IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF UTAH

THORNE RESEARCH, INC. and SOFTGEL FORMULATORS, INC., Plaintiffs, v. ATLANTIC PRO-NUTRIENTS, INC. d/b/a/ XYMOGEN, Defendant	MEMORANDUM DECISION AND ORDER ON CLAIM CONSTRUCTION Case No. 2:13-CV-784 TS District Judge Ted Stewart

This matter is before the Court on the parties' Cross-Motions for Claim Construction. In a Joint Claim Construction Chart and Status Report, the parties listed nine terms for claim construction, but agreed on the construction of seven of those terms. Therefore, in this Order, the Court will only construe the two contested terms. For the reasons discuss below, the Court will adopt a variation of Plaintiffs' construction of the term "Non-Crystalline" and construe the term "Carrier Oil" combining both Plaintiffs' and Defendant's proposed constructions in accordance with the patent specification.

I. BACKGROUND

On August 22, 2013, Plaintiffs Thorne Research, Inc. and Softgel Formulators, Inc. (collectively "Thorne") filed suit against Atlantic Pro-Nutrients, Inc. d/b/a Xymogen ("Xymogen") for infringement of United States Patent No. 8,491,888 (the "'888 Patent"). Xymogen filed a counterclaim seeking a declaratory judgment of non-infringement and invalidity of the '888 Patent. The parties filed Cross-Motions for Claim Construction.

The ’888 Patent is titled “Highly Absorbable Coenzyme Q10 Composition and Method of Producing Same.”[1] Coenzyme Q10 (“CoQ10”) is a natural material present in all living cells. In human cells, it is responsible for electron transfer in the production of energy, and therefore important for heart health.[2] Diet, genetics, aging, or medical conditions can lower CoQ10 levels in the body. Supplementation to restore CoQ10 to normal levels is touted as having health benefits.[3] CoQ10 manufactured for supplementation is produced in a pure crystalline form. However, crystalline formulations of CoQ10 are poorly absorbed.[4] Only .6% to 2.8% of a 100 mg ingested dose is absorbed by the body and transferred to the blood plasma after 6 to 8 hours.[5] Prior formulations made with crystalline CoQ10 required high doses of the supplement to meaningfully raise the levels of CoQ10 in the blood plasma.[6] The nutritional supplement at issue is a softgel[7] containing a CoQ10 composition which is more readily absorbable and usable by the body than prior CoQ10 supplements.[8] This softgel achieves a 7-10% absorption level with the same 100 mg dose.[9] The higher absorption rate is a result of the crystalline CoQ10 being mixed with a solvent and carrier oil, heated until the CoQ10 dissolves, and then

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[1] ’888 Patent col. 1, lines 1–3 (A copy of the patent can be found at Docket No. 53-1).

[2] *Id.* at col. 1, lines 22–27.

[3] *Id.* at col. 1, lines 30–32.

[4] *Id.* at col. 1, lines 33–35.

[5] *Id.* at col. 1, lines 37–39.

[6] *Id.* at col. 1, lines 36–37.

[7] *Id.* at col. 2, lines 19–20 (“As used herein the term ‘softgel’ is defined as a soft gelatin shell surrounding a liquid for an oral dosage form.”).

[8] *Id.* at col. 1, lines 50–55.

[9] *Id.* at col. 2, lines 44–45.

encapsulated into a softgel.[10] The parties request construction of the following terms: "Non-Crystalline" and "Carrier Oil."

II. DISCUSSION

The Supreme Court, in *Markman v. Westview Instruments, Inc.*,[11] held that claim construction is a matter exclusively within the province of the court.[12] Claim terms are generally given their ordinary and accustomed meaning as understood by one of ordinary skill in the art.[13]

> 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.[14]

However, extrinsic evidence such as dictionaries, treatises, and expert and inventor testimony are "less significant than the intrinsic record in determining the legally operative meaning of claim language."[15] The intrinsic record includes "the words of the claim themselves, the remainder of the specification, [and] the prosecution history."[16] A court looks to these sources in that order. First, in composing the claims, a patentee may choose, "to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history."[17] "[S]econd, it is always necessary to review the specification to determine whether the inventor has used any

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[10] *Id.* at col. 2, lines 14–16.

[11] 517 U.S. 370 (1996).

