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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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"

b. *Defendant's proposed construction*: "one or more high molecular weight polyethylene oxide supplied in a grade having an approximate molecular weight of 4,000,000 daltons, 7,000,000 daltons, or a combination of 4,000,000 and 7,000,000 daltons based on rheological measurements"

c. *Court's 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"

This term appears in claim 1 of the '392 and '393 patents.

The parties' dispute in regard to this term is twofold.

First, the parties seem to dispute whether, as Plaintiffs argue, the polyethylene oxide ("PEO") component of the "at least one high molecular weight polyethylene oxide" can include more than one PEO, or whether, as Defendant maintains, the term is limited to a single grade of PEO.

In support of their proposed construction, Plaintiffs submit that, "when either (or both) of the . . . PEO ingredients is a single grade, the molecular weight of that grade is in reality an overall average of the molecular weights of different PEO molecules." (D.I. 48 at 27). Plaintiffs further point to the claim construction hearing in the related civil action, No. 15-1152, during which Plaintiffs "demonstrated" that a 4,000,000 PEO can be made by combining different PEOs or different grades. (*Id.*). Contrary to Defendant's assertions, contend Plaintiffs, nothing in the intrinsic record supports the requirement that a PEO component be limited to specific grades. (*Id.* at 29).

In response, Defendant acknowledges, and notes its disagreement with, my prior finding in the 15-1152 action that, "at least one polyethylene oxide" in claim 1 of the related '987 patent, which has the same specification as the '392 and '393 patents, is not limited to a single commercial product grade. (*See id.* at 33 n.11). Further, at oral argument, Defendant preserved

its objection to my prior construction, in light of its understanding that I would adopt that construction again. (*See* Tr. at 13:23–14:2).

I agree with Plaintiffs. Like the claims at issue in the 15-1152 action, the claims here in which the disputed term appears are not so narrowly drawn that they limit the PEO components to a single grade. I think the "at least one high molecular weight" PEO from claim 1 of the '392 and '393 patents is a PEO component that, whether it is a single grade or a blend of different grades, meets the specifications' definitions of PEO with "an approximate molecular weight" of 4,000,000 or 7,000,000. (*See* '392 patent, 8:26–31, 36–41; '393 patent, 8:28–33, 38–43).

Second, the parties dispute whether the recited molecular weight is an "overall weight average molecular weight." To support their position that "molecular weight" refers to "weight average molecular weight," Plaintiffs again point to my *Markman* opinion in the 15-1152 action. (*See* D.I. 48 at 29). Plaintiffs also point to information related to Dow POLYOX™ PEOs and a patent application cited by the examiner during prosecution of the '988 and '741 patents, two related patents with the same specification. (*Id.* at 9, 30–31).

Defendant responds by arguing that Plaintiffs' proposed "overall weight average" language ignores my prior construction in the 15-1152 action. (*Id.* at 32–33, 36–40). More specifically, Defendant maintains that Plaintiffs' attempt to add a weight average formula into the construction for this term "renders the Court's rheological measurement requirement in the claim construction moot." (*Id.* at 33). Instead, the rheology test should control, and the "overall weight average molecular weight" language should be rejected. (*Id.* at 34). Further, according to Defendant, Plaintiffs' proposal violates the Markush drafting requirement. (*Id.* at 36). More specifically, Defendant contends that Plaintiffs' "construction adds uncertainty, ambiguity, and

unnamed elements" into the claims. (*Id.*). Under Plaintiffs' proposal, maintains Defendant, "unnamed PEO grades may be used even though not listed in the claim." (*Id.* at 39).

I am not persuaded by Defendant's arguments.

My claim construction in the 15-1152 action referred to "overall weight average molecular weight" and "rheological measurements." Thus, I do not see how including "overall weight average molecular weight" in this construction would conflict with my prior ruling. Further, I do not think, as Defendant contends, that including "overall weight average molecular weight" "avoid[s] the inventor's express rheological test." (*Id.* at 39). The construction I previously adopted and Plaintiffs' proposal here both require a PEO or combination of PEOs having an "overall weight average molecular weight . . . based on rheological measurements." In any event, it seems to me that, as I stated in the 15-1152 action, the intrinsic evidence indicates that the inventors were referring to weight average molecular weight. (*See* No. 15-1152, D.I. 120 at 9).

Finally, I find Defendant's argument in regard to Markush drafting requirements unconvincing. As an initial matter, I note that my *Markman* opinion in the 15-1152 action did not involve Markush claims. Here, on the other hand, the disputed claims are written in Markush form. They denote a Markush group by listing three alternatives for the "at least one high molecular weight" PEO component—4,000,000, 7,000,000, and a combination thereof. *See Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1357 (Fed. Cir. 2016) ("Markush claims create a customized 'Markush group' . . . [which] lists specified alternatives in a patent claim, typically in the form: a member selected from the group consisting of A, B, and C."). The claims use the transitional phrase, "consisting of," indicating that the group is "closed." *See id.* at 1358 ("Use of the transitional phrase 'consisting of' to set off a

patent claim element creates a very strong presumption that that claim element is 'closed' and therefore 'exclude[s] any elements, steps, or ingredients not specified in the claim.'" (alteration in original)).

I do not agree with Defendant that Plaintiffs' proposed "overall weight average molecular weight" language violates Markush drafting requirements by adding unnamed elements into the claims. The Markush group lists alternatives for the "approximate molecular weight[s]" of the PEO component. They are 4,000,000, 7,000,000, and a combination thereof. The Markush group does not appear to relate to how the molecular weight is calculated nor does it appear to limit the PEO component to a single grade of PEO. Thus, I do not see how including Plaintiffs' proposed language would conflict with the closed nature of the Markush group in the claims.

For the reasons stated above, I will construe this term to mean, "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."

2. "at least one low molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight of less than 1,000,000"

a. *Plaintiffs' proposed construction*: "one or a combination of polyethylene oxides having an overall weight average molecular weight of less than approximately 1,000,000 daltons based on rheological measurements"

b. *Defendant's proposed construction*: "one or more low molecular weight polyethylene oxides supplied in a grade having an approximate molecular weight of less than 1,000,000 daltons based on rheological measurements"

c. *Court's construction*: "one or a combination of polyethylene oxides having an overall weight average molecular weight of less than approximately 1,000,000 daltons based on rheological measurements"

This term appears in claim 1 of the '392 and '393 patents.

The parties' dispute in regard to this term is essentially the same as the previous term. For the reasons stated above, I will adopt Plaintiffs' proposed construction.

3. "at least 1 kg of the oxycodone HC1 is prepared"

This term appears in dependent claims 3 and 17 in the '919 patent. Those claims are no longer a part of the case. (*See* Tr. at 30:14–18, 31:11–20). Accordingly, there is no reason for the Court to construe this term.

V. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.