

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----x
KANEKA CORPORATION,

Plaintiff,

-against-

COCRYSTAL TECHNOLOGY (JIAXING) CO.,
LTD. (f/k/a SHANGHAI COCRYSTAL
PHARMACEUTICAL TECHNOLOGY CO.,
LTD.) and COCRYSTAL HEALTH INDUSTRY
(ZHEJIANG) CO., LTD.

Defendants.

-----x
BULSARA, United States District Judge:

In this litigation, Kaneka Corporation (“Plaintiff” or “Kaneka”) alleges that Defendants Cocystal Technology (Jiaxing) Co., Ltd. (f/k/a Shanghai Cocystal Pharmaceutical Technology Co., Ltd.) and Cocystal Health Industry (Zhejiang) Co., Ltd. (collectively the “Defendants” or “Cocystal”) infringed one of its patents, U.S. Patent number 7,829,080 (“’080 Patent”). (Am. Compl. dated Nov. 16, 2023 (“Compl.”), Dkt. No. 5 ¶¶ 1–6). The ’080 Patent involves the production of coenzyme Q₁₀ (“CoQ₁₀”), an antioxidant that promotes cell growth and maintenance, often used in nutritional supplements and other health-related products, including those sold and manufactured by Kaneka and Cocystal. (Pl.’s Opening Claim Construction Br. dated Oct. 11, 2024 (“Pl.’s Op. Br.”), Dkt. No. 35 at 1, 4; *Markman* Hr’g Tr. dated Jan. 24, 2025 (“Tr.”) at 9:3–9:11). CoQ₁₀ comes in two forms: oxidized and reduced. (Pl.’s Op. Br. at 1). The reduced form is a more effective product than the oxidized form; however, reduced

CoQ₁₀ is less stable and easily oxidizes when exposed to air, diminishing its value and making it difficult to preserve. (*Id.* at 3). The '080 Patent addresses this by introducing a method for producing a stabilized form of reduced CoQ₁₀ that is protected from oxidization, making it more suitable for a variety of nutritional and pharmaceutical purposes. (*Id.* at 4). To do so, claim 15 of the '080 Patent first presents an initial, oxidized form of CoQ₁₀, then a method of reducing the oxidized CoQ₁₀ alongside other oxidized coenzymes to create a final composition. (*Id.* at 4-6).

Kaneka commenced this action on October 5, 2023, (Compl. dated Oct. 5, 2023, Dkt. No. 1), and filed an Amended Complaint on November 16, 2023 (Compl.), claiming Cocrystal infringed on claims 5 and 15 of Kaneka's '080 Patent. The parties filed a Joint Claim Construction Statement on September 11, 2024, identifying their dispute as whether certain terms of claim 15 are invalid because they are indefinite. (Joint Claim Construction Statement, Dkt. No. 34 at 1). Briefing concluded on November 18, 2024, (*see* Pl.'s Reply Claim Construction Br. dated Nov. 18, 2024 ("Pl.'s Reply Br."), Dkt. No. 40), and the Court held a *Markman* hearing on January 24, 2025. (Minute Entry and Order dated Jan. 24, 2025).

The sole issue is the meaning of the term "composition" in the limitations of claim 15 of the '080 Patent. Defendants contend that the claim is ambiguous because it sets forth two compositions – the initial and reduced – and the limitations fail to specify which of the two compositions each clause refers to. (Defs.' Claim Construction Br. dated Nov. 11, 2024 ("Defs.' Br."), Dkt. No. 39 at 1-2). Kaneka argues that the plain language, structure, and logic of claim 15 make clear that each limitation can only be

read as referencing the final, reduced composition. (Pl.'s Reply Br. at 1-2). For the reasons that follow, the Court finds that the term "composition" in claim 15 is not indefinite, and construes it to mean the final, reduced CoQ₁₀-containing composition.

DISCUSSION

To be valid, "a patent must describe the exact scope of an invention and its manufacture to 'secure to [the patentee] all to which he is entitled, [and] to apprise the public of what is still open to them.'" *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) (alterations in original) (quoting *McClain v. Ortmyer*, 141 U.S. 419, 424 (1891)). To this end, patents must include both a "specification describing the invention 'in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same'" and "'claims,' which 'particularly poin[t] out and distinctly clai[m] the subject matter which the applicant regards as his invention.'" *Id.* (alterations in original) (quoting 35 U.S.C. § 112). The claim "defines the scope of the patentee's rights." *Id.* at 372. And the scope of such a claim, or "'the construction of a patent, including terms of art within its claim,'" is "'exclusively' for 'the court' to determine." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321 (2015) (quoting *Markman*, 517 U.S. at 372).

To "determin[e] the proper construction of a claim, 'the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification, and if in evidence, the prosecution history.'" *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1152 (Fed. Cir. 1997) (quoting *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Such "intrinsic evidence" is "the most significant

source of the legally operative meaning of the claim language.” *Id.* (quoting *Vitronics Corp.*, 90 F.3d at 1582). “[T]he words of a claim ‘are generally given their ordinary and customary meaning.’” *Easyweb Innovations, LLC v. Twitter, Inc.*, No. 11-CV-4550, 2016 WL 1253674, at *5 (E.D.N.Y. Mar. 30, 2016) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005)), *aff’d*, 689 F. App’x 969, 971 (Fed Cir. 2017). This “ordinary and customary meaning” is determined with reference to how “a person of ordinary skill in the art in question . . . as of the effective filing date of the patent application” would understand them. *Id.* (quoting *Phillips*, 415 F.3d at 1313). Because a patent is presumptively valid, 35 U.S.C. § 282, the party seeking to establish invalidity must do so by clear and convincing evidence. *See Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 95 (2011); *Maxell, Ltd. v. Amperex Tech. Ltd.*, 94 F.4th 1369, 1372 (Fed. Cir. 2024). “[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.*, 572 U.S. 898, 901 (2014); *see also Simpson Strong-Tie Co. v. Columbia Ins. Co.*, No. 23-CV-1944, 2025 WL 39807, at *4 (Fed. Cir. Jan. 7, 2025).

CoQ₁₀ exists in two states: oxidized CoQ₁₀, known as ubiquinone, and reduced CoQ₁₀, known as ubiquinol. (Pl.’s Op. Br. at 1). Ubiquinol, though easier to absorb than ubiquinone, oxidizes when exposed to air, which diminishes its potency and shelf-life. (*Id.* at 3). Claim 15 of Kaneka’s ‘080 patent discloses a method of stabilizing ubiquinol to protect against oxidization by combining reduced CoQ₁₀ with reduced coenzyme Q₉ (“CoQ₉”) and/or reduced coenzyme Q₁₁ (“CoQ₁₁”). (*Id.* at 3–6). Claim 15 protects:

(Claim 15[preamble]) A method for producing a reduced coenzyme Q₁₀-containing composition, which method comprises (claim 15[a]) providing a composition comprising oxidized coenzyme Q₁₀ with one or both of oxidized coenzyme Q₉ and oxidized coenzyme Q₁₁, (claim 15[b]) and then reducing oxidized coenzyme Q₁₀ and reducing one or both of oxidized coenzyme Q₉ and oxidized coenzyme Q₁₁ to prepare the reduced coenzyme Q₁₀-containing composition, (claim 15[c]) wherein the composition comprises reduced coenzyme Q₁₀ and one or both of (a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q₉ relative to reduced coenzyme Q₁₀ and (b) reduced coenzyme Q₁₁, (claim 15[d]) wherein not less than 0.01 wt % of reduced coenzyme Q₁₀ is contained in the composition, and (claim 15[e]) wherein the proportion of reduced coenzyme Q₁₀ relative to the total amount of coenzyme Q₁₀ is not less than 90 wt %.

'080 Patent, col. 18:4-21.

In short, claim 15 presents a method for transforming CoQ₁₀ from its initial oxidized state into its stabilized, more useful form. The claim first introduces the initial composition, described as "a composition comprising oxidized coenzyme Q₁₀." *Id.* at 18:6-7; (Pl.s' Op. Br. at 6). The initial composition then undergoes a process whereby the oxidized CoQ₁₀ is reduced alongside oxidized CoQ₉ and/or CoQ₁₁, to produce the final composition, the "reduced coenzyme Q₁₀-containing composition." '080 Patent, col. 18:9-12; (Pl.s' Op. Br. at 6). That final composition must have three characteristics, as reflected in the limitation clauses (claims 15[c]-[e]): it must (1) be comprised of reduced CoQ₁₀ along with some portion of reduced CoQ₉ and/or reduced CoQ₁₁; (2) contain at least 0.01 weight percentage of reduced CoQ₁₀; and (3) contain at least 90 weight percentage of reduced CoQ₁₀ relative to the total amount of CoQ₁₀ present. '080 Patent, col. 18:13-21.

Defendants assert that the term "composition" in the limitation clauses of claim 15 is indefinite as to the initial or final composition, rendering the entirety of claim 15

invalid. (Defs.' Br. at 1-2). For instance, the use of "composition" in "wherein the composition comprises reduced coenzyme Q₁₀," (claim 15[c], '080 Patent, col. 18:13-14), and "wherein not less than 0.01 wt % of reduced coenzyme Q₁₀ is contained in the composition" (claim 15[d], '080 Patent, col. 18:18-19), could, according to Defendants, refer to either the initial or final composition. (Tr. at 29:14-30:2 ("If they were to refer to the reduced coenzyme Q₁₀-containing composition, those 'wherein' clauses should say, wherein the reduced coenzyme-containing composition, because that is the way the claim earlier uses – distinguishes these terms, it's a composition, a reduced coenzyme-containing composition.")).

The Court concludes that Defendants have not satisfied their burden of establishing, by clear and convincing evidence, that claim 15 is indefinite. The Court therefore adopts the term's plain and ordinary meaning: the term "composition" in claims 15[c] and 15[d] refers to the final composition. In making this determination, the Court relies exclusively on the patent specification itself, rather than considering prior art, prosecution history, expert testimony, or the like (none of which was proffered by either party). See *CVI/Beta Ventures, Inc.*, 112 F.3d at 1152-53 ("[W]hen 'an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term,' it is improper to rely on extrinsic evidence." (quoting *Vitronics Corp.*, 90 F.3d at 1583)).

As an initial matter, Defendants' contention that the term "composition" in the limitation clauses is ambiguous – because they essentially lack the modifier "initial" or "final" – ignores the structure of the claim. See *Credle v. Bond*, 25 F.3d 1566, 1571 (Fed. Cir. 1994) ("In determining the true meaning of the language of the count, the

grammatical structure and syntax thereof may be instructive.”). It makes little sense to read a set of limitations on the final composition as referring back to (and somehow limiting) the initial composition of chemicals upon which the process is performed. To do so would require ignoring the logical progression of the claim’s text: from initial composition to performance and ending in a final composition. The claim is broken into steps to directionally orient the reader towards reaching the final composition, not in a circle. *Cf. TALtech Ltd. v. Esquel Apparel, Inc.*, 279 F. App’x 974, 978 (Fed. Cir. 2008) (“[T]he claim requires an ordering of steps when the claim language, as a matter of logic or grammar, requires that the steps be performed in the order written[.]”).

Claim 15[c] provides “wherein the composition comprises reduced coenzyme Q₁₀ and one or both of (a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q₉ relative to reduced coenzyme Q₁₀ and (b) reduced coenzyme Q₁₁[.]” ‘080 Patent, col. 18:13–16. Claim 15[c] immediately follows the phrase “reduced coenzyme Q₁₀-containing composition[.]” *Id.* at 18:11–16. The term “composition” in 15[c] could only be referring to the final composition: its placement after those words and after a comma requires such a reading. And the existence of the word “wherein” seals the deal. “Wherein” – understood as “which” or “that” – inexorably means what follows is a limitation, descriptor, or modifier of what immediately precedes it – here, the final, reduced CoQ₁₀-containing composition. *E.g., Griffin v. Bertina*, 285 F.3d 1029, 1033–34 (Fed. Cir. 2002) (the limiting effect of wherein clauses “relate back to and clarify what is required by the [claim]”); *Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.*, No. 21-CV-1015, 2023 WL 4314485, at *11 (D. Del. July 3, 2023) (use of commas to set off

“wherein” and “in which” clauses suggests that the text following a “wherein” or “in which” clause modifies the antecedent subject). To read this limitation otherwise would create an illogical and chemically impossible claim phrasing: “reduced coenzyme Q₁₀-containing composition that is the initial composition.” See *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008) (“[R]eferential and qualifying words and phrases, where no contrary intention appears, refer solely to the last antecedent, which consists of the last word, phrase, or clause that can be made an antecedent without impairing the meaning of the sentence[.]” (emphasis and internal quotations omitted)). Logic, syntax, and common-sense require that “composition” in claim 15[c] refers to the final composition.

