal, Kushwaha, Djupesland, and the '291 patent[7]
25–27	Davies in view of HPE, Bahal, Kushwaha, Djupesland, and Wyse

[1] PCT Publication WO 00/62757, published October 26, 2000 (Ex. 1009).
[2] Handbook of Pharmaceutical Excipients 56–60, 64–66, 78–81, 220–22, 242–44, 270–72, 441–45, 517–22, 596–98 (Raymond C. Row et al. eds., 6th ed. 2009) (Ex. 1012).
[3] U.S. Patent 5,866,154, issued February 2, 1999 (Ex. 1014).
[4] Swatantra Kushwaha et al., *Advances in Nasal Trans-Mucosal Drug Delivery*, 01(07) J. Applied Pharm. Sci. 21–28 (2011) (Ex. 1013).
[5] U.S. Patent 9,192,570, issued November 24, 2015 (Ex. 1007).
[6] Per Gisle Djupseland, *Nasal Drug Delivery Devices: Characteristics and Performance in a Clinical Perspective—a Review*, 3 Drug. Deliv. & Transl. Res. 42–62 (2013) (Ex. 1010).
[7] U.S. Patent 8,198,291, issued June 12, 2012 (Ex. 1015).

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