

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE
PHARMACEUTICALS L.P., THE P.F.
LABORATORIES, INC., RHODES
TECHNOLOGIES, and GRUNENTHAL
GMBH,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS, LLC,

Defendant.

Civil Action No. 1:15-cv-01152-RGA-SRF

PURDUE PHARMA L.P., PURDUE
PHARMACEUTICALS L.P., THE P.F.
LABORATORIES, INC., RHODES
TECHNOLOGIES, and GRUNENTHAL
GMBH,

Plaintiffs,

v.

ABHAI, LLC and KVK-TECH, INC.,

Defendants.

Civil Action No. 1:16-cv-0025-RGA-SRF

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. 8,808,741 (“the ’741 patent”), 8,894,987 (“the ’987 patent”), 8,894,988 (“the ’988 patent”), 8,309,060 (“the ’060 patent”), and 9,073,933 (“the ’933 patent”). The Court has considered the Parties’ Joint Claim Construction Brief. (Civ. Act. No. 15-1152-RGA-SRF, D.I. 117; Civ. Act. No. 16-25-RGA-SRF, D.I. 87).¹ The Court heard oral argument on February 10, 2017.

I. BACKGROUND

This suit arises from Defendant Amneal’s filing an Abbreviated New Drug Application (“ANDA”).² Plaintiff filed suit against Defendant Amneal on December 15, 2015, 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 claim analgesic compounds with abuse deterrent properties, processes for making such compounds, and methods of treating pain using such compounds.

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) (internal quotation marks omitted). “[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

¹ Unless otherwise specifically noted, all references to the docket refer to Civil Action No. 15-1152-RGA-SRF.

² Abhai is participating in claim construction pursuant to the Court’s Order of November 2, 2016. (Civ. Act. No. 16-25, D.I. 50).

literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (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 (internal quotation marks omitted).

“[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 (citations and internal quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). “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 Pharm. 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 (internal quotation marks omitted). 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 and internal quotation marks omitted).

III. CONSTRUCTION OF DISPUTED TERMS

The '741 patent is directed to methods of pain treatment using tamper resistant oral dosage forms. Claim 1 is representative and reads as follows:

1. A method of treating pain comprising administering to a patient in need thereof a convection cured shaped tablet comprising an extended release matrix comprising a composition, wherein said tablet comprises:

- (1) *at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of 4,000,000, and*
- (2) oxycodone or a pharmaceutically acceptable salt, and

wherein said tablet is prepared by a process comprising the steps of:

- (a) combining at least (1) and (2) to form a blend;
- (b) shaping said blend to form a shaped tablet; and
- (c) convection curing said shaped tablet by subjecting the shaped tablet to a temperature from about 60 to about 90° C. for a time of from about 15 minutes to about 10 hours, wherein said [sic]

wherein said convection cured shaped tablet comprises:

- (i) 5, 7.5, 10, 15, 20, or 30 mg of said oxycodone or pharmaceutically acceptable salt and at least 79% by weight, based upon the total weight of said composition, of said *at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of 4,000,000;*
- (ii) 40 mg of said oxycodone or pharmaceutically acceptable salt and at least 72% by weight, based upon the total weight of said composition, of said *at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of 4,000,000;*
- (iii) 60 mg of said oxycodone or pharmaceutically acceptable salt and at least 57% by weight, based upon the total weight of said composition, of said *at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of 4,000,000;* or

(iv) 80 mg of said oxycodone or pharmaceutically acceptable salt and at least 54% by weight, based upon the total weight of said composition, of said *at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of 4,000,000.*

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

The '987 patent is directed to tamper resistant oral dosage formulations of analgesics and processes for making such analgesics. Claim 1 is representative and reads as follows:

1. A process of preparing a solid oral extended release pharmaceutical dosage form, comprising at least the steps of:

(a) combining at least (1) at least one polyethylene oxide and (2) at least one active agent comprising oxycodone hydrochloride, to form a composition;

(b) shaping the composition to form an extended release matrix formulation; and

(c) curing said extended release matrix formulation comprising at least a curing step of subjecting the extended release matrix formulation to a temperature which is at least the softening temperature of said polyethylene oxide for a time period of at least about 1 minute,

wherein the *at least one polyethylene oxide, based on rheological measurements, has a molecular weight of approximately 4,000,000* and is at least 79% by weight of the composition; and wherein