This conclusion determines the meaning of the term “composition” in claim 15[d], which provides “wherein not less than 0.01 wt % of reduced coenzyme Q₁₀ is contained in the composition[.]” ‘080 Patent, col. 18:17-18. Claim 15[d] follows a comma and contains a “wherein” clause that is tied to and follows claim 15[c], which refers to the final composition. Put differently, having determined that claim 15[c] is a limitation on the final composition, it would upend all sense to read a secondary limitation on that clause as somehow referring to the initial composition of the product.

Defendants contend that claims 15[c] and 15[d] *could* be read as referring to different compositions as one another. This argument is without merit. Indeed, Defendants concede that this is a less plausible reading. (Tr. at 40:23-41:6 (“I think the other [readings] are less plausible[.]”). Following the logical sequence and structure of the claim, if 15[c] refers to the final composition, so too does 15[d], and no ordinary

person skilled in the art would reasonably construe the claim otherwise, as Kaneka correctly points out. (See Tr. at 12:6–12:10 (“[W]here you have a term, you know, with a comma and a ‘wherein’ clause, it’s obvious in the reading grammatically that the composition referred to afterwards is referring back to that initial term, the one preceding the ‘wherein’ clause, which is ‘reduced coenzyme Q₁₀.’”), 46:19–46:21 (“No one, no person of ordinary skill in the art would possibly read this language to refer to the initial oxidized form that’s later reduced.”)).

Defendants also contend that, because the composition in claim 15[d] requires only “0.01 wt % of reduced coenzyme Q₁₀,” that composition could be the initial composition. (Tr. at 42:6–42:17; Defs.’ Br. at 3–4). But claim 15[d] refers to and imposes a limitation on the quantity of “reduced coenzyme Q₁₀,” that must exist, *i.e.*, the composition must contain at least 0.01 percentage by weight of the reduced product. “Reduced coenzyme Q₁₀” is the post-reaction, post-process result, whereas the initial composition is the “oxidized coenzyme Q₁₀.” It makes no sense – and is indeed implausible – to impose a limitation on the initial composition by using the terminology that is used to describe the final product and composition.

Additionally, Defendants’ argument overlooks the other properties of the final, reduced composition specified by the claim. The reduction process of claim 15 and limitation of 15[c] provide that the final product must contain, in addition to the minimum weight percentage of reduced CoQ₁₀ specified in claim 15[d], some quantity of reduced CoQ₉ and/or reduced CoQ₁₁. ‘080 Patent, col. 18:9–16. Defendants’ position that the weight percentage of reduced CoQ₁₀ specified in claim 15[d] should be

“significantly higher” if the claim refers only to the reduced CoQ₁₀, (Defs.’ Br. at 3–4), is therefore unpersuasive, as it discounts, if not eliminates, the other required elements of the final composition.

Claim 15[e] provides that “wherein the proportion of reduced coenzyme Q₁₀ relative to the total amount of coenzyme Q₁₀ is not less than 90 wt %.” ‘080 Patent, col 18:19–21. The claim 15[e] limitation does not contain the word “composition.” But for 15[e] to have any meaning at all, it must be imposing limits on the final composition (*i.e.*, the 15[c] composition that 15[e] limits must refer to the final composition).

Indeed, Defendants recognize it would be “nonsensical” for claim 15[e] to refer to the initial composition, considering the high proportion of reduced CoQ₁₀ that must be present for the limitation to be satisfied. (Tr. at 36:13–37:2). Because claim 15[e] specifies only the minimum relative amount of reduced CoQ₁₀—90 wt %—Defendants’ interpretation would render it possible for the initial, pre-reduced composition to be comprised entirely of reduced CoQ₁₀ (relative to the total) and none of the initial, oxidized CoQ₁₀—a result that would effectively read the reduction process out of the claim. This construction is illogical, to say the least. Claim 15[e], which refers to 15[c], can only be reasonably interpreted as imposing limits on the final, reduced composition. There is no other plausible interpretation. *See Lucent Techs, Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1215 (Fed. Cir. 2008) (“[W]hen the claims are susceptible to only one reasonable construction, we will construe the claims as the patentee drafted them.” (citing *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1356–57 (Fed. Cir. 1999))).

CONCLUSION

For the reasons stated above, the Court concludes that claim 15 is not indefinite. The term “composition” in claim 15, and specifically its use in claims 15[c] and 15[d], is construed to mean the final, reduced CoQ₁₀-containing composition.

SO ORDERED.

/s/ Sanket J. Bulsara March 12, 2025
SANKET J. BULSARA
United States District Judge

Central Islip, New York