IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COLLEGIUM PHARMACEUTICAL, INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 18-300-LPS-CJB (Consolidated)
TEVA PHARMACEUTICALS USA., INC.,	)	
Defendant.	)	

REPORT AND RECOMMENDATION

In these consolidated Hatch-Waxman patent litigation matters filed by Plaintiff Collegium Pharmaceutical, Inc. ("Plaintiff") against Defendant Teva Pharmaceuticals USA, Inc. ("Defendant"), Plaintiff alleges infringement of 13 patents: United States Patent Nos. 7,771,707 (the "'707 patent"), 8,449,909 (the "'909 patent"), 8,557,291 (the "'291 patent"), 8,758,813 (the "'813 patent"), 8,840,928 (the "'928 patent"), 9,044,398 (the "'398 patent"), 9,248,195 (the "'195 patent"), 9,592,200 (the "'200 patent"), 9,682,075 (the "'075 patent"), 9,737,530 (the "'530 patent"), 9,763,883 (the "'883 patent"), 9,968,598 (the "'598 patent") and 10,004,729 (the "'729 patent" and collectively with the other patents, "the asserted patents"). Presently before the Court is the matter of claim construction. The Court recommends that the District Court adopt the constructions set forth below.

I. BACKGROUND

Plaintiff filed a Complaint in Civil Action No. 18-300-LPS-CJB on February 22, 2018, in which it asserted that Defendant's submission of ANDA No. 209431 to the United States Food and Drug Administration—a submission that sought approval to engage in the commercial

manufacture, use, sale, offer for sale, or importation of Oxycodone Extended-Release Capsules, CII, 9 mg, 13.5 mg, 18 mg, and 36 mg—was an act of infringement of, *inter alia*, the first 11 of the asserted patents listed above. (D.I. 1; D.I. 84)[1] On November 30, 2018, Plaintiff filed a second Complaint in Civil Action No. 18-900-LPS-CJB, asserting infringement of the '598 patent and the '729 patent, which were issued after ANDA No. 209431 was filed. (Civil Action No. 18-1900-LPS-CJB, D.I. 1; D.I. 84) Both cases have been referred to the Court to hear and resolve all pretrial matters, up to and including case-dispositive motions. (D.I. 8; Civil Action No. 18-1900-LPS-CJB, D.I. 7) On January 29, 2019, at the parties' request, the Court consolidated the cases for all purposes. (D.I. 48)

According to Plaintiff, the patented inventions "make attempts to abuse powerful pain medications more difficult or less rewarding, generally by protecting against unintended exposure of drugs such as opiates." (D.I. 54 at 1) The claims of the asserted patents purport to "involve new ways to dissolve [such drugs] in very small beads of wax that will release the drug over time when administered as intended, but that make it difficult to manipulate the formulation for purposes of abuse and misuse." (*Id.*; *see also* D.I. 1 at ¶¶ 33-34)

The parties filed simultaneous opening claim construction briefs on February 22, 2019, and simultaneous responsive briefs on March 22, 2019. (D.I. 54; D.I. 55; D.I. 69; D.I. 71) The Court held a *Markman* hearing on April 12, 2019. (D.I. 83 (hereinafter, "Tr.")) Following the hearing, the parties submitted supplemental letter briefs relating to Defendant's use of deposition

[1] Citations herein will be to the docket in Civil Action No. 18-300-LPS-CJB unless otherwise noted.

testimony at the claim construction hearing. This supplemental briefing was completed on April 29, 2019. (D.I. 85)

II. STANDARD OF REVIEW

It is well-understood that "[a] claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). Claim construction is a generally a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015).

The Court should typically assign claim terms their "ordinary and customary meaning[,]" which is "the meaning that the term[s] would have to a person of ordinary skill in the art ['POSITA'] in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). However, when determining the ordinary meaning of claim terms, the Court should not extract and isolate those terms from the context of the patent; rather it should endeavor to reflect their "meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321; *see also Eon Corp. IP Holdings LLC v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1320 (Fed. Cir. 2016).

In proceeding with claim construction, the Court should look first and foremost to the language of the claims themselves, because "[i]t 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*, 415 F.3d at 1312 (internal quotation marks and citations omitted). For example, the context in which a term is used in a claim may be "highly instructive." *Id.* at 1314. In addition,

"[o]ther claims of the patent in question, both asserted and unasserted, can . . . be valuable" in discerning the meaning of a particular claim term. *Id.* This is "[b]ecause claim terms are normally used consistently throughout the patent, [and so] the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Id.* Moreover, "[d]ifferences among claims can also be a useful guide[,]" as when "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15.