[12] *Id.* at 372.

[13] *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

[14] *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc).

[15] *Id.* at 1317 (internal quotation marks omitted).

[16] *Id.* at 1314.

[17] *Vitronics Corp.*, 90 F.3d at 1582.

terms in a manner inconsistent with their ordinary meaning."[18] "Third, the court may also consider the prosecution history of the patent, if in evidence."[19]

A. "NON-CRYSTALLINE"

Term	Thorne	Xymogen	Court's Construction	Patent Reference
Non-Crystalline	"lacking crystals visible by light microscope at magnifications of 640X"	"lacking crystals"	"no CoQ10 crystals are visible by light microscope at magnifications of 640X"	Claims 1, 14 & 16

The parties request construction of the term "non-crystalline" as it appears in claims 1, 14, and 16 of the '888 Patent.[20] Claims 1and 14 teach "a crystal-free coenzyme Q10 composition comprising: non-crystalline coenzyme Q10 present in an amount of 5.3% by weight to about 12% by weight."[21] Claim 16 further teaches "[a] crystal-free coenzyme Q10 composition comprising: 50 mg non-crystalline coenzyme Q10."[22]

Thorne argues that the term "non-crystalline" in all claims should be construed as: "lacking crystals visible by light microscope at magnifications of 640X." Thorne cites the patent specification for its construction and argues that any construction that does not specify a testing method and detection limit for crystals would "impermissibly imbue the patent scope with uncertainty."[23] However, Thorne's proposed construction is less specific than the patent specification that reads "no CoQ10 crystals are visible by light microscope at magnifications of

[18] *Id.*

[19] *Id.*

[20] '888 Patent cols. 7–8.

[21] *Id.*

[22] *Id.*

[23] Docket No. 54, at 5.

640X."[24] Xymogen does not believe the term needs construction, but counters that if the Court "believes construction is needed" that "non-crystalline" means "lacking crystals."[25] Xymogen cites the patent prosecution history and the American Heritage Dictionary for its construction.

In claim construction, courts should not rely on extrinsic evidence if it contradicts the intrinsic evidence available. "[U]ndue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the 'indisputable public records consisting of the claims, the specification and the prosecution history.'"[26] As extrinsic evidence, the dictionary definition should be given very little weight unless the intrinsic evidence supports using the dictionary definition. Xymogen argues that its dictionary definition supports the patent prosecution history. Xymogen contends that during the patent prosecution, the inventors conceded that they were attempting to patent a composition that completely lacked crystals, and that this construction is consistent with a dictionary definition of "non-" as "indicates not." Xymogen reasons that "non-crystalline means not crystalline or lacking crystals."[27]

In a July 22, 2010 rejection of the patent, the examiner rejected claim 5 as indefinite because independent claim 1 recited a "non-crystalline" composition, and dependent claim 5 recited an "essentially crystal-free" composition. In the rejection, the examiner interpreted "non-crystalline" as an "absolute limitation barring crystals from the composition."[28] In response, the inventors cancelled claim 5.[29] In the same July 2010 rejection document, the examiner rejected

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[24] '888 Patent at col. 2, lines 31–33.

[25] Docket No. 55, at 10.

[26] *Nystrom v. Trex Co. Inc.*, 424 F.3d 1136, 1143 (Fed. Cir. 2005) (quoting *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995)).

[27] Docket No. 55, at 11.

[28] Docket No. 53-2, at 210.

[29] *Id.* at 194.

claims 1, 5, 12, and 13 as anticipated by the Udel Patent. In the inventors' response, they argued that "the Udel Patent does not disclose a complete lack of crystals, as claimed in the instant claims."[30] Xymogen argues that the prosecution history shows that the inventors viewed their invention as completely "lacking crystals."

Xymogen's argument is not persuasive for several reasons. Even though Xymogen finds support in the patent prosecution history and the fact that claim 5 was cancelled, the "essentially crystal-free" language remains in the '888 patent specification with the limitation of the CoQ10 crystals not being "visible by a light microscope at magnifications of 640x."[31] In *Vitronics Corp. v. Conceptronic Inc.*,[32] the Federal Circuit outlined the procedure to follow when engaging in claim construction. A court should look first to "the words of the claims themselves," and second, to "the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms *by implication*."[33] In fact, "[u]sually it is dispositive; it is the single best guide to the meaning of a disputed term."[34] Later, in *Phillips v. AWH Corp.*,[35] the Federal Circuit reiterated en banc that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs."[36] This is because

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[30] *Id.* at 198.