(i) wherein the cured shaped extended release formulation is flattened without breaking to no more than about 60% of its thickness before flattening, said flattened cured shaped extended release formulation has an in-vitro dissolution, when measured in a USP Apparatus 1 (basket) at 100 rpm and at 37° C. in 900 ml of simulated gastric fluid having no enzymes and having 40% ethanol, wherein the percent amount of oxycodone hydrochloride release at 0.5 hours of dissolution deviates no more than about 20% points from the corresponding in-vitro dissolution of said formulation when measured in a USP Apparatus 1 (basket) at 100 rpm and at 37° C., in 900 ml of simulated gastric fluid having no enzymes and having no ethanol;

(ii) between 5 and 40% (by weight based upon total weight of oxycodone hydrochloride in said cured shaped extended release matrix formulation) of oxycodone hydrocodone in said cured shaped extended release matrix formulation is released after 0.5 hours, when measured in a USP Apparatus 1 (basket) at 100 rpm and at 37° C. in 900 ml of simulated gastric fluid having no enzymes and having 40% or 0% ethanol; or

(iii) a combination of (i) and (ii).

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

The '988 patent is directed to tamper resistant analgesic tablets. Claim 1 is representative and reads as follows:

1. A cured shaped tablet comprising an extended release matrix comprising a composition, wherein said tablet comprises:
 - (1) *at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of 4,000,000*, and
 - (2) oxycodone or a pharmaceutically acceptable salt, andwherein said tablet is prepared by a process comprising the steps of:
 - (a) combining at least (1) and (2) to form a blend;
 - (b) shaping said blend to form a shaped tablet; and
 - (c) curing said shaped tablet by subjecting the shaped tablet to a temperature from about 60 to about 90° C. for a time of from about 15 minutes to about 10 hours, wherein said cured shaped tablet comprises:
 - (i) 5, 7.5, 10, 15, 20, or 30 mg of said oxycodone or pharmaceutically acceptable salt and at least 79% by weight, based upon the total weight of said composition, of said *at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of 4,000,000*;
 - (ii) 40 mg of said oxycodone or pharmaceutically acceptable salt and at least 72% by weight, based upon the total weight of said composition, of said *at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of 4,000,000*;
 - (iii) 60 mg of said oxycodone or pharmaceutically acceptable salt and at least 57% by weight, based upon the total weight of said composition, of said *at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of 4,000,000*; or
 - (iv) 80 mg of said oxycodone or pharmaceutically acceptable salt and at least 54% by weight, based upon the total weight of said composition, of said *at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of 4,000,000*.

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

The '060 patent is directed to abuse-proofed oral analgesics.³ Claim 1 is representative and reads as follows:

1. An abuse-proofed, thermoformed dosage form comprising one or more active ingredients with abuse potential (A) optionally together with physiologically acceptable auxiliary substances (B), *at least one synthetic or natural polymer (C), wherein the polymer (C) has a molecular weight of at least 0.5 million according*

³ The '060 patent was the subject of previous litigation during which the asserted claims were found to be invalid. *Endo Pharmaceuticals Inc. v. Amneal Pharmaceuticals, LLC*, 2015 WL 9459823, at *2 (S.D.N.Y. Aug. 18, 2016). This ruling is currently on appeal. (D.I. 116 at 129).

to rheological measurements, and optionally at least one wax (D), wherein the dosage form exhibits a breaking strength of at least 500 N.

('060 patent, claim 1) (disputed terms italicized). Some disputed terms of the '060 patent appear only in claim 9, which reads as follows:

9. A dosage form according to claim 1, which additionally comprises at least one of the following components a)-f):
 - (a) at least one substance which irritates the nasal passages and/or pharynx,
 - (b) at least one *viscosity-increasing agent*, which, with the assistance of *a necessary minimum quantity of an aqueous liquid*, forms a gel with the extract obtained from the dosage form, which gel optionally remains visually distinguishable when introduced into a further quantity of an aqueous liquid,
 - (c) at least one antagonist for the active ingredient or active ingredients with abuse potential,
 - (d) at least one emetic,
 - (e) at least one dye as an aversive agent,
 - (f) at least one bitter substance.

('060 patent, claim 9) (disputed terms italicized).

The '933 patent is directed to compositions with reduced 14-hydroxycodeinone and processes for making such compositions. Claim 10 is representative and reads as follows:

10. A process for preparing an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone, comprising *removing 8 α ,14-dihydroxy-7,8-dihydrocodeinone from an oxycodone base composition* and converting the oxycodone base composition to an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone.

('933 patent, claim 10) (disputed terms italicized).