In addition to the words of the claims, the Court should look to other intrinsic evidence. For example, the Court should analyze the patent specification, which "may reveal a special definition given to a claim term . . . that differs from the meaning [that term] would otherwise possess" or may reveal an intentional disclaimer of claim scope. *Id.* at 1316. Even if the specification does not contain such revelations, it "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." *Id.* at 1315 (internal quotation marks and citation omitted). That said, however, the specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). And a court should also consider the patent's prosecution history, if it is in evidence, because it "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution[.]" *Phillips*, 415 F.3d at 1317.

Extrinsic evidence, "including expert and inventor testimony, dictionaries, and learned treatises[,]" can also "shed useful light on the relevant art[.]" *Id.* (internal quotation marks and

citations omitted). Overall, while extrinsic evidence may be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* (internal quotation marks and citations omitted); *accord Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 981 (Fed. Cir. 1995).

In utilizing these resources during claim construction, courts should keep in mind that "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

III. DISCUSSION

The parties currently have disputes regarding six terms or sets of terms (hereinafter, "terms"). This Report and Recommendation addresses two of the terms: "homogeneous single phase" and "solidified solution." The other terms will be addressed in one or more forthcoming Report and Recommendations.

A. "homogeneous single phase"

The "homogeneous single phase" term appears in the asserted claims of the '200 patent, which all recite abuse-deterrent oral dosage forms. Independent claim 1 is representative; that claim is reproduced below, with the disputed term highlighted:

> **1.** An abuse-deterrent oral dosage form comprising a plurality of microparticles, wherein each microparticle comprises a *homogeneous single phase* comprising:
>
> (a) oxycodone; and
>
> (b) one or more fatty acids;
>
> wherein the molar ratio of fatty acid to oxycodone is in excess of about 7:1 and the oxycodone is in the form of a fatty acid salt.

('200 patent, col. 19:47-54 (emphasis added))

The parties' competing proposed constructions for "homogeneous single phase" are set out in the chart below:

Term	Plaintiff's Proposed Construction	Defendant's Proposed Construction
"homogeneous single phase"	"drug is dissolved in the excipient matrix and uniformly and molecularly dispersed"	Plain and ordinary meaning.

(D.I. 54 at 10) The parties' main dispute here is about how the drug is dispersed in a "homogeneous single phase." Plaintiff argues that the term should be construed in such a way that requires the drug to be "molecularly dispersed." (*Id.*; Tr. at 89) Defendant disagrees, and asserts that pursuant to the term's plain and ordinary meaning, "homogeneous single phase" only requires that the drug be "uniformly dispersed in a mixture in one phase"—not that the drug must necessarily be "molecularly dispersed." (D.I. 55 at 17)[2] For the three reasons set forth below, the Court concludes that Defendant is correct and that Plaintiff's proposed construction should not be adopted.

First, the patentee's definition of another phrase—"solid solution"—helps to explain why Plaintiff's proposed construction for "homogeneous single phase" is off the mark. On this front, the '928 patent specification states as follows:

> The term "solid solution" is defined as a system in a solid state wherein the drug is *molecularly dispersed* throughout a matrix

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[2] Defendant does not dispute that the term means that the drug is "*uniformly* dispersed in the matrix in one phase[,]" (D.I. 55 at 17 (emphasis added)), and argues that the use of the word "homogenous" is what conveys the requirement for such uniformity. (*Id.*) And Defendant asserts that "single phase" refers to "the number of phases of matter (i.e., gas, liquid, or solid) present in the mixture." (*Id.*) According to Defendant, then, a "homogenous single phase" has a drug that is present as particles, such particles are uniformly dispersed in a matrix, the particles and the matrix are the same phase, and such dispersed particles may be larger than molecules. (*Id.* at 18)

> such that the system is chemically and physically uniform or homogenous throughout.

('928 patent, col. 11:10-13 (emphasis added)) As Defendant notes, the '928 patent (which issued over a year before the '200 patent) thus provides evidence that when the patentee wished to make clear that a solution included a drug that was molecularly dispersed throughout, it knew how to do so and said so expressly. (D.I. 55 at 18; Defendant's Markman Presentation, Slide 65) The fact that the patentee did *not* expressly state that a "homogenous single phase" is one where the drug must be molecularly dispersed in turn suggests that no such absolute requirement is to be found in the patent.

