IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., THE P.F. LABORATORIES, INC., and RHODES TECHNOLOGIES, Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC, Defendant.	Civil Action No. 17-210-RGA

MEMORANDUM OPINION

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May 21, 2018

ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 9,492,392 ("the '392 patent"), 9,492,393 ("the '393 patent"), and 9,522,919 ("the '919 patent"). The Court has considered the parties' joint claim construction brief. (D.I. 48). The Court heard oral argument on February 14, 2018. (D.I. 80 ("Tr.")).

I. BACKGROUND

This suit arises from Defendant's filing an Abbreviated New Drug Application ("ANDA"). Plaintiffs filed suit on March 1, 2017, alleging that the generic product that is the subject of the ANDA filing would infringe a number of Plaintiffs' patents. (D.I. 1). The patents-in-suit relate to OxyContin®, an extended-release pain medication. They are from two of the same patent families asserted by Plaintiffs in an earlier related action, in which I issued a *Markman* opinion. (No. 15-1152, D.I. 120). More specifically, the '392 and '393 patents are related to and have the same specification as U.S. Patent Nos. 8,808,741 ("the '741 patent"), 8,894,987 ("the '987 patent), and 8,894,988 ("the '988 patent"). (D.I. 48 at 9). The '919 patent is related to and has the same specification as U.S. Patent No. 9,073,933 ("the '933 patent"). (*Id.*).

II. LEGAL STANDARD

"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." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in

original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315.

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13. "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321. "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19. Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation omitted).

III. PATENTS-IN-SUIT

The '392 and '393 patents relate to a tamper resistant dosage form of OxyContin®. Claim 1 of the '392 patent is representative and reads as follows:

1. A cured shaped pharmaceutical tablet comprising:

> (1) at least a first compression shaped and then air cured matrix, wherein said curing is without compression, by heated air having a temperature of at least about 62° C. for a duration of at least about 5 minutes, said matrix comprising oxycodone or a pharmaceutically acceptable salt thereof in combination with *at least one high molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof*, and optionally further comprising *at least one low molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight of less than 1,000,000*;
>
> (2) optionally a second air cured matrix comprising oxycodone or a pharmaceutically acceptable salt thereof in combination with at least one low molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight of less than 1,000,000; and
>
> (3) optionally a coating,

wherein, in said tablet:

> (i) said oxycodone or pharmaceutically acceptable salt thereof is provided in a dose selected from the group consisting of 10 mg, 15 mg, 20 mg, and 30 mg;
>
> the total combined weight of said low molecular weight polyethylene oxide, if present, and said high molecular weight polyethylene oxide is at least 79% by weight of the total weight of said tablet, excluding the weight of any coatings; and

> said low molecular weight polyethylene oxide, if present, is at least 10% by weight of the total weight of said tablet, excluding the weight of any coatings; or
>
> (ii) said oxycodone or pharmaceutically acceptable salt thereof is provided in a dose selected from the group consisting of 40 mg, 60 mg, and 80 mg;
>
> the total combined weight of said low molecular weight polyethylene oxide, if present, and said high molecular weight polyethylene oxide is at least 65% by weight of the total weight of said tablet, excluding the weight of any coatings; and
>
> said low molecular weight polyethylene oxide, if present, is at least 10% by weight of the total weight of said tablet, excluding the weight of any coatings; and
>
> said tablet provides a dosage form for twice-daily extended release administration of oxycodone or pharmaceutically acceptable salt thereof.

('392 patent, claim 1) (disputed terms italicized).

The '919 patent relates to a process for preparing an oxycodone hydrochloride composition. The sole disputed term in the '919 patent appears in claims 3 and 17, which depend from claims 1 and 12, respectively. Claims 1 and 3 read:

> 1. An oxycodone HCl composition comprising oxycodone HCl and 8α,14-dihydroxy-7,8-dihydrocodeinone, wherein the ratio of 8α,14-dihydroxy-7,8-dihydrocodeinone to oxycodone HCl is 0.04% or less as measured by HPLC.

('919 patent, claim 1).

> 3. The oxycodone HCl composition of claim 1, wherein *at least 1 kg of the oxycodone HCl is prepared.*

(*Id.* at claim 3) (disputed term italicized).

IV. CONSTRUCTION OF DISPUTED TERMS

1. "at least one high molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof"

a. *Plaintiffs' proposed construction*: "one or a combination of polyethylene oxides having an overall weight average molecular weight of approximately 4,000,000 daltons, 7,000,000 daltons, or a combination thereof based on rheological measurements"

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