1. "at least one polyethylene oxide, based on rheological measurements, has a molecular weight of approximately 4,000,000"
 - a. *Plaintiffs' proposed construction*: "one or a combination of polyethylene oxides having an overall weight average molecular weight of approximately 4,000,000 daltons based on rheological measurements"
 - b. *Amneal's proposed construction*: "one or more polyethylene oxide ingredients each supplied in a grade having a molecular weight of approximately 4,000,000, based on rheological measurements"

- c. *Abhai's proposed construction:* The term is indefinite. If the Court chooses to defer ruling on indefiniteness, the term should be construed as: "a measure of the mass of the polyethylene oxide molecule(s) is approximately 4,000,000 based on a measurement of the deformation and flow of matter"
- d. *Court's construction:* "one or a combination of polyethylene oxides having an overall weight average molecular weight of approximately 4,000,000 daltons based on rheological measurements"

As an initial matter, I reject Abhai's argument that this term is indefinite. Abhai contends that "the intrinsic evidence fails to identify which measure of molecular weight (e.g., M_n , M_v , M_w , M_z) is required by the asserted claims." (D.I. 116 at 57). Abhai further argues that the viscosity tests described in the specification "fail to clarify the objective bounds of the molecular weight limitations." (*Id.* at 58). "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). While it seems clear to me that the intrinsic evidence indicates that the inventors were referring to weight average molecular weight, I do not think it is necessary to decide the issue in order to find that this term is not indefinite. The specification defines polyethylene oxide ("PEO") as having a molecular weight of 4,000,000 by reference to a specific test performed on a specific instrument. ('741 patent at 7:64-8:1). Abhai objects that this "does not overcome the indefiniteness problem . . . [because this] measurement does not directly measure molecular weight." (D.I. 116 at 59). Whether that test measures molecular weight is immaterial as the statement in the specification constitutes an express definition of what the inventor considered to be a PEO having an approximate molecular weight of 4,000,000. Therefore, this case is distinguishable from the cases cited by Abhai and I think that a person of ordinary skill in the art would understand the scope of the invention.

The remaining dispute appears to be whether, as Plaintiffs argue, the “at least one polyethylene oxide” encompasses any PEO mixture whose molecular weight, as a whole, is approximately 4,000,000 (D.I. 116 at 36), or whether, as Amneal argues, the term is limited to a single specific grade of commercially available PEO which has this approximate molecular weight. (*Id.* at 44). I agree with Plaintiffs. Although the examples in the specification discuss certain commercially available grades of PEO, the claims are not so narrowly drawn. Rather, I think that any PEO that satisfies the definition of PEO having a molecular weight of 4,000,000 provided in the specification falls within this claim term. This is not to say, however, that every PEO combined in the final product is used to determine the approximate 4,000,000 molecular weight. For example, claim 1 of the '987 patent calls for “at least one polyethylene oxide . . . [having] a molecular weight of approximately 4,000,000.” Dependent claim 28 calls for, “The process of claim 1, wherein the composition further comprises at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of less than 1,000,000.” It seems to me that the “at least one PEO” from claim 1 is a PEO component that, whether it is a single commercially available grade or a blend of several different grades, meets the specification’s definition of PEO with a molecular weight of 4,000,000. The PEO component with a molecular weight of less than 1,000,000 called for in claim 28 is a different component which also, whether it is a single grade or a blend of grades, meets the specification’s definition of PEO with a molecular weight of 1,000,000. In other words, Amneal’s apparent concern about Plaintiffs’ averaging of the weights of multiple PEOs that are each components of the final composition is misplaced. (D.I. 116 at 49). It seems clear to me that these are two different components and the additional PEO called for in some dependent claims is not to be averaged with anything else to achieve the PEO with a molecular weight of 4,000,000 called for in the independent claim.

2. “[at least one synthetic or natural polymer (C),] wherein the polymer (C) has a molecular weight of at least 0.5 million according to rheological measurements”
 - a. *Plaintiffs’ proposed construction*: “wherein the polymer (C) has a weight average molecular weight of at least 0.5 million according to rheological measurements”
 - b. *Amneal’s proposed construction*: “one or more synthetic or natural polymer (C) ingredients each supplied in a grade having a molecular weight of at least 0.5 million based on rheological measurements”
 - c. *Abhai’s proposed construction*: The term is indefinite. If the Court chooses to defer ruling on indefiniteness, the term should be construed as: “wherein the mass of the molecule(s) of polymer (C) is at least 0.5 million according to measurements based on the deformation and the flow of matter”
 - d. *Court’s construction*: “wherein the polymer (C) has a weight average molecular weight of at least 0.5 million according to rheological measurements”

The parties’ dispute with respect to this term is essentially the same as for the previous term. For the same reasons as above, I reject both Abhai’s argument that the term is indefinite and Amneal’s argument that the polymer ingredients must be supplied in a specific grade. As above, I will adopt Plaintiffs’ proposed construction with the understanding that the polymer (C) is a component of the dosage form that itself alone meets the specification’s definition of a PEO with a molecular weight of at least 0.5 million.