Second, one of Plaintiff's key arguments—an argument linked to the patentee's use of the term "intimately dispersed"—is unavailing. According to Plaintiff, the patentee made it clear that the drug must be "molecularly dispersed" when it used the phrase "intimately dispersed" in the specification and during prosecution. Here Plaintiff points to the statement in the '200 patent specification that in order to "create a composition that protects [the] drug from exposure upon mechanical disruption ([e.g.], grinding, chewing, or chopping), the drug is *intimately dispersed* within the carrier material." ('200 patent, col. 10:7-10 (emphasis added) (*cited in* D.I. 54 at 10)) And Plaintiff notes that in describing their invention to the Examiner during prosecution, the inventors similarly stated that:

> [I]n order to create a composition that protects the drug from exposure, and therefore extraction, upon mechanical disruption (e.g., grinding or chopping), the drug should be *intimately dispersed* within the microparticle. In order to do this, the components of the microparticle, including the drug and fatty acids, *must form a homogenous single phase*.

(D.I. 47, ex. B-7 at 8 (emphasis added) (*cited in* D.I. 54 at 10))

Yet the Court is unconvinced that, pursuant to the intrinsic record, "intimately dispersed" means the same thing as "molecularly dispersed." To that end, it is relevant that the parties seem to agree that if a substance is described as being "fully dissolved" or dispersed, this is akin to the form of "molecular dispersion" that Plaintiff asserts is required by the claims. (Tr. at 103-04) Conversely, if a substance is described as being "partially dissolved" or dispersed, such a description is not typically in line with what it means to be "molecularly" dispersed. (*Id.*) This understanding is in turn helpful when looking at another portion of the patent specification, which describes an embodiment of the invention:

> The modified drug is then homogenously dispersed within one or more carrier materials that are either slowly soluble or not soluble in water. Dispersion within these materials further reduces the accessibility of the drug when crushed and exposed to an aqueous media. *In some embodiments, the drug may be partially or fully dispersed in the carrier materials on a molecular level.* The *intimate mixture* of modified drug and carrier materials is subsequently formulated into microparticles[.]

('200 patent, col. 5:5-13 (emphasis added)) This portion of the patent thus appears to suggest that an "intimate" dispersion of the drug can include one where the drug is only "partially" dissolved or dispersed (i.e., not "fully" dissolved or dispersed). *See Wasica Fin. GmbH v. Cont'l Auto Sys., Inc.*, 853 F.3d 1272, 1280 (Fed. Cir. 2017) (stating that the United States Court of Appeals for the Federal Circuit generally interprets the use of the word "or" in a patent as designating "distinct alternatives"). And if "partial" dispersion is not typically akin to "molecular" dispersion, then this all suggests that when the patentee states that the drug should be "intimately dispersed" within the microparticle, it was not requiring molecular dispersion.[3]

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[3] Indeed, other portions of the patent state that the drug may be "partially" dissolved and yet still may be part of a "homogenous[]" dispersion. ('200 patent, cols. 9:4-14, 11:8-17, 14:24-29)

Third, Plaintiff relies heavily on a declaration that inventor Dr. Alison Fleming submitted to the Examiner during prosecution, (D.I. 54 at 10-11; Tr. at 89), but that declaration does not do the work Plaintiff asks of it. In her declaration, Dr. Fleming stated the following:

> *[I]n order to obtain a "homogenous single phase" as recited in the pending claims, the drug must be dissolved or molecularly dispersed in the excipient matrix.* The ability of a drug to dissolve or molecularly disperse in a matrix is dependent on the chemical characteristics of the drug, the excipients, and the processing conditions.

(D.I. 47, ex. B-6 at ¶ 15 (emphasis added)) However, as Defendant notes, (D.I. 69 at 17; Defendant's Markman Presentation, Slide 68), when discussing how one obtains a "homogenous single phase," here Dr. Fleming wrote that the drug "must be dissolved *or* molecularly dispersed" in the matrix, (D.I. 69 at 17 (emphasis in original)). Above, the Court noted that a drug may be either partially "dissolved" or fully "dissolved" in a matrix—and that the former is typically understood to require less than molecular dispersion. Thus, Dr. Fleming's choice of words here could be credibly read as allowing for, on the one hand, something less than molecular dispersion (i.e., partially "dissolved") *or*, alternatively, for molecular dispersion.[4] And in light of this, Dr. Fleming's declaration does not clearly indicate that Plaintiff's construction is appropriate.

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[4] Although Plaintiff suggested that Dr. Fleming was here using "dissolved" and "molecularly dispersed" as synonyms and that the two terms "mean the same thing[,]" (Tr. at 91-92), this is not clear at all from Dr. Fleming's declaration. And, as noted above, typically when a patentee uses the word "or," he or she is not understood to be listing two words that mean the same thing. *See Wasica Fin. GmbH*, 853 F.3d at 1280. Moreover, Plaintiff did not put forward any expert testimony suggesting that a POSITA would have interpreted Dr. Fleming's reference here to "dissolved" as a synonym for the phrase Dr. Fleming uses next ("molecularly dispersed"). (Tr. at 92)

For the foregoing reasons, the Court recommends that "homogeneous single phase" be construed as "drug is dissolved in the excipient matrix and uniformly dispersed."

B. "solidified solution"

The "solidified solution" term appears in the '291 patent and the '195 patent. (D.I. 55 at 19) Its use in independent claim 2 of the asserted '291 patent is representative, and that claim is reproduced below, with the disputed term highlighted:

> **2.** An abuse-deterrent oral dosage form comprising a plurality of microparticles, where each microparticle comprises:
> a *solidified solution* of a fatty acid salt of one or more drugs prone to abuse; and
> one or more carrier material(s) comprising fats, fatty substances, waxes, wax-like substances or mixtures thereof.

('291 patent, col. 19:8-14 (emphasis added))

The parties' competing proposed constructions for "solidified solution" are set out in the chart below:

Term	**Plaintiff's Proposed Construction**	**Defendant's Proposed Construction**
"solidified solution"	"a system in a solid state wherein the drug is molecularly dispersed throughout a matrix such that the system is chemically and physically uniform or homogeneous throughout"	Plain and ordinary meaning.

(D.I. 54 at 8) The parties' dispute is over whether a "solidified solution" requires that the drug be "molecularly dispersed" in the matrix (as Plaintiff argues), (*id.* at 9-10), or whether it simply refers to "a solution that has transitioned to a solid form" (as Defendant argues), (D.I. 55 at 19). For the reasons set out below, the Court again agrees with Defendant.

As an initial matter, the language of the '291 patent's claims provides support for Defendant's position. Although the term "solidified solution" only appears in claim 2, claim 18 of the '291 patent, which depends from claim 2, further recites that the "one or more drugs prone to abuse is *uniformly dispersed* in the carrier material of each microparticle." ('291 patent, col. 20:26-29 (emphasis added)) If claim 18 requires that the drugs be "uniformly dispersed," the doctrine of claim differentiation suggests that claim 2 (and its reference to a "solidified solution" of the fatty acid salt of one or more such drug) does not absolutely require such uniform dispersion (and, thus, certainly does not require molecular dispersion of the drug). (D.I. 69 at 15 (citing *Phillips*, 415 F.3d at 1314-15))

The specification also supports Defendant's position. For example, the '291 patent states that in certain embodiments, within the microparticles the drug is "preferably homogeneously dispersed in the form of fine particles within the carrier material" and that "[m]ore preferably, the drug is partially solubilized in a molten carrier material or *partially dissolved* with the carrier material[.]" ('291 patent, col. 8:52-56 (emphasis added)) For reasons set out above when discussing the prior claim term, this reference to the drug product being "partially dissolved" strongly suggests that molecular dispersion is not required in the claimed invention. (D.I. 55 at 20) And this in turn indicates that it would be error to import a "molecularly dispersed throughout a matrix" limitation into the claim term at issue. (*Id.*)

Plaintiff's arguments to the contrary are not persuasive. For example, Plaintiff argues that "solidified solution" has the same meaning as "solid solution"—and that since the latter term (as discussed above) is defined in related patents to require molecular dispersion of the drug in the matrix, then "solidified solution" must in turn carry the same meaning. (D.I. 54 at 9) But as Defendant rightly notes, (D.I. 55 at 19; D.I. 69 at 15), "solidified solution" is nowhere defined in

the asserted patents, and these two *different* terms are thus generally presumed to have *different* meanings. *See, e.g., Chi. Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1369 (Fed. Cir. 2012). Additionally, although Plaintiff points to a description of one embodiment in the '291 patent in support of its proposal, (D.I. 54 at 9 (citing '291 patent, col. 10:15-26)), the text at issue says nothing about the drug being uniformly dispersed at the molecular level, (*see* D.I. 69 at 16).

For all of the above reasons, the Court recommends that "solidified solution" be construed to mean "a solution that has transitioned to a solid form."

IV. CONCLUSION

For the foregoing reasons, the Court recommends that the District Court adopt the following constructions:

1. "homogeneous single phase" should be construed to mean "drug is dissolved in the excipient matrix and uniformly dispersed"

2. "solidified solution" should be construed to mean "a solution that has transitioned to a solid form"

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: September 11, 2019

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE