Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Defendants.

**OPINION**

**LINARES**, Chief District Judge,

This matter comes before the Court by way of an application for claims construction by Plaintiffs Adapt Pharma Operations Limited, Adapt Pharma, Inc., and Opiant Pharmaceuticals, Inc. ("Adapt") and Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd. ("Teva"). Specifically, the parties seek construction of certain language contained in Claim 1 of United States Patent Numbers 9,211,253 ("'253 patent") and 9,468,747 ("'747 patent"), Claim 10 of the '253 patent and '747 patent, and Claim 29 of United States Patent No. 9,629,965 ("'965 patent").[1] The Court has considered the parties' written submissions, (ECF Nos. 65, 70, 160, 162), and the oral arguments advanced at the *Markman* hearing held on March 31, 2019. (ECF No. 188).

[1] The parties additionally sought the Court's construction of the terms "about 0.2 mg of a stabilizing agent / about 0.2 mg disodium edetate / about 0.2% (w/v) disodium edetate as the stabilizing agent" found in Claims 1 and 3 of the '253 patent, Claims 3 and 33 of the '747 patent, Claims 5 and 27 of United States Patent No. 9,561,177 ("'177 patent"), and Claims 1 and 22 of the '965 patent. They have since resolved their dispute regarding these terms. (ECF No. 194).

The subject patents deal with, and relate to, the administration of a nasal spray form of an opioid receptor antagonist known as the drug "naloxone." ('253 patent at 1:8–12; 2:9–11).[2] Naloxone is used to reverse opioid overdoses and for "adjunct" use to treat septic shock. (*Id.* at 13–15). The FDA has previously approved naloxone treatments in the form of injection. (*Id.* at 9–11). There is debate about the relative effectiveness of the nasal delivery method of naloxone ingestion compared to various injection methods via IV, intramuscular injection, or subcutaneous administration. (*Id.* at 2:43–6:4).

Adapt asserts that the patents cover its brand name drug Narcan®, which is a nasal spray comprising 4mg of naloxone hydrochloride. (ECF No. 65 at 6, '253 patent at 9:34). Adapt received FDA approval for Narcan® on November 18, 2015 (NDA No. 208411, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208411). Narcan is the first and only FDA approved nasal spray to combat opioid overdose. (ECF No. 65 at 6). The patents-in-suit describe pre-primed "devices adapted for nasal delivery of a pharmaceutical composition to a patient, comprising a therapeutically effective amount of an opioid antagonist selected from naloxone and pharmaceutically acceptable salts," in amounts ranging from 2mg to 12mg of naloxone hydrochloride. ('253 patent at 6:54–60). The patents-in-suit also describe methods of treating an opioid overdose using this device, "comprising nasally

[2] A copy of the '253 patent can be found at ECF No. 65-2. The Court cites only to the '253 patent except for issues that refer specifically to one of the other patents-in-suit.

antagonist to an opioid overdose patient." ('253 patent at 6:43–47).

### B. Disputed Term and Proposed Construction

The parties have asked the Court to construe the following terms:

| Disputed Term | Patent Claims that the Term Appears In |
|---|---|
| "delivery time" | Claim 10 of the '253 patent, Claim 10 of the '747 patent, and Claim 29 of the '965 patent |
| "a single reservoir comprising a pharmaceutical composition which is an aqueous solution of about 100 µL"[3] | Claim 1 of the '253 patent and Claim 1 of the '747 patent |

Adapt proposes that this Court construe the above terms in the following manner:

| Disputed Term | Plaintiffs' Proposed Construction |
|---|---|
| "delivery time" | "the amount of time that elapses between a determination made by a healthcare professional, or an untrained individual that an individual is in need of nasal delivery of an opioid antagonist and completion of the delivery." |
| "a single reservoir comprising a pharmaceutical composition which is an aqueous solution of about 100 µL" | Requires no construction |

(ECF No. 65 at 13, 15).

[3] µL stands for microliter, which is one millionth of a liter and is numerically represented as 1 $10^{-6}$ m.

| | |
|---|---|
| "a single reservoir comprising a pharmaceutical composition which is an aqueous solution of about 100 µL" | "a single device reservoir filled with approximately 100 µL of an aqueous pharmaceutical composition." |

(ECF No. 70 at 8, 21).

## II. LEGAL STANDARD

A court's analysis of a patent infringement claim is two-fold. *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1365 (Fed. Cir. 2002). The court must first define the meaning and scope of the patent claims as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). The court then engages in a comparison of the claims as construed to the alleged infringing product or method. *Tate*, 279 F.3d at 1365. At this stage, the Court must only engage in the first step.

Claim construction is a matter of law to be determined solely by the court. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006). "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Id.* at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). In construing the terms of a patent, a court should look first to the language of the claim itself. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The terms in the claim "are generally given their ordinary and customary meaning." *Id.* at 1582. "[T]he ordinary and customary meaning of a claim term is

(quoting *DeMarini Sports, Inc. v. Worth*, 239 F.3d 1314, 1324 (Fed. Cir. 2001)). The court should turn to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Innova/Pure*, 381 F.3d at 1116.

To this end, the court should first examine the intrinsic record—the patent itself, including the claims, the specification and, if in evidence, the prosecution history. *Vitronics*, 90 F.3d at 1582 (citing *Markman*, 52 F.3d at 979). The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Id.* Indeed, the Federal Circuit has explained that the specification is "'usually . . . dispositive . . . [and] the single best guide to the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). It is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1317. The specification is also an important guide in claims construction as it may contain "an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* at 1316.

Additionally, the court should consult the patent's prosecution history as it "provides evidence of how the PTO and the inventor understood the patent." *Id.* at 1317. Courts should be circumspect in reviewing a prosecution history as it represents "an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation." *Id.* A district court may also examine extrinsic evidence: "all evidence external to the patent and prosecution history." *Markman*, 52 F.3d at 980; *see also Phillips*, 415 F.3d at 1317 (stating that the Federal Circuit

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