3. “viscosity-increasing agent”⁴
 - a. *Plaintiffs’ proposed construction*: “a substance that increases the resistance of a fluid to flow”
 - b. *Amneal’s proposed construction*: “requires a substance different from the synthetic or natural polymer and is not limited to the specific substances set out in the specification at 8:63-9:14”
 - c. *Abhai’s proposed construction*: “requires a substance different from the synthetic or natural polymer and is not limited to the specific substances set out in the specification at 8:63-9:14”

⁴ This term was construed in previous litigation to mean “requiring a substance distinct from the hardening polymer.” *Endo Pharmaceuticals Inc. v. Amneal Pharmaceuticals, LLC*, 2015 WL 9459823, at *24 (S.D.N.Y. Aug. 18, 2016); see also *In re OxyContin Antitrust Litigation*, 2014 WL 2198590, at *11 (S.D.N.Y. May 27, 2014) (finding viscosity-increasing agent distinct from polymer (C)).

- d. *Court's construction*: “requires a substance different from the synthetic or natural polymer and is not limited to the specific substances set out in the specification at 8:63-9:14”

The only dispute between the parties with respect to this term is whether the “viscosity-increasing agent” in claim 9 of the '060 patent must be a substance different from the “at least one synthetic or natural polymer (C)” of claim 1, from which claim 9 depends. Plaintiffs argue that there is nothing in the claims or specification that limits the role of the polymer of claim 1 such that it could not also function as the “viscosity-increasing agent.” (D.I. 116 at 125). The plain language of the claims, however, supports Defendants’ construction. Claim 9 recites, “A dosage form according to claim 1, which additionally comprises . . . at least one viscosity-increasing agent.” It seems to me that the phrase “additionally comprises” means that the viscosity-increasing agent required by claim 9 is a component that is distinct from the ingredients required by claim 1. This is confirmed by the language of the specification. The polymer (C) is included in the compound to increase hardness, thereby preventing the dosage form from being crushed into a powder. ('060 patent at 6:20-27). The specification goes on to state that “in order to prevent any possible abuse in the event of . . . pulverization of the dosage form . . . by application of extreme force, the dosage forms . . . may, in a preferred embodiment, contain further agents which complicate or prevent abuses as auxiliary substances (B).” (*Id.* at 6:28-34). A viscosity-increasing agent is listed as one of the auxiliary substances (B) that may be included. (*Id.* at 6:3). I think that the phrases “further agents” and “auxiliary substances” clearly indicate that the “viscosity-increasing agent” is something different from the ingredients already included in the compound. For these reasons, I reject Plaintiffs’ proposed construction. The parties agree that the agent is not limited to the specific substances listed in the specification. (D.I. 116 at 124). Therefore, I will adopt Defendants’ proposed construction.

4. “a necessary minimum quantity of an aqueous liquid”⁵
 - a. *Plaintiffs’ proposed construction*: “10 ml of water at a temperature of 25°C”
 - b. *Amneal’s proposed construction*: “an aqueous liquid in a necessary minimum quantity”
 - c. *Abhai’s proposed construction*: The term is indefinite. If the Court chooses to defer ruling on indefiniteness, the term should be construed as: “an aqueous liquid in a necessary minimum quantity”
 - d. *Court’s construction*: “an aqueous liquid in a necessary minimum quantity”

As an initial matter, I will reject Abhai’s argument that the term is indefinite. Abhai argues that a person of ordinary skill in the art would not know, in practicing the claim, “whether she had not yet applied a ‘necessary minimum quantity’ of the aqueous liquid.” (D.I. 116 at 137). I disagree. The specification provides guidance for how much water is required in the form of an exemplary embodiment. (’060 patent at 8:55-62). Furthermore, Abhai’s argument that a practitioner “could supply gallons of aqueous liquid without knowing” if more liquid was required (D.I. 116 at 137) makes no sense to me as adding more liquid would only make the mixture more dilute (and less likely to gel). I decline to find this term indefinite.

