IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KANEKA CORPORATION, *Plaintiff*, v. DESIGNS FOR HEALTH, INC., and AMERICAN RIVER NUTRITION LLC, *Defendants*.	§ § § § § § § § § § §	Civil Action No. 21-209-WCB

MEMORANDUM OPINION AND ORDER

Plaintiff Kaneka Corporation brought this action against defendants Designs for Health, Inc., and American River Nutrition LLC (collectively, "DFH").[1] Fact discovery and expert discovery are complete. DFH now moves for summary judgment of invalidity and to preclude the testimony of two experts retained by Kaneka. For the reasons set forth below, the motion for summary judgment is GRANTED IN PART and DENIED IN PART and the motions to preclude expert testimony are DENIED.

I. Background

In this case, Kaneka alleges that DFH infringes claims 1 and 13 of U.S. Patent No. 7,145,044 ("the '044 patent") and claims 5 and 15 of U.S. Patent No. 7,829,080 ("the '080 patent").

[1] In its complaint, Kaneka alleges that the founder of defendant American River Nutrition LLC created two products that are manufactured and sold by defendant Designs for Health, Inc. Dkt. No. 75 ¶ 2. Kaneka alleges that Designs for Health, Inc., directly infringes the asserted patent claims in this case, and that American River Nutrition LLC induces that infringement. *Id.* For purposes of the present motions, the two defendants will not be treated separately.

The asserted patents are generally directed to compositions containing reduced coenzyme Q_{10} and methods for producing those compositions.

Coenzyme Q_{10} is a naturally occurring compound that is present in human, plant, and animal tissue. In humans, coenzyme Q_{10} acts "as a nutrient in restoring . . . cell activity . . . and rejuvenating the body." '044 patent, col. 1, ll. 28–31. According to the specification of the '044 patent, the presence of coenzyme Q_{10} is "indispensable for body function maintenance." *Id.* at col. 1, ll. 41–42. The '044 patent discloses that coenzyme Q_{10} can be used "as an ingredient" in items such as foods, nutritional supplements, drinks, cosmetics, and medicines. *Id.* at col. 1, ll. 19–22.

Coenzyme Q_{10} exists in two forms: oxidized coenzyme Q_{10} (also known as "ubiquinone") and reduced coenzyme Q_{10} (also known as "ubiquinol"). As the specification of the '044 patent explains, "[r]educed coenzyme Q_{10} shows a higher level of oral absorbability as compared with oxidized coenzyme Q_{10}." *Id.* at col. 1, ll. 17–18. However, "[r]educed coenzyme Q_{10} is readily oxidized to oxidized coenzyme Q_{10} by molecular oxygen." *Id.* at col. 2, ll. 3–4. Thus, the inventors of the asserted patents sought to obtain a stable form of reduced coenzyme Q_{10} that is protected from oxidation.

The '044 patent discloses a method of crystallizing reduced coenzyme Q_{10} using certain classes of solvents. Claim 1 of the '044 patent recites such a method:

> 1. A method of crystallizing reduced coenzyme Q_{10},
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> which comprises crystallizing the reduced coenzyme Q_{10} using, as a solvent, at least one species selected from the group consisting of hydrocarbons, fatty acid esters, ethers, and nitriles.

'044 patent, cl. 1. Claim 13 of the '044 patent recites a composition:

> 13. A reduced coenzyme Q_{10} crystal with a reduced coenzyme Q_{10}/oxidized coenzyme Q_{10} weight ratio of not lower than 96/4.

'044 patent, cl. 13.

The '080 patent discloses a method of preparing a composition of reduced coenzyme Q_{10} that also comprises one or both of reduced coenzyme Q_9 and reduced coenzyme Q_{11}.[2] Claim 15 of the '080 patent recites such a method:

> 15. A method for producing a reduced coenzyme Q_{10}-containing composition, which method comprises
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> providing a composition comprising oxidized coenzyme Q_{10} with one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11}, and then
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> reducing oxidized coenzyme Q_{10} and reducing one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11} to prepare the reduced coenzyme Q_{10}-containing composition,
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> wherein the composition comprises reduced coenzyme Q_{10} and one or both of (a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10} and (b) reduced coenzyme Q_{11},
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> wherein not less than 0.01 wt % of reduced coenzyme Q_{10} is contained in the composition, and
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> wherein the proportion of reduced coenzyme Q_{10} relative to the total amount of coenzyme Q_{10} is not less than 90 wt %.

'080 patent, cl. 15. Claim 5 of the '080 patent recites a corresponding composition:

> 5. A reduced coenzyme Q_{10}-containing composition comprising reduced coenzyme Q_{10} and one or both of (a) and (b):
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> (a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}, and
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> (b) reduced coenzyme Q_{11}
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> wherein not less than 0.01 wt % of reduced coenzyme Q_{10} is contained in the composition, and
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> wherein the proportion of reduced coenzyme Q_{10} relative to the total amount of coenzyme Q_{10} is not less than 90 wt %.

'080 patent, cl. 5.

[2] As the specification of the '080 patent explains, coenzymes Q_9 and Q_{11} are "analog[s]" of coenzyme Q_{10}. '080 patent, col. 4, ll. 37–38. Reduced coenzymes Q_9 and Q_{11} "show the same effect in the body as reduced coenzyme Q_{10}." *Id.* at col. 4, ll. 46–48.

