UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CIPHER PHARMACEUTICALS INC., et al.,	:	Civil No. 13-6502 (JEI/AMD)
Plaintiffs,	:	**OPINION**
v.	:	
ACTAVIS LABORATORIES FL, INC., et al.,	:	
Defendants.	:	

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IRENAS, Senior United States District Judge:

This is a patent infringement suit. The Court conducted a *Markman* hearing on April 2, 2015, which included extensive testimony from the parties' expert witnesses. This opinion construes the five remaining disputed terms[1] of the two related patents, the '427 patent[2] and the '102 patent[3], both of which disclose a "pharmaceutical semi-solid composition of isotretinoin," commercially known as the prescription drug Absorica.

I.

According to Plaintiffs, Absorica is an improvement on the well-known acne drug, Accutane, which is another formulation of isotretinoin.[4]

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[1] The parties' Joint Claim Construction and Prehearing Statement, *see* Local Patent Rule 4.3, identified nine terms to be construed. By the time of the *Markman* hearing, the parties had narrowed that number to five.

[2] U.S. Patent No. 7,435,427, issued October 14, 2008.

[3] U.S. Patent No. 8,367,102, issued February 5, 2013.

[4] Outside the United States, Accutane is marketed as Roaccutane. The patents-in-suit refer to Roaccutane.

Isotretinoin, a retinoid (related to Vitamin A), is a difficult drug with which to work for three reasons. First, it degrades when exposed to light and air. Second, it is very poorly water soluble. Third, it has a narrow therapeutic window, meaning that there is a small range between the dose at which the drug is effective and the dose at which it is toxic.[5]

Accutane purportedly sought to address at least some of these problems by dissolving isotretinoin in a gelatin capsule (to be taken orally) largely composed of oily, fatty ingredients such as beeswax and vegetable oil. However, when patients ingested Accutane, it did not mix well in the aqueous (watery) environment of the human body, leading to poor bioavailability of the isotretinoin active ingredient. Thus, to boost absorption, patients were instructed to take Accutane with food.

However, this approach, according to Plaintiff, was not ideal. The "food effect" was strong, resulting in radical spikes in absorption and an increased risk of overshooting the therapeutic window. Decreased absorption associated with low food intake was also a problem; it could lead to "re-treatment" which itself carries a risk of toxic exposure simply due to

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[5] Toxic effects include severe birth defects, liver toxicity, vomiting, headaches, skin anemia, severe mucosal irritation, and appendicitis.

taking the drug for a longer period of time.[6] The absorption problem was magnified by the reality that typical isotretinoin patients are teenagers, who, as a group, are known to be "notoriously non-compliant." (Plaintiffs' tutorial, p. 2)

Absorica allegedly solves the "food effect" absorption problem by creating a novel semi-solid formulation of isotretinoin. Absorica, like Accutane, has an oily vehicle (i.e., oily excipient); but, *unlike* Accutane, Absorica also has a water-soluble component (i.e., hydro**phil**ic excipient). This new formulation allegedly obviates the need to take the drug with food. Absorica is the only isotretinoin product currently on the market with the dosage instruction that the capsules should be taken "without regard to meals."

The terms to be construed are:

Term 1: "semi-solid suspension"

Term 2: "hydro**phob**ic lip**id**ic balance (HLB) value"

Term 3: "having an HLB value equal to or greater than 10" / "has an HLB value of at least [12, 13]"

Term 4: "the isotretinoin is partially in suspension and/or partially in solution"

Term 5: "an amount of about 1 to 10% of at least one additional surfactant" / "about 1 – 10% of an additional surfactant"

[6] A typical course of treatment with isotretinoin lasts 15-20 weeks.

II.

Claim construction is a matter of law for the Court to decide. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). "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, 1319 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)).

The Court begins a claim construction analysis by examining the intrinsic evidence, which includes the claims, the specification, and the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "A claim construction analysis must begin and remain centered on the claim language itself." *Innova*, 381 F.3d at 1116. There is a heavy presumption that a claim term conveys its 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." *Phillips*, 415 F.3d at 1313. But a patentee may overcome this presumption and choose "to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term." *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1999); *see also*

Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1353 (Fed. Cir. 2000); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979–80 (Fed. Cir. 1995), aff'd 517 U.S. 370 (1996).

The claims themselves and the context in which a term is used within the claims can "provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. In addition, other claims of the patent may be useful in construing a claim term, as "claim terms are normally used consistently throughout the patent." *Id*. Similarly, claims that differ from each other may provide insight into how a term should be read. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991).

After examining the claims, "it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." *Vitronics*, 90 F.3d at 1582. "For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims." *Markman*, 52 F.3d at 979. For this reason, "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." *Vitronics*, 90 F.3d at 1582.

Finally, the Court should also examine the prosecution history, if it is in evidence. *Phillips*, 415 F.3d at 1317.

"The prosecution history 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, making the claim scope narrower than it would otherwise be." *Id.*

"[I]deally there should be no 'ambiguity' in claim language to one of ordinary skill in the art that would require resort to evidence outside the specification and prosecution history." *Markman*, 52 F.3d at 986. But if the term remains unclear or ambiguous after examining the intrinsic evidence, the Court may turn to extrinsic evidence. *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1216 (Fed. Cir. 1995). "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Although extrinsic evidence is useful in determining how a person of ordinary skill in the art would understand the term, it is less reliable for the purposes of claim construction than the patent and its prosecution history. *Phillips*, 415 F.3d at 1318-19. Therefore, extrinsic evidence must be viewed within the context of intrinsic evidence. *Id.* at 1319.

III.

The Court addresses one initial issue before turning to the disputed terms.

A.

Defendants assert that four out of the five disputed claim terms are indefinite. Defendants urge the Court to decide that issue now, at the claim construction phase of this suit.

Plaintiffs argue that neither the parties, nor the governing scheduling order, contemplated addressing indefiniteness at the *Markman* hearing. Plaintiffs urge the Court to address indefiniteness later, upon an appropriate motion for summary judgment.

There is no dispute that the issues of indefiniteness and claim construction are-- or at least, often will be-- intertwined. *See generally* Manzo, Patent Claim Construction in the Federal Circuit (2012 ed.) § 4:1 ("The determination of indefiniteness arises out of the court's performance of its duty to construe claims"; "[Indefiniteness] is intimately related to claim construction.").

Indeed, the Supreme Court's recent *Nautilus* decision appears to draw indefiniteness and claim construction even closer together. *See Nautilus, Inc. v. Boisig Instruments, Inc.*, 134 S.Ct. 2120 (June 2, 2014). The indefiniteness inquiry no longer asks whether claim terms are insolubly ambiguous.

Rather, the *Nautilus* Court held, "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." 134 S.Ct. at 2124. Thus, the question of whether the Court should decide indefiniteness at claim construction is, in this respect, relatively new.[7]

In this Court's view, taking a claim-by-claim approach to Defendants' indefiniteness arguments is necessary because the asserted reasons for the disputed terms' indefiniteness are different.[8] Those reasons are sometimes very closely intertwined with the actual meaning or construction of the words[9], but other

[7] Even before *Nautilus* however, courts were deciding indefiniteness at, or even before, the claim construction phase. *See, e.g.*, *Teva Pharmaceuticals USA, Inc., et al. v. Sandoz, Inc., et al.,* 810 F.Supp.2d 578, 581 (S.D.N.Y. 2011). There seems to be little reasonable dispute that the Court *can* decide indefiniteness now. The issue presented here is, *should* the Court-- in the context of this particular case, and the parties' disputes as they currently stand-- decide indefiniteness now?

[8] *See generally*, Manzo, Patent Claim Construction in the Federal Circuit (2012 ed.) § 4:1 (cataloging eight "types" of indefiniteness assertions).

[9] *See, e.g.,* Manzo § 4:1 ("A sixth type [of indefiniteness assertion] is when the claim language is not intentionally imprecise but the meaning cannot reasonably be discerned.").

times the reasons may not be so intertwined.[10] Two of this case's disputed terms provide contrasting examples.

First, Defendants argue that hydrophobic lipidic balance (term 2) is indefinite because there is no such term of art; the term has no meaning to one skilled in the art and therefore is indefinite. Plaintiffs on the other hand, agree there is no such term of art, they simply urge the Court to draw a different conclusion-- namely, that the term is a typographical error.

This type of indefiniteness dispute is, for lack of a better term, "ripe," for decision at the *Markman* stage. If the Court accepts Defendants' conclusion, the term undisputedly would be indefinite because even Plaintiffs concede, hydrophobic lipidic balance does not exist. But, if the Court concludes that there was a typographical mistake, even Defendants concede that hydrophilic lipidic balance is a term of art, and they agree with Plaintiffs on what that term of art means. Either way, construing the term, or concluding that it cannot be construed, simultaneously resolves the indefiniteness issue.

Not so, however, with respect to term 5 ("about 1 - 10%"). As to that term, Defendants' indefiniteness argument does not

[10] *See, e.g.,* Manzo § 4:1 ("The first type [of indefiniteness assertion is] imprecision by design. This occurs when claim drafters include words to indicate affirmatively that precision is not required. Examples of such words are 'substantially,' 'about,' and the like. Such words have routinely been used in patent drafting.").

directly implicate the construction of the word “about” because Defendants argue that even if the Court, consistent with governing caselaw, *see infra*, construes “about” to mean “approximately,” the indefiniteness problem persists.

Here, Defendants argue that the scope of the claim is unreasonably uncertain not because a person skilled in the art would not understand the term, but rather, that person would not know where to draw the line between several readily understandable alternatives: does “about 1%” include 0.9%? 0.85%? 0.5%? etc. Thus, this dispute, unlike the dispute over term 2, ventures far beyond the inherent meaning of the words, and therefore is not appropriately decided at the *Markman* stage. Construing the term in this instance does not resolve the indefiniteness issue.

Thus, whether to decide indefiniteness during claim construction depends on why the alleged infringer asserts that the claim is indefinite. When a claim is asserted to be indefinite because it has *no* meaning to a person skilled in the art, an indefiniteness decision at the claim construction stage may be practically unavoidable. But in other situations, the issues may not be as closely dependent on each other, and therefore an indefiniteness decision will be better left for decision at summary judgment, on a more developed record.

With these principles in mind, at this time the Court will rule upon Defendants' indefiniteness arguments as to disputed terms 2 and 4, but not 3 and 5.

B.

(1) "semi-solid suspension"

Plaintiffs argue that "suspension" is a term of art and should not be replaced with any other words. They assert that "suspension" has a plain meaning to a person of ordinary skill in the art and that the patent and the prosecution history support this plain meaning.

Defendants, on the other hand, would like the Court to "provide an explanation of the claim language as it would have been understood by a person of ordinary skill," (Opening brief, p. 17), therefore, they propose a construction that attempts to define "suspension" without using the word "suspension." Defendants' proposed construction is: "a semi-solid composition in which isotretinoin is predominantly undissolved and is dispersed in the at least two lipidic excipients."

The issue is whether "suspension" should be limited to suspensions in which isotretinoin is "*predominantly* undissolved," i.e., where *more than 50%* of the isotretinoin particles are in suspension, as opposed to being in solution. (See Hr. Tr. 117:10-15) ("THE COURT: Basically, you've just

really added the word 'predominantly.' That's what it comes down to. [Mumper]: That is correct."); (See also Hr. Tr. 174:2-12).

Plaintiffs are correct that limiting "suspension" in this way would be inconsistent with the patents' specifications:

- "For suspensions, it was possible to dissolve a high fraction of isotretinoin in the mix of excipients and even the whole quantity of the active ingredient if the manufacturing conditions . . . and the formulations were optimized." ('102 Patent, column 5, lines 20-25; '427 Patent, column 5 lines 16-21)

- "the isotretinoin may be solubilized in the mix of excipients or partially solubilized" ('102 Patent, column 3, lines 4-5; '427 Patent, column 2, lines 61-62)

- the invention contains excipients that "totally or partially (depending on the ratio between excipients) dissolve isotretinoin." ('102 Patent, column 5, lines 16-19; '427 Patent, column 5, lines 12-15)

There simply is no support in the patents' claims or specifications for Defendants' proposed qualifier of "predominantly."

Defendants mischaracterize Plaintiff's position by arguing that Plaintiffs equate solution and suspension. According to Defendants, Plaintiffs argue for a construction wherein all of the isotretinoin could be dissolved in suspension. This is not Plaintiffs' position insofar as they urge the Court to construe

"suspension" as "suspension," and suspension does not mean "solution." (See Davies Testimony, Hr. Tr. 38:18-20; 60:24-61:1) ("Q: And if all of the [drug] particles are dissolved, would you consider that to be a suspension? A: No. That would be a solution."; "if that formulation was one where the drug was completely dissolved, it would not be considered a suspension.").[11] The parties do not dispute that a "suspension" wherein *all* of the API is dissolved simply is not a suspension, it is a solution.

The Court holds that "semi-solid suspension" means "a semi-solid composition wherein the isotretinoin is not 100% in solution."

(2) "hydrophobic lipidic balance (HLB) value"

The issue is whether "hydrophobic lipidic" is an obvious typographical error which the Court may correct to say "hydrophilic lipophilic." Plaintiffs assert that it is. Defendants assert that "this term is not amenable to construction," and is indefinite.

[11] (See also Plaintiffs' closing argument, Hr. Tr. 200:1-5) ("in defendants' rebuttal *Markman* brief, they made statements that plaintiffs are arguing that a suspension means that all of the particles can be dissolved, and that is not what we're arguing.").

"'A district court can correct a patent only if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." *CBT Flint Partners, LLC v. Return Path, Inc.*, 654 F.3d 1353, 1358 (Fed. Cir. 2011).

Plaintiffs' position has ample support in: (a) the claim in which the term appears (claim 1); (b) the specification; and (c) the prosecution history. Plaintiffs' position is also supported by (d) the claims and specification of the '427 patent.

First, claim 1 of the '102 patent discloses:

> A method of treating a skin disorder, which comprises . . . a semi-solid preparation containing two lipidic excipients, at least one of them being hydrophilic having a Hydrophobic Lipidic Balance (HLB) value equal to or greater than 10, the other being an oily vehicle, whereby the at least one hydrophilic lipidic excipients(s) with an HLB value of at least 10 is selected . . .

(emphasis added).

The facial inconsistency of the claim is immediately obvious: a hydrophilic excipient logically cannot have a hydrophobic lipidic balance. It makes no sense; the two terms are diametrically opposed, as Defendants' own expert recognized in his testimony at the *Markman* hearing. (Mumper Testimony, Hr. Tr. 111:20-25) (See also Mumper Decl. ¶ 20) ("a person of ordinary skill in the art would have considered [hydrophobic and

hydrophilic] to be opposites.") The parties agree, hydrophilic literally means "water loving," whereas hydrophobic means "water fearing."

Second, the very first sentence of the specification reads: "[t]he present invention relates to an oral pharmaceutical composition of isotretinoin containing at least two excipients, one of them being hydrophilic (i.e., having an HLB value superior or equal to 10), the other being an oily vehicle." (emphasis added)

In four other places, the specification clearly refers to a "hydrophilic/lipophilic balance value (HLB)" (column 3, line 16-17), or a hydrophilic excipient having an HLB value of at least 10 (see column 4, line 10-11; column 4, line 16-17; column 5, line 15-16).[12]

Third, the prosecution history shows that the Patent Examiner himself understood "hydrophobic" to be a mistake. In the Notice of Allowability, the examiner stated that the

[12] Defendants' expert all but conceded this point during the *Markman* hearing: "THE COURT: Isn't there other things in the specifications that tell you what [hydrophobic lipidic balance] really means, that it really means hydrophilic? Mumper: There are, in the specifications, uses the term hydrophilic lipophilic balance." (Hr. Tr. 135:24-136:3)

The Court finds Mumper's testimony as to this particular claim evasive and disingenuous, and therefore discredits Mumper's ultimate conclusion that a person skilled in the art would conclude that hydrophobic lipidic balance is indefinite, rather than a typographical mistake.

predecessor to claim 1 “should be amended by replacing the term hydrophobic in line 4 with the term hydrophilic.” (Davies Decl. Ex. 22, ‘102 Patent prosecution history, RANB00000320) Unfortunately, as Plaintiff observes, hydrophobic appeared twice-- “one of them being hydrophobic having a Hydrophobic Lipidic Balance (HLB) value equal to or greater than 10” (Id. at RANB00000296)-- yet only the first instance was corrected.

Considering the claim, the specification and the prosecution history together, hydrophobic lipidic balance appears only a single time. While Defendants argue that this fact supports the inference that the departure was intentional, the Court concludes precisely the opposite. Hydrophobic lipidic balance sticks out like a sore thumb when considered in the context of all of the intrinsic evidence.

Fourth, in eight different places in the ‘427 patent, the H in HLB clearly stands for hydrophilic. (column 1, line 6-7; column 3, line 5-6; column 4, line 6-7; column 4, line 12-13; column 4, line 16-17; column 5, line 11-12; column 11, line 50; column 14, line 2-3) Nowhere does the ‘427 patent speak of hydrophobic lipidic balance.

Moreover, and perhaps most tellingly, Defendants provide no definition or explanation for what hydrophobic lipidic balance could mean. Both experts testified at the *Markman* hearing that there is no such term of art. (Davies Testimony, Hr. Tr. 63:5-

12) (“THE COURT: is there such a thing as hydrophobic lipidic balance? A: No. THE COURT: It doesn’t exist, does it? A: No. THE COURT: In science, I mean. A: No. It’s not something scientists know. Scientists know hydrophilic lipidic balance.”); (Mumper Testimony, Hr. Tr. 135:16-22).

While Defendants use this fact to support their argument that “hydrophobic lipidic balance” must be indefinite, the Court disagrees because all of the evidence before the Court clearly establishes that HLB is a standard term used in the industry that means hydrophilic lipidic balance. (See Davies Testimony, Hr. Tr. 62:5-11; Mumper Testimony, Hr. Tr. 161:5-9); (See also Davies Decl. ¶¶ 40, 44). Where, as here, the claim term is an obvious mistake, and importantly, the evidence unequivocally shows what the replacement term should be (see Davies Testimony, Hr. Tr. 99:11-15) (“hydrophilic lipidic balance is what everybody knows. The hydrophobic lipophilic balance isn’t something that’s in the art.”); (Mumper Testimony, Hr. Tr. 113-114:24-1) (“a person of skill in the art would recognize the term hydrophilic lipophilic balance. Would not recognize the term hydrophobic lipidic balance.”), the disputed term is not indefinite. Rather, it is a mistake that the Court will correct.

Lastly, Defendants’ distinction between lipidic and lipophilic is a red herring. Plaintiffs have presented

persuasive evidence that the L in HLB can stand for either lipidic, lipophilic, or lipophile. (Davies Decl. ¶ 44; Davies Rebuttal Decl. ¶¶ 15-17) Most notably, both parties' experts agree that a 1998 article published in *International Journal of Pharmaceutics* defined HLB as "hydrophilic-lipidic balance." (Davies Rebuttal Decl. ¶ 17; Mumper Dep. 261:7-9, 265:17-20)

In conclusion, what makes Absorica unique, and an improvement on Accutane, is the fact that it contains a hydrophilic excipient which increases bioavailability. A hydrophobic excipient could not achieve the same result. A person of ordinary skill in the art would understand hydrophobic lipidic balance to be a typographical error.

The Court holds that "hydrophobic lipidic balance (HLB) value" means "hydrophilic lipophilic balance (HLB) value."

(3) "having an HLB value equal to or greater than 10" / "has an HLB value of at least [12, 13]"

Defendants argue that "HLB value" is indefinite because various methods exist for determining HLB values, with different formulas producing different values, yet the patents-in-suit do not specify which method to use.

Plaintiffs argue that the terms should be given their plain meaning, i.e., they mean exactly what they say.

As discussed *supra*, this indefiniteness issue goes beyond the meaning of the disputed term. HLB value is a term of art, and Defendants do not dispute its meaning.

Accordingly, the Court holds that "having an HLB value equal to or greater than 10" / "has an HLB value of at least [12, 13]" needs no construction.

(4) "the isotretinoin is partially in suspension and/or partially in solution"

Defendants argue the use of "and/or" renders this term indefinite. Specifically, Defendants take no issue with the "and" part. They concede that if the term used only "and," the term would "make sense." (Responsive Markman Brief p. 15) (See also Defendants' closing argument, Hr. Tr. 222:22-223:4) But Defendants argue, partially in suspension *or* partially solution makes no sense because "or" indicates "two mutually exclusive states," meaning that the isotretinoin would have to be "in some third, undefined state," (Id.)-- a crystalline lump (Defendants' closing argument, Hr. Tr. 226-229)-- which the parties agree is not pharmacologically acceptable.

Plaintiffs assert that this term covers products where the isotretinoin is (1) partially in suspension; (2) partially in solution; and (3) partially in suspension and partially in solution. Conversely, Plaintiffs assert that isotretinoin that

is neither partially in suspension nor partially in solution is not covered by the term.

Plaintiffs' construction comports with the plain meaning of the term "and/or," which the Merriam-Webster Dictionary defines as "a function word to indicate that two words or expressions are to be taken together or individually."[13] According to Plaintiffs, "partially in suspension and/or partially in solution" can be taken together: option (3) above; or it can be taken individually: options (1) and (2) above.

Nothing in the patent or the prosecution history indicates the inventors' intention to use "or" in the mutually exclusive sense of the word. Stated in formal logic terms, "or" can be used to form two types of compound sentences: inclusive disjunctions and exclusive disjunctions. An *inclusive* disjunction is "a complex sentence in logic that is true when *either or both* of its constituent propositions are true." Merriam-Webster Dictionary (emphasis added). An *exclusive* disjunction is "a compound proposition in logic that is true when *one and only one* of its constituent statements is true." Id. (emphasis added)

[13] *See also* Oxford English Dictionary, "and/or" ("either or both of two possibilities"); Cambridge Dictionary of American English, "and/or" ("used to refer to both things or either one of the two mentioned").

Defendants propose a construction consistent with an exclusive disjunction but such a construction would render the "and" in "and/or" completely superfluous. In this Court's view, the use of "and/or" clearly indicates an inclusive disjunction (See Hr. Tr. 127-128; 216-217; 220), and therefore the claim is not indefinite.

The Court holds that "the isotretinoin is partially in suspension and/or partially in solution" means "the isotretinoin is either partially in suspension, partially in solution, or both."

(5) "an amount of about 1 to 10% of at least one additional surfactant" / "about 1 – 10% of an additional surfactant"

Plaintiffs propose that "about" should be construed as "approximately." Defendants argue that "Plaintiffs' proposed substitution . . . does nothing to advance the ball," (Responsive Markman Brief, p. 18), and that using either "about" or "approximately" renders the term indefinite.

The Court will adopt Plaintiffs' proposed construction. As the Federal Circuit has stated time and again, there is a heavy presumption that a claim term conveys its ordinary and customary meaning. *Starhome GmbH v. AT&T Mobility LLC*, 743 F.3d 849, 857 (Fed. Cir. 2014)(internal citation omitted). "About" has an ordinary and customary meaning of "approximately." *See Ferring*

B.V. v. Watson Labs, Inc., 764 F.3d 1382, 1389 (Fed. Cir. 2014) (in an ANDA case, holding, "[w]e affirm the district court's construction of 'about' to mean 'approximately,' as well as its refusal to construe 'about' to represent a particular numerical error rate."); *see also Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1369-70 (Fed. Cir. 2005) ("the term 'about' should be given its ordinary and accepted meaning of 'approximately' unless the patentee clearly redefines 'about' in the specification").

As stated above, whether "approximately 1 - 10%" is indefinite will not be decided now.

Likewise, the Court will not address whether "additional surfactant" is indefinite.

The Court holds that "about 1 - 10%" / "about 1 to 10%" means "approximately 1 - 10%" / "approximately 1 to 10%."

IV.

For the foregoing reasons, the disputed terms are construed as set forth above. An appropriate order accompanies this opinion.

Dated: April 20, 2015

s/ Joseph E. Irenas
Joseph E. Irenas, S.U.S.D.J.