Plaintiffs seek to import a specific limitation from the specification as to how much liquid, what type of liquid, and what temperature the liquid should have. It is inappropriate to import this limitation as there is no indication in the specification that this is the only way to practice the claim. It seems to me that if the inventor wished for the method of claim 9 to be so limited, he would have written those limitations into the claim itself. I will adopt Amneal’s proposed construction.

⁵ This term was construed in previous litigation to mean “an aqueous liquid in a necessary minimum quantity.” *In re OxyContin Antitrust Litigation*, 2014 WL 2198590, at *15 (S.D.N.Y. May 27, 2014).

5. “forms a gel with the extract obtained from the dosage form”⁶
 - a. *Plaintiffs’ proposed construction*: “an aqueous extract obtained from the dosage form with 10 ml of water at 25°C forms a gel”
 - b. *Amneal’s proposed construction*: “forms a gel with the extract obtained from the dosage form, which gel is difficult or impossible to pass through a needle or inject”
 - c. *Abhai’s proposed construction*: “forms a gel with the extract obtained from the dosage form, which gel is difficult or impossible to pass through a needle or inject”
 - d. *Court’s construction*: “no construction necessary”

There are two disputes with respect to this term. First, Plaintiffs wish to include a limitation on the amount and temperature of the liquid to be used in practicing this claim. I already rejected Plaintiffs’ arguments above and do so again for this term for the same reasons. Second, the parties dispute whether to include the functional description proposed by Defendants. It would be improper to import a functional limitation into this non-functional claim term so as to make “infringement turn on the use to which [the compound] is later put.” *Paragon Sols., LLC v. Timex Corp.*, 566 F.3d 1075, 1091 (Fed. Cir. 2009). Therefore, I reject Defendants’ proposed construction. Furthermore, I think “gel” is not used in any sort of technical sense in this claim and a lay person would understand what is meant by “forms a gel.” Since Defendants’ proposed construction is identical to the claim language if the functional description is deleted, there is no reason to construe this term, and I decline to do so.

6. “removing 8 α ,14-dihydroxy-7,8-dihydrocodeinone [8 α] from an oxycodone base composition”
 - a. *Plaintiffs’ proposed construction*: “the amount of 8 α ,14-dihydroxy-7,8-dihydrocodeinone [8 α] present in an oxycodone base composition is reduced”

⁶ This term was construed in previous litigation to mean “forms a gel with the extract obtained from the dosage form, which gel is difficult or impossible to pass through a needle or inject.” *In re OxyContin Antitrust Litigation*, 2014 WL 2198590, at *16 (S.D.N.Y. May 27, 2014).

- b. *Amneal's proposed construction*: "eliminating 8 α ,14-dihydroxy-7,8-dihydrocodeinone [8 α] from an oxycodone base composition"
- c. *Abhai's proposed construction*: "eliminating 8 α ,14-dihydroxy-7,8-dihydrocodeinone [8 α] from an oxycodone base composition"
- d. *Court's construction*: "the amount of 8 α ,14-dihydroxy-7,8-dihydrocodeinone [8 α] present in an oxycodone base composition is reduced"

The parties' sole dispute with respect to this term is whether the amount of 8 α in the composition must be completely eliminated or merely reduced. Defendants rely on a single definition of "removing" from a single dictionary to argue strenuously that "remove" means "to get rid of," a definition it seems to think is the equivalent of "eliminate." (D.I. 116 at 153). I do not agree that Defendants' preferred definition necessarily means "eliminate" in the sense of eliminating completely. Furthermore, I do not think that resort to a dictionary is necessary. Here, the specification provides sufficient evidence that "removing" was not intended to mean "eliminating." None of the embodiments described in the specification contemplates a complete elimination of 8,14-dihydroxy-7,8-dihydrocodeinone. In fact, while all embodiments describe a substantially reduced amount of the compound, in every case, some 8,14-dihydroxy-7,8-dihydrocodeinone remains. (*See, e.g.*, '933 patent at 26:36-38). Defendants attempt to counter this obvious weakness in their argument by pointing to the fact that the patent defines 8,14-dihydroxy-7,8-dihydrocodeinone as including either the 8 α form of the compound, the 8 β form, or a mixture of both types. (*Id.* at 159). Defendants seem to be arguing that, since the embodiments do not specifically indicate which form is reduced, the 8 α form could be completely eliminated and all of the remaining 8,14-dihydroxy-7,8-dihydrocodeinone is of the 8 β form. I am not persuaded. Therefore, I will adopt Plaintiffs' proposed construction.