[31] '888 Patent col 2, lines 27–33.

[32] 90 F.3d 1576.

[33] *Id.* at 1582 (citing *Markman*, 52 F.3d at 979) (emphasis added).

[34] *Id.*

[35] 415 F.3d 1303.

[36] *Id.* at 1316.

"the prosecution history . . . often lacks the clarity of the specification and thus is less useful for claim construction purposes."[37]

Furthermore, Thorne presents its own extrinsic evidence that supports the intrinsic evidence of the patent specification. Xymogen's own promotional literature for its product limits its claim of a "crystal-free" composition to one that is "crystal-free when examined by a light microscope."[38] The data sheet for Xymogen's product does not specify a magnification power, but a study commissioned by Xymogen's manufacturer on formulations of CoQ10 used "magnification powers of 60, 140 and 600 X" to determine the presence of crystals.[39] This data from an independent laboratory suggests that using magnification powers of a light microscope to determine whether a compound contains CoQ10 crystals is an industry standard. Thus, "the ordinary meaning of claim language as understood by a person of skill in the art"[40] would support a definition of "non-crystalline" that was limited by the ability to view the crystals under a microscope at some specified magnification.

Finally, "[i]t is an established canon of claim construction that for 'close cases in which competing constructions are each supported to an extent by the patent claim language, the specification, and the prosecution history,' claims are to be construed so as to uphold the patent's validity."[41] "Claims amenable to more than one construction should, when it is reasonably

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[37] *Id.* at 1317.

[38] Docket No. 62-1, at 1.

[39] Docket No. 65 Ex. B, at 3.

[40] *Phillips*, 415 F.3d at 1314.

[41] *Petter Investments Inc. v. Hydro Engineering, Inc.*, No. 2:14-CV-45-DB, 2015 WL 1442592, at *6 (D. Utah, March 27, 2015) (quoting Chisum on Patents § 18.03 (2006)).

possible to do so, be construed to preserve their validity."[42] Even if the Court gave equal weight to the specification and prosecution history, the Court must construe the term "non-crystalline" in order to preserve the validity of the patent. If "non-crystalline" meant absolutely lacking in crystals under any circumstances, then it would likely invalidate the '888 patent for indefiniteness.

A patent is indefinite when "one skilled in the art could not determine whether a given compound was within the scope of the claims" and when the claims are "not sufficiently precise to permit a potential competitor to determine whether or not he is infringing."[43] The tutorial provided by Thorne explains that "when CoQ10 is produced commercially, crystals melt upon heating but then recrystallize upon cooling, sometimes resulting in even larger crystals."[44] One skilled in the art of manufacturing CoQ10 supplements would understand that, in this compound, "non-crystalline" is a relative term, not an absolute term. One skilled in the art knows that some CoQ10 supplements have larger crystals than others, and those with no crystals visible by light microscope absorb into the body better than those with visible crystals.

The Federal Circuit has invalidated claims for indefiniteness when a term was "completely dependent on a person's subjective opinion,"[45] or "the claims were insolubly ambiguous."[46] If non-crystalline were construed as unequivocally "lacking crystals," it introduces a level of subjectivity and ambiguity as to whether a competing composition is infringing. A competitor should not be required to use an electron microscope to ascertain if his

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[42] *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1384 (Fed. Cir. 2001).

[43] *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1340 (Fed. Cir. 2005).

[44] Docket No. 87, at 10.

[45] *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005).

[46] *Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008).

product is non-infringing if that is not the standard for "one skilled in the art." Xymogen's proposed construction is too vague to "permit a potential competitor to determine whether or not he is infringing"[47] and is thus rejected.

The Court, therefore, construes "non-crystalline" similar to Thorne's proposed construction: "lacking crystals visible by light microscope at magnifications of 640X," but instead includes the actual specification language "no CoQ10 crystals visible by light microscope at magnifications of 640X," which clarifies that "non-crystalline" refers specifically to the CoQ10 in the compound.

B. "CARRIER OIL"

Term	Thorne	Xymogen	Court's Construction	Patent Reference
Carrier Oil	"an oil that increases the volume of an individual dosage of CoQ10 delivered into the intestines of the human taking the present invention, which increases the overall surface area from which the CoQ10 can be absorbed"	"an oil that carries CoQ10 molecules [in the passive facilitated diffusion process][48] across the absorptive cells in the intestine"	"an oil that carries CoQ10 molecules across the absorption cells in the intestine, increases the volume of the dose, and increases the overall surface area from which the CoQ10 can be absorbed"	Claims 1, 8, 9, 14 & 15

Thorne requests that "carrier oil" be construed as "an oil that increases the volume of an individual dosage of CoQ10 delivered into the intestines of the human taking the present invention, which increases the overall surface area from which the CoQ10 can be absorbed."

[47] *SmithKline Beecham Corp.*, 403 F.3d at 1340.

[48] Xymogen has offered an alternate construction omitting the bracketed words.

This definition is taken directly from the patent specification.[49] The paragraph that includes this sentence also includes the sentence with Xymogen's proposed construction. Thorne argues that it has picked the correct sentence out of the paragraph because only its construction construes the claim with "reference to the substance's effect on the composition."[50] Thorne argues that all the other sentences in the paragraph evaluate the composition "primarily based upon their effect on the body" and that "[r]equiring a determination of an ingredient's effect on humans would unnecessarily complicate a determination of the scope of the patent."[51] Thorne points out that the increased "volume both establishes a beneficial concentration range of CoQ10 to maintain its non-crystalline state and increases surface area of an individual dosage, which ultimately influences absorption of the CoQ10."[52] The Court agrees with the elements of Thorne's construction for the reasons that Thorne states, but finds it incomplete without the other part of the paragraph in the specification cited by Xymogen requiring the "carrier oil" to act as a "transporter." In fact, the portion of the specification relied on by Thorne begins, "The lipid carrier *also* . . . "[53] suggesting that the description of the oil's role is incomplete without the preceding portions of the paragraph.

Xymogen argues "carrier oil" should be construed as "an oil that carries CoQ10 molecules in the passive facilitated diffusion process across the absorptive cells in the intestine" or alternatively, "an oil that carries CoQ10 molecules across the absorptive cells in the

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[49] '888 Patent col. 3, lines 5–9.

[50] Docket No. 54, at 7.

[51] *Id.*

[52] Docket No. 61, at 9.

[53] '888 Patent col. 3, line 4 (emphasis added).

intestine."[54] Xymogen contends that Thorne's construction is inadequate because it does not require the oil to carry anything, and therefore reads the word "carrier" out of "carrier oil."[55] Using a security checkpoint analogy, Xymogen explains that without the oil to carry them, the CoQ10 molecules do not have "clearance to pass through the checkpoint" and be absorbed by the intestines.[56] Xymogen also argues that Thorne's proposed definition is overbroad because it includes any substance that increases the volume of the dosage and not just those lipids that are suitable "carriers" for the CoQ10 molecule to be absorbed. Thorne disputes this interpretation because Thorne believes that Xymogen incorrectly describes the science behind the absorption of CoQ10 molecules.

It is well established that "an inventor need not know how or why his or her invention does work in order to obtain a patent."[57] All that is required is that "a person of ordinary skill in the art, following the teaching of the specifications, would [] be able to practice the claimed invention."[58] Thorne conceded at the *Markman* hearing that exactly how the CoQ10 is absorbed by the body is not completely understood by the scientific community. Furthermore, it does not matter whether the CoQ10 molecules are carried through the cells by passive facilitated diffusion, or across the surface of the cell membrane where they are absorbed by simple diffusion, they are still dissolved in the carrier oil and "transported" or "carried" to the cells of the intestines for absorption. Therefore, the Court agrees with Xymogen that part of the function

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[54] Xymogen proposed an additional alternative construction at the *Markman* hearing, but since there was not a meaningful opportunity for Thorne to respond, the Court does not consider this additional proposed construction, but construes the terms based on the parties' briefing and arguments at the *Markman* hearing.

[55] Docket No. 55, at 7.

[56] *Id.*

[57] *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1377 (Fed. Cir. 1999).

[58] *Id.*

of a "carrier oil" must be to carry something. Furthermore, not all oils "carry" CoQ10 effectively. Claim 15 teaches that only "flax seed oil, soy lipids, borage lipids, marine lipids and combinations thereof" are suitable "carrier oils."[59] Xymogen's manufacturer found that for a lipid to be an appropriate carrier oil, it must be one of the "lipid substances in which the CoQ10 crystals would dissolve and stay in solution at room temperature."[60] Therefore, the Court finds that the correct construction must include both the functions described by Thorne and by Xymogen.

As argued by Thorne, the role of the "carrier oil" is important to this compound both because the increased volume of the dosage reduces re-crystallization and increases the surface area from which the CoQ10 can be absorbed in the intestines. One reason why this patent was found distinguishable from prior art was the lower concentration of CoQ10 in the compound. Claim 1 teaches that this composition has CoQ10 "present in an amount of 5.3% by weight to about 12% by weight" where the Udel patent, a prior art, contained 10-16% CoQ10 by weight.[61] Too high a concentration of CoQ10 causes it to fall out of solution and crystalize, and once crystalized, cannot be absorbed by the body. Claim 2 further elaborates that "the composition in accordance with claim 1 [contains] about 50 mg coenzyme Q10 [that] is encapsulated in a 700-900 mg capacity softgel."[62] In contrast, the Udel patent teaches 30 mg of CoQ10 in 220 mg capsules.[63] But, increasing volume and surface area are not enough. As Xymogen points out, not every oil that dilutes the concentration of CoQ10 aids in its absorption making it an

[59] '888 Patent col. 8, lines 24–26.

[60] Docket No. 65 Ex. B, at 9.

[61] Docket No. 53-2, at 142.

[62] '888 Patent col. 7, lines 5–13.

[63] Docket No. 53-2, at 143.

appropriate "carrier." In his May 4, 2007 Declaration, one of the inventors, while distinguishing his work from prior art, explained that some oils were unsuitable "carrier oils." He stated that "bee's wax is not a suitable carrier oil"[64] and then implied that rice bran oil was not a suitable carrier because "CoQ10 is not soluble in Rice Bran Oil."[65]

The claims also teach that a correct construction must focus on what the "carrier oil" does for the body, not just the compound. Claims 11, 12, and 13 teach that the compound is designed to have an impact on the human body, namely that "the plasma coenzyme Q10 level is increased significantly from basal level"[66] and "is at least 4μg/mL."[67] The whole point of preventing crystallization and increasing the surface area for absorption is to increase the concentration of CoQ10 in the blood plasma. This "bioavailability level"[68] is what produces any therapeutic effect to the person taking the supplement. The inventors included detailed research in the '888 patent specification describing how their formulation outperformed prior art based on significantly higher blood plasma concentrations both after 36 hours and after 29 days.[69] What impact the carrier oil has on the body is relevant to the nature of the compound, and therefore relevant to the construction of the term "carrier oil." Since both proposed constructions are important in construing the meaning of carrier oil and both are found in the specification, the Court construes "carrier oil" by combining the two proposed constructions as follows: "an oil that carries CoQ10 molecules across the absorption cells in the intestine, increases the volume of the dose, and increases the overall surface area from which the CoQ10 can be absorbed."

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[64] *Id.* at 142.

[65] *Id.* at 143.

[66] '888 Patent col. 8, lines 1–12.

[67] *Id.* at col. 8, lines 7–8.

[68] *Id.* at col. 8, line 7.

[69] *Id.* at cols. 5–6.

III. CONCLUSION

It is therefore

ORDERED that the parties' motions to determine *Markman* issues (Docket Nos. 54 & 55) are granted in part and denied in part. Specifically, the patent claims shall be construed consistent with the specification as follows:

Non-Crystalline: No CoQ10 crystals are visible by light microscope at magnifications of 640X.

Carrier Oil: An oil that carries CoQ10 molecules across the absorption cells in the intestine, increases the volume of the dose, and increases the overall surface area from which the CoQ10 can be absorbed.

The parties have 30 days to submit motions for summary judgment on the issue of infringement. The court will establish a deadline for the submission of motions for summary judgment on the issue of validity, if needed, after considering Plaintiffs' Motion for Reconsideration.

DATED this 8th day of October, 2015.

BY THE COURT:

Ted Stewart
United States District Judge