Kaneka and DFH are manufacturers and sellers of dietary supplements that contain coenzyme Q_{10}. Kaneka alleges that DFH manufactures and sells three such supplements: DuoQuinol, CoQnol, and Q10.1. Dkt. No. 75 ¶ 17. Kaneka further alleges that DFH's activities with respect to those three supplements infringe Kaneka's rights in the '044 and '080 patents.

II. Legal Standard

The court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In deciding a motion for summary judgment, the court must draw all factual inferences in favor of the non-movant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). In the case of an issue on which the moving party bears the burden of proof at trial, the party seeking summary judgment must establish "the absence of a genuine factual issue," and if that party does not establish such an absence, "the district court should deny summary judgment even if no opposing evidentiary matter is presented." *Resol. Tr. Corp. v. Gill*, 960 F.2d 336, 340 (3d Cir. 1992). However, "[o]nce a moving party with the burden of proof makes such an affirmative showing, it is entitled to summary judgment unless the non-moving party comes forward with probative evidence that would demonstrate the existence of a triable issue of fact." *In re Bressman*, 327 F.3d 229, 238 (3d Cir. 2003).

Motions to exclude expert testimony are governed by Federal Rule of Evidence 702 and the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). The Advisory Committee on Evidence Rules has recently approved a clarifying amendment to Rule 702, which is set to take effect in December 2023. Courts have begun applying the amended rule because the changes are "not substantive" and simply "clarify how the Rule was meant to be applied." *In re Anderson*, No. 15-21681, 2023 WL 2229355, at *3 (Bankr. W.D. Tenn. Jan. 19,

2023); *see also Sardis v. Overhead Door Corp.*, 10 F.4th 268, 283–84 (4th Cir. 2021); *White v. City of Greensboro*, 586 F. Supp. 3d 466, 477 (M.D.N.C. 2022). The amended version of Rule 702 recites as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training or education may testify in the form of an opinion or otherwise if *the proponent has demonstrated by a preponderance of the evidence that*:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
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> (d) the *expert's opinion reflects a reliable application of* the principles and methods to the facts of the case.

Committee on Rules of Practice & Procedure, Standing Committee Agenda Book 891–92 (June 7, 2022), https://www.uscourts.gov/sites/default/files/2022-06_standing_committee_agenda_book_final.pdf (amendments shown in italics). Thus, in ruling on a motion to exclude expert testimony, the court must find by a preponderance of the evidence that the expert's opinion "reflects a reliable application" of the principles and methods underlying the opinion. *See id.*; *Sardis*, 10 F.4th at 283–84.

III. Discussion

DFH moves for summary judgment of invalidity, arguing that the asserted claims are directed to patent-ineligible subject matter under 35 U.S.C. § 101, anticipated under 35 U.S.C. § 102, and obvious under 35 U.S.C. § 103. DFH also moves for summary judgment that claims 5 and 15 of the '080 patent are invalid under 35 U.S.C. § 112 for lack of an adequate written description, lack of enablement, and indefiniteness. DFH further moves for summary judgment that Kaneka is not entitled to lost profits as a remedy for the asserted infringement of either asserted patent, or to injunctive relief or ongoing damages for the asserted infringement of the '044 patent.

Lastly, DFH moves to exclude the testimony of two of Kaneka's experts under Rule 702 of the Federal Rules of Evidence.

A. Claim Construction

At the outset, it has become clear from the parties' briefing that the parties disagree on the proper construction of the term "relative to" in the claims of the '080 patent. Although the parties stipulated that all claim terms should be construed in accordance with their plain and ordinary meanings, Dkt. No. 55, the court is obligated to construe a claim term if the parties do not agree about what the plain and ordinary meaning of that term is. *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361–63 (Fed. Cir. 2008).

Specifically, the parties disagree about the limitation in claims 5 and 15 of the '080 patent that requires the composition to contain "not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}." DFH and its expert, Dr. Richard Taylor, argue that the weight percentage of reduced coenzyme Q_9 relative to the weight percentage of reduced coenzyme Q_{10} refers to the proportion of coenzyme Q_9 compared to the sum of the weights of reduced coenzymes Q_9 and Q_{10}. In other words, DFH proposes calculating the relative weight percentage as $Q_9 / (Q_9 + Q_{10})$. Dkt. No. 110-1, Exh. 5 ¶ 18. Kaneka and its expert, Dr. Allan S. Myerson, argue that the relative weight percentage is calculated as a ratio, i.e., Q_9 / Q_{10}. *See* Dkt. No. 125-4 at 37.

DFH has the more persuasive position, for two reasons. First, the specification of the '080 patent sheds light on how the inventors calculated relative weight percentages in the context of the patented inventions. In "Production Example 3," the specification discloses a composition that is a mixture of 9.85 g of reduced coenzyme Q_{10} and 0.15 g of reduced coenzyme Q_9. '080 patent, col. 14, ll. 4–11. The specification explains that the mixture was "reduced coenzyme Q_{10}

containing 1.5 wt % of reduced coenzyme Q_9." *Id.* at col. 14, ll. 9–10. Although that expression does not use the words "relative to," it is clear from context that the 1.5% weight percentage is the same as the 1.5% weight percentage that is disclosed as the lower bound of the relative weight of reduced coenzyme Q_9 in the claims. And the 1.5% weight percentage expressed in that example is consistent with DFH's construction, as 0.15 g / (0.15 g + 9.85 g) is equal to 1.5 percent.

Second, Kaneka's construction would limit the claims to compositions in which the weight of reduced coenzyme Q_9 did not exceed the weight of reduced coenzyme Q_{10} in the composition. *See* Dkt. No. 125-4 at 37. If the relative weight of reduced coenzyme Q_9 were expressed as a ratio, a composition containing equal weights of reduced coenzymes Q_9 and Q_{10} would have a 100% relative weight percentage of coenzyme Q_9, which would fall outside the scope of the claims. However, the specification explains that "the upper limit of reduced coenzyme Q_9 . . . contained in reduced coenzyme Q_{10} is not particularly limited." *Id.* at col. 5, ll. 39–41. And there is no clear basis in the specification to conclude that the weight of reduced coenzyme Q_9 in the claimed composition cannot exceed the weight of reduced coenzyme Q_{10} in that composition.

For those reasons, the court will adopt DFH's construction of the phrase "relative to" as that phrase is used in the limitation requiring the composition to contain "not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}." That is, the relative weight percentage is to be calculated using the formula $Q_9 / (Q_9 + Q_{10})$.

B. 35 U.S.C. § 101

DFH argues that the asserted claims are directed to patent-ineligible subject matter because they are directed to "natural products or natural phenomena," and they do not contain an inventive concept sufficient to render the claims patent-eligible. Kaneka argues that the claims are not directed to natural products or natural phenomena.

Section 101 of the Patent Act defines patent-eligible subject matter. It states: "Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." 35 U.S.C. § 101. The Supreme Court has interpreted that provision to carve out exceptions to that broad characterization of patentable subject matter for "laws of nature, natural phenomena, and abstract ideas." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013).

The framework for determining whether a patent is directed to an unpatentable natural product or phenomenon is well settled. The Supreme Court's decisions in *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014), and *Mayo Collaborative Services v. Prometheus Laboratories*, 566 U.S. 66 (2012), established the now-familiar two-step test for patentability in that context. The first step entails determining whether the claim at issue is directed to "laws of nature" or "natural phenomena." The second step involves determining whether the claim contains an "inventive concept" that removes the claimed subject matter from the realm of abstraction. *Alice*, 573 U.S. at 218; *see also Nat. Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1342 (Fed. Cir. 2019).

At *Alice* step one, DFH contends that the asserted claims are directed to the natural product of reduced coenzyme Q_{10}, which is undisputedly present in nature. In cases involving claims that recite products of nature, the Federal Circuit has made clear that "[a] claim to a manufacture or composition of matter made from a natural product is not directed to the natural product where it has different characteristics and 'the potential for significant utility.'" *Nat. Alternatives*, 918 F.3d at 1348. Kaneka contends that, although reduced coenzyme Q_{10} is present in nature, the

compositions recited in the claims have different characteristics and exhibit additional utility as compared to reduced coenzyme Q_{10} as it appears in nature.

1. The '044 Patent

Claim 13 of the '044 patent, which is the only claim of the '044 patent directed to a composition rather than a method, recites a "reduced coenzyme Q_{10} crystal with a reduced coenzyme Q_{10}/oxidized coenzyme Q_{10} ratio of not lower than 96/4." DFH argues that because reduced coenzyme Q_{10} occurs in nature and the crystallization techniques disclosed in the '044 patent are "conventional," claim 13 is directed merely to reduced coenzyme C_{10}, which is a naturally occurring composition. Dkt. No. 112 at 14–15.

As Kaneka points out, however, the specification of the '044 patent indicates that the reduced coenzyme Q_{10} crystal recited in claim 13 of that patent differs from the reduced coenzyme Q_{10} that occurs in nature. The '044 patent specification explains that reduced coenzyme Q_{10} "tends to occur [in nature] as a low-purity crystalline, semisolid, or oily product containing such impurities as oxidized coenzyme Q_{10}." '044 patent, col. 1, ll. 57–60. The specification further explains that particular solvents have an "oxidation-protective effect," which was discovered "for the first time by the present inventors"; that effect, according to the specification, allows for the synthesis and crystallization of "high-quality reduced coenzyme Q_{10}." *Id.* at col. 3, ll. 11–24.

In order to establish that a patent is directed to a naturally occurring product, the patent challenger must show that the substance claimed in the patent is not "markedly different" from the natural product. *See ChromaDex, Inc. v. Elysium Health, Inc.*, 59 F.4th 1280, 1284 (Fed. Cir. 2023) (citing *Nat. Alternatives*, 918 F.3d at 1348–49). DFH has failed to point to any evidence that the composition recited in claim 13 of the '044 patent is not markedly different from the reduced coenzyme Q_{10} compositions found in nature. In particular, DFH has not shown that a

composition of reduced coenzyme Q_{10} with the high purity recited in claim 13 of the '044 patent occurs in nature. Nor has DFH pointed to evidence rebutting Kaneka's contention that the reduced coenzyme Q_{10} crystal recited in claim 13 is less susceptible to oxidation than the form of reduced coenzyme Q_{10} that occurs in nature. As a result, DFH has not established that there is no genuine dispute of material fact regarding whether claim 13 is directed to a natural product.

Likewise, DFH has also not rebutted the suggestion in the specification of the '044 patent that crystallizing reduced coenzyme Q_{10} using the solvents recited in claim 1 results in a composition having less susceptibility to oxidation. Moreover, unlike claim 13, claim 1 does not recite a reduced coenzyme Q_{10} crystal; it recites a method for producing such a crystal. It may be that the technique of producing a reduced coenzyme Q_{10} crystal using particular solvents would have been known or obvious to a person of ordinary skill, but that is an issue more properly considered under the rubric of anticipation and obviousness rather than patent eligibility under section 101.

Accordingly, DFH has not shown that claims 1 and 13 of the '044 patent are directed to a product of nature under *Alice* step one, and summary judgment of invalidity as to that patent will therefore not be granted under 35 U.S.C. § 101.

2. The '080 Patent

Claim 5 of the '080 patent recites a composition containing reduced coenzyme Q_{10} and one or both of reduced coenzyme Q_9 and reduced coenzyme Q_{11}. DFH argues that reduced coenzyme Q_9 and reduced coenzyme Q_{10} occur naturally in combination in human and rat tissue, and that the composition recited in the claim does not exhibit markedly different characteristics from the combination of coenzymes Q_9 and Q_{10} that occurs in nature.

In support of its argument that a combination of reduced coenzyme Q_9 and reduced coenzyme Q_{10} occurs in nature in the amounts recited in claim 5, DFH points to a prior art reference, "Åberg," which discloses the proportions of coenzymes Q_9 and Q_{10} that were present in various samples of rat and human tissue. Dkt. No. 112 at 12 (citing Dkt. No. 110-1, Exh. 8). Dr. Taylor explained in his report that the relative proportions of reduced coenzyme Q_9 and reduced coenzyme Q_{10} disclosed in Åberg fall within the ranges recited in claim 5, including for tissue samples that the Åberg reference describes as containing coenzyme Q_{10} that was "completely reduced." Dkt. No. 110-1, Exh. 3 ¶¶ 51–52. In view of that reference, Dr. Taylor offered the opinion that the composition recited in claim 15 is naturally occurring. *Id.* ¶ 55.

In response to DFH's arguments regarding the Åberg reference, Kaneka points to the expert report of Dr. Myerson. First, Dr. Myerson contended that Dr. Taylor incorrectly calculated the weight percentage of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}. Dkt. No. 125-4 at 37. Dr. Myerson proposed that the correct calculation was to compare the relative weights of reduced coenzymes Q_9 and Q_{10} as a ratio, i.e., Q_9 / Q_{10}. *See id.* As discussed above, that calculation is inconsistent with the proper construction of claims 5 and 15. Dr. Myerson's opinions regarding the relative weight percentages of reduced coenzymes Q_9 and Q_{10} therefore do not serve to rebut Dr. Taylor's testimony.

Second, Dr. Myerson contended that the tissue samples disclosed in Åberg do not contain at least "0.01 wt % of reduced coenzyme Q_{10}," as required by claims 5 and 15. Dkt. No. 125 ¶¶ 75–78. The relative weights of coenzymes Q_9 and Q_{10} disclosed in Åberg were reported on a per-gram basis. Dkt. No. 110-1, Exh. 8, at 232. Dr. Myerson explained that for the weight percentage of reduced coenzyme Q_{10} to fall within the scope of the claims, the sample would need to contain at least 100 micrograms of reduced coenzyme Q_{10}. Dkt. No. 125 ¶ 75. But according

to Dr. Myerson, none of the tissue samples disclosed in Åberg contained as much as 100 micrograms of reduced coenzyme Q_{10}. *Id.* ¶¶ 76–78.

In its reply brief, DFH asserts that Dr. Myerson's analysis on that point is flawed because the "composition" recited in claims 5 and 15 need not be a tissue sample, but can be "any form of matter," such as the "samples of isolated [coenzyme Q_9] and [coenzyme Q_{10}] shown in Åberg's Table III." Dkt. No. 133 at 12. Essentially, DFH argues that in the course of obtaining the weight measurements of coenzymes Q_9 and Q_{10} disclosed in Table III of Åberg, the authors of that reference would have created other compositions besides the tissue samples that satisfied all the limitations of claim 5.

That argument is not persuasive. DFH has not established that Åberg discloses any composition, other than the tissue samples, that contains both reduced coenzymes Q_9 and Q_{10}, or that such a composition would have satisfied the relative weight requirements of claim 5. For example, Figure 1 of Åberg indicates that an analysis of "ubiquinone isolated from [a] human heart" demonstrated the presence of "cholesterol," reduced and oxidized "ubiquinone-6," and reduced and oxidized "ubiquinone-10." Dkt. No. 110-1, Exh. 8, at 231. That discussion fails to indicate that reduced coenzyme Q_9 was present in the composition depicted in Figure 1, and it is also not clear what quantities of cholesterol and ubiquinone-6 would have been present in that composition. *See id.* For those reasons, DFH has not established that Åberg discloses a composition containing reduced coenzymes Q_9 and Q_{10} that would satisfy the limitations of claim 5. And, in any event, DFH has not shown that any compositions disclosed in Åberg other than the tissue samples (e.g., the "isolated" ubiquinone depicted in Figure 1) would have been naturally occurring, as the Åberg reference discloses that "ubiquinone-6 was added" after the tissue samples were taken. *Id.* at 230–31.

Accordingly, there is at least a genuine dispute of material fact regarding whether the samples disclosed in Åberg fall within the scope of claims 5 and 15 of the '080 patent, and likewise whether the composition recited in claim 5 is present in nature.

To be sure, the Federal Circuit has recently indicated that the claimed composition itself need not be present in nature in order for the claim to be directed to a natural product. In *ChromaDex*, the elements of the composition recited in the patent claims at issue were all found in milk, a natural product, except that one of the required elements was "isolated" nicotinamide riboside ("NR"), and milk contains NR that is not isolated. *ChromaDex*, 59 F.4th at 1283. Despite that difference, the court explained that "the claimed compositions remain indistinguishable from natural milk because, other than separation from some other components, the isolated NR is no different structurally or functionally from its natural counterpart in milk." *Id.* at 1284. That is, the claims did not "exhibit markedly different characteristics from milk" and were therefore invalid. *Id.*

Applying that approach, DFH asserts that the composition of claim 5 is not "markedly different" from compositions found in nature. Dkt. No. 112 at 11. That is to say that even if Åberg does not disclose that the composition of claim 5 is naturally occurring, DFH can prevail on its section 101 argument if it can prove that the composition recited in claim 5 does not "exhibit markedly different characteristics" from compositions found in Åberg's rat and human tissue samples. *See ChromaDex*, 59 F.4th at 1284. However, DFH bears the burden of proof on the issue of ineligibility, and DFH has proffered no evidence that the composition of claim 5 is not markedly different than the samples disclosed in Åberg. Accordingly, DFH is not entitled to summary judgment that the composition of claim 5 is directed to a natural product by virtue of being not markedly different from the naturally occurring compositions in rat and human tissue.

Claim 15 of the ’080 patent recites a method of producing a composition having the same characteristics as the composition of claim 5. DFH’s argument regarding claim 15 is essentially that the steps of claim 15 “confer no distinction between [claim 15 and] the naturally occurring composition of claim 5, thereby causing claim 15 to begin and end with a natural phenomenon.” Dkt. No. 112 at 12. As noted, however, DFH has not established that it is entitled to summary judgment that claim 5 is directed to a natural product. Because DFH’s arguments regarding claim 15 are predicated on claim 5 being directed to a natural product, DFH is not entitled to summary judgment that claim 15 recites patent-ineligible subject matter.

Moreover, as with claim 1 of the ’044 patent, claim 15 of the ’080 patent is directed to a method of producing a composition containing reduced coenzyme Q_{10}, rather than the composition itself. DFH cites a series of cases for the proposition that “method steps that lack any specificity or inventiveness should be given little, if any, patentable weight.” Dkt. No. 112 at 9–10. It is generally true that method claims are directed to a natural phenomenon if they “begin and end” with that phenomenon. *Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co. KG*, 933 F.3d 1302, 1317 (Fed. Cir. 2019). However, when the claims require that “specific steps be taken in order to . . . alter[] the subject’s natural state,” the claims are not directed to a natural phenomenon. *Nat. Alternatives*, 918 F.3d at 1345. Because there is a genuine dispute of material fact regarding whether the composition of claim 5, and by extension the result of claim 15, is naturally occurring, DFH is not entitled to summary judgment that claim 15 is directed to a natural phenomenon.

C. Anticipation and Obviousness

DFH next argues that the asserted claims are invalid because they are anticipated under 35 U.S.C. § 102 or, in the alternative, would have been obvious under 35 U.S.C. § 103.

1. The '044 Patent

As an initial matter, the specification of the '044 patent acknowledges that certain elements of the claims were previously known in the art. For example, the specification explains that the reduced coenzyme Q_{10} that is ultimately crystallized "can be obtained in the conventional manner." '044 patent, col. 12, ll. 44–45. The specification also explains that "the crystallization can be carried out by utilizing a conventional crystallization method." *Id.* at col. 13, ll. 24–25.

In support of its assertion that claims 1 and 13 of the '044 patent are anticipated and obvious, DFH cites several prior art references: an article authored by A.C. Page, Jr., et al. ("Page"); U.S. Patent No. 3,066,080 ("Folkers"); an article authored by F.L. Crane ("Crane"); Japanese Patent Pub. No. 55-58098 ("Shigeru"); Japanese Patent Pub. No. 53-133687 ("Nisshin"); U.S. Patent No. 3,769,170 ("Kondo"); U.S. Patent No. 4,205,125 ("Aida"); and U.S. Patent No. 6,740,338 ("Chopra").

In his expert report, Dr. Myerson responds that none of those references disclose all the limitations of the asserted claims and thus none of them anticipate those claims. For example, Dr. Myerson states that the Page, Folkers, Crane, Shigeru, Nisshin, Kondo, and Aida references do not disclose the crystallization of reduced coenzyme Q_{10} in particular, as opposed to oxidized coenzyme Q_{10}. Dkt. No. 125 ¶¶ 119–20, 122–26. DFH does not offer a meaningful rebuttal of that opinion. Accordingly, there remains a genuine dispute of material fact regarding whether any one of those references discloses all the limitations of claims 1 and 13.

With respect to Chopra, the remaining reference, DFH argues that Chopra discloses a composition that satisfies the 96/4 ratio recited in claim 13. Dkt. No. 112 at 21–22. In support of its assertion that Chopra discloses a composition that satisfies the 96/4 ratio, DFH cites the expert

report of Dr. Taylor, who offered the opinion that Chopra discusses compositions that are "substantially ubiquinone-free." Dkt. No. 110-1, Exh. 3 ¶ 84 (citing Chopra, col. 7, ll. 31–40).

Upon closer examination of Chopra, the passage of that reference that Dr. Taylor cited is somewhat detached from the compositions disclosed in that reference. Chopra defines the term "substantially ubiquinone-free" to refer to "a composition which contains ubiquinol and little or no ubiquinone." Chopra, col. 7, ll. 31–33. Such a composition, Chopra explains, can "contain[] ubiquinol and ubiquinone in a ratio no less than 9:1, preferably no less than 19:1, [and] even more preferably no less than 99:1." *Id.* at col. 7, ll. 33–37. However, the term "substantially ubiquinone-free" is not used in the Chopra reference outside of that discussion. It is therefore not clear that the particular compositions disclosed in Chopra were "substantially ubiquinone-free." And even if they were, the ratios of 9:1 and 19:1 that are recited in the definition of that term would fall outside the scope of claim 13 of the '044 patent. As Dr. Myerson observed, "[t]he notion of a composition being 'substantially ubiquinone-free' does not specifically disclose the particular weight ratio disclosed in claim 13." Dkt. No. 125-4 at 43. DFH has therefore failed to show that there is no genuine dispute of material fact as to whether Chopra discloses a composition that satisfies the 96/4 ratio recited in claim 13 of the '044 patent.

In addition, DFH recognizes that "Chopra does not expressly state that the recited process would likely produce a crystalline product." *Id.* at 22. DFH nevertheless argues that the Chopra reference "describes a process that . . . could lead to crystallization." *Id.* In his report, however, Dr. Myerson contends that Chopra "never indicates even the possibility of crystallization," and instead indicates that the coenzyme Q_{10} discussed in the reference is "completely dissolved." Dkt. No. 125 ¶ 95. For that reason, even assuming that the composition disclosed in Chopra satisfies

the ratio recited in claim 13, DFH has failed to show that there is no genuine dispute of material fact regarding whether Chopra discloses crystallizing that composition.

Having failed to establish that any one of its cited prior art references discloses each element of claims 1 and 13 of the '044 patent, DFH is not entitled to summary judgment that those claims are anticipated under 35 U.S.C. § 102.

On the issue of obviousness, DFH has not set forth any particular combination of references that it contends renders claims 1 and 13 obvious under 35 U.S.C. § 103. As the Federal Circuit has explained, "[t]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Innogenetics, N.V. v. Abbott Lab'ys*, 512 F.3d 1363, 1373 (Fed. Cir. 2008) (citation omitted). That is, it is insufficient to "merely list[] a number of prior art references and then conclude[]" with the assertion that the claims are obvious in view of those references. *Id.*; *see also Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*, No. 3:11-cv-345, 2012 WL 6562220, at *20 (E.D. Va. Aug. 13, 2012), *aff'd*, 726 F.3d 1370 (Fed. Cir. 2013) (The defendant "cannot merely present a list of prior art combinations and then leave it to the court to determine how the references fit together to render the claims obvious.").

The discussion of obviousness in DFH's briefing is limited. In its discussion of the '044 patent, DFH argues that "it would have been obvious to the skilled artisan at the time of the invention of claims 1 and 13 of the '044 patent to crystallize reduced [coenzyme Q_{10}] using known methods because crystallization provides several well-known benefits." Dkt. No. 112 at 22. But DFH does not point to any particular combination of references that a skilled artisan would combine to arrive at claims 1 and 13 of the '044 patent. Nor does it explain why a skilled artisan would have been motivated to combine two or more of its cited references.

DFH also suggests in passing that "it would have been obvious" in view of Chopra "to produce a crystalline product because the skilled artisan would have understood at the time of the alleged invention of the '044 patent that crystallization was an effective way to maintain the purity of the desired product." Dkt. No. 112 at 22. There are two problems with that argument. First, it does not account for the fact that there is a genuine dispute of material fact as to whether Chopra discloses the 96/4 ratio recited in claim 13. Second, DFH does not explain which reference or references of the eight references it cites supplies the crystallization limitation. Because there is a genuine dispute of material fact as to whether the references other than Chopra disclose crystallizing reduced coenzyme Q_{10}, to prevail on summary judgment DFH would need to show that a skilled artisan would be motivated to combine Chopra's composition with the crystallization techniques for oxidized coenzyme Q_{10} disclosed in the other references. DFH has made no such showing in its briefing on the present motions.

For the above reasons, DFH is not entitled to summary judgment that claims 1 and 13 of the '044 patent are obvious under 35 U.S.C. § 103. *See Hamilton Beach*, 2012 WL 6562220, at *20 (denying summary judgment because the defendant "failed to set forth sufficient evidence showing *why* it would have been obvious to combine elements from the prior art references it cites").

2. The '080 Patent

In support of its assertion that claims 5 and 15 of the '080 patent are anticipated and would have been obvious, DFH relies on the Aida and Åberg references. As noted above, however, there is a genuine dispute of material fact as to whether the Åberg reference discloses a composition that falls within the ranges recited in claim 5 of the '080 patent. Accordingly, summary judgment will not be granted that the claims of the '080 patent are anticipated by the Åberg reference.

With respect to the Aida reference, the only discussion of that reference in DFH's opening brief is DFH's assertion that "Aida describes crystallization of Coenzyme[s] Q_{10}, Q_9, and Q_8." Dkt. No. 112 at 24. As Dr. Myerson points out, however, Aida appears to disclose "a method of crystallizing oxidized [coenzyme] Q_{10}," not a method of crystallizing reduced coenzyme Q_{10}. Dkt. No. 125 ¶ 126. For that reason, DFH has failed to establish that there is no genuine dispute of material fact as to whether Aida anticipates claims 5 and 15 of the '080 patent.

On the issue of obviousness generally, DFH asserts that "it would have been obvious to arrive at the claimed amounts of [coenzyme Q_9] and [coenzyme Q_{10}] because those amounts would have been produced by combining known [coenzyme Q_9] and [coenzyme Q_{10}] sources to produce compositions with the claimed ranges in a predictable manner." Dkt. No. 112 at 27. But as was the case with respect to the '044 patent, DFH has failed to set forth any particular combination of references that would render claims 5 and 15 obvious. Nor has DFH offered any basis to conclude that a skilled artisan would have been motivated to combine those references. For those reasons, DFH is not entitled to summary judgment that claims 5 and 15 of the '080 patent would have been obvious under 35 U.S.C. § 103. *See Hamilton Beach*, 2012 WL 6562220, at *20.

D. Written Description and Enablement

DFH argues that claims 5 and 15 of the '080 patent are invalid for failing to satisfy the written description and enablement requirements of 35 U.S.C. § 112. In its opening brief, DFH devotes a single paragraph to this issue. And in that paragraph, DFH simply sets forth the legal standard and then makes the conclusory assertion that "the '080 patent is invalid under the written description and/or enablement requirements." Dkt. No. 112 at 28. In its reply brief, DFH expands on that point slightly, contending that Kaneka's arguments regarding patent eligibility under

section 101 effectively import limitations from the specification into the claims, and that those supposedly imported limitations lack written description support. Dkt. No. 133 at 13–14.

The arguments raised by DFH for the first time in its reply brief are waived. *EIS, Inc. v. WOW Tech Int'l GmbH*, No. 19-1227, 2020 WL 7027528, at *7 (D. Del. Nov. 30, 2020); *see also* D. Del. L.R. 7.1.3(c)(2) ("The party filing the opening brief shall not reserve material for the reply brief which should have been included in a full and fair opening brief."). And in its opening brief, DFH failed to identify any limitation of either claim 5 or claim 15 that it contends was not supported or enabled by the specification of the '080 patent. DFH has therefore failed to establish that there is no genuine dispute of material fact that claims 5 and 15 of the '080 patent are invalid for inadequate written description and lack of enablement.

DFH contends that it did not waive its written description and enablement arguments by failing to raise them in its opening brief, because it raised those issues in its invalidity contentions and discussed those issues in its expert reports.[3] But the fact that such issues may have been mentioned elsewhere in the record, such as in expert opinions and invalidity contentions, is not sufficient to support a claim for summary judgment, for which the argument and supporting evidence must be set forth with clarity and specificity in the party's summary judgment brief. *See In re Cygnus Telecomms. Tech., LLC, Pat. Litig.*, 536 F.3d 1343, 1352–53 (Fed. Cir. 2008) ("In ruling on the . . . summary judgment motion we will not consider any part of the record that was

[3] In its reply brief, DFH asserts that it adequately raised its written description and enablement arguments in its opening brief, but as discussed above, that is not so. The single paragraph in the opening brief that was devoted to written description and enablement consists of three sentences setting forth the applicable legal standards and one sentence asserting, without elaboration, that to the extent Kaneka contends the claimed proportions of claims 5 and 15 are inventive and non-obvious, those claims are "invalid under the written description and/or enablement requirements." That is not a developed argument and cannot support a summary judgment of invalidity.

not presented to or cited to the district judge in connection with that motion, even if that evidence can be found somewhere in the voluminous materials that are part of the record . . . .").

Even if the court were to consider the contents of the parties' expert reports on the issues of written description and enablement, those reports demonstrate that there is a genuine dispute of material fact with respect to those issues. For example, Dr. Taylor offered the opinion that claims 5 and 15 lack written description support because the '080 patent "fails to explain how to ascertain the amounts of coenzyme Q_9 and/or coenzyme Q_{11} that is contained in claims 5 and 15." Dkt. No. 110 ¶ 125. Dr. Myerson responded to that opinion, indicating that the disclosure of "[P]roduction Example 3" in the patent "would allow a POSA to make any mixture at any ratio desired, including those as described in Claims 5 and 15." Dkt. No. 125 ¶ 155. Dr. Myerson added that "Dr. Taylor's own references" demonstrate that a skilled artisan would have known how to measure the amounts of coenzymes Q_9, Q_{10}, and Q_{11} in a composition. *Id.* ¶¶ 156–57. In light of that evidence, I find that DFH has failed to establish that there is no genuine dispute of material fact on the issues of written description and enablement.

Not content with defeating DFH's motion for summary judgment, Kaneka argues that given DFH's failure to cite any fact or expert opinion in support of its position on the issues of written description and enablement, Kaneka is entitled to summary judgment in its favor on those issues. Dkt. No. 123 at 26–27. But the fact that DFH has failed to make a sufficient showing that it is entitled to summary judgment in its favor is not a basis for entering summary judgment against it. While it is permissible for a court, in limited circumstances, to grant summary judgment to a non-moving party, such measures are rare, and before entering such an order, the court must exercise "great care . . . to ensure that the original movant has had an adequate opportunity to show that a genuine factual dispute remains and that the opponent is not entitled to judgment as a matter

of law." 10A Charles Alan Wright et al., Federal Practice and Procedure § 2720.1 (4th ed., April 2022 update); *Gibson v. Mayor & Council of City of Wilmington*, 355 F.3d 215, 222–25 (3d Cir. 2004).

In this case, it would be inappropriate to enter summary judgment in Kaneka's favor on the issues of written description and enablement for two reasons. First, neither party has devoted significant attention to the issues of written description and enablement in their briefing. In its brief, Kaneka cites the report of its expert but otherwise makes no affirmative showing that the patents are not invalid for inadequate written description and enablement. *See* Dkt. No. 123 at 27–28. Second, both sides' experts have offered competing opinions on these issues. Dkt. No. 125 ¶¶ 153–60 (Dr. Myerson); Dkt. No. 110 ¶¶ 121–28 (Dr. Taylor). In light of those opinions, and particularly in light of the parties' limited briefing on the issues of written description and enablement, I am persuaded that neither side is entitled to judgment as a matter of law on those issues. Accordingly, summary judgment will not be granted to either side with respect to the validity of the '080 patent under the written description and enablement requirements.

E. Indefiniteness

DFH argues that claims 5 and 15 of the '080 patent are invalid under 35 U.S.C. § 112 because they are indefinite. As the Supreme Court has explained, "a patent is invalid for indefiniteness if its claims, read in light of the specification . . . 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).

DFH points to two aspects of the claims that it argues do not inform a skilled artisan of the scope of the claimed inventions. First, DFH argues that the phrase "the total amount of coenzyme Q_{10}" recited in claims 5 and 15 is indefinite. Dkt. No. 112 at 28–29. Second, DFH argues that the

phrase "relative to" is indefinite in light of the competing approaches of the parties' experts in calculating the relative weight percentages of reduced coenzyme Q_9 and reduced coenzyme Q_{10}. *Id.* at 29.

With respect to the first argument, DFH argues that the phrase "the total amount of coenzyme Q_{10}" is indefinite because the specification states that "reduced coenzyme Q_{10} can contain oxidized coenzyme Q_{10}." *Id.* at 28–29 (quoting '080 patent, col. 4, line 64). However, the language immediately following that statement in the specification adds significant clarity. It states: "When oxidized coenzyme Q_{10} is also present, the proportion of reduced coenzyme Q_{10} in the total amount of coenzyme Q_{10} (i.e., the total amount of reduced coenzyme Q_{10} and oxidized coenzyme Q_{10}) is not particularly limited." '080 patent, col. 4, line 64, through col. 5, line 1. Thus, the inventor expressly defined "the total amount of coenzyme Q_{10}" as "the total amount of reduced coenzyme Q_{10} and oxidized coenzyme Q_{10}." *See id.* DFH has not explained how that language as used in the claims is susceptible to any other interpretation, and thus DFH is not entitled to summary judgment that claims 5 and 15 of the '080 patent are indefinite because of that phrase.

With respect to the second argument, DFH contends that the competing approaches of Dr. Taylor and Dr. Myerson in calculating the relative weight percentage of reduced coenzyme Q_9 indicate that a skilled artisan "could not ascertain, with reasonable certainty, the scope and meaning of claims 5 and 15 of the '080 patent." Dkt. No. 112 at 29. As discussed above, however, the phrase "relative to" in claims 5 and 15 is readily susceptible to construction, and the proper construction of those claims requires the calculation method proposed by Dr. Taylor, i.e., $Q_9 / (Q_9 + Q_{10})$. Because the claim language, in context, would be reasonably clear to a person of skill in the art, it is not indefinite. *See Nautilus*, 572 U.S. at 910. The claims cannot be deemed indefinite simply because Dr. Myerson embraced a construction of the claims that was ultimately rejected.

If the rule were otherwise, any disagreement between experts regarding claim construction would result in the invalidation of the subject patent based on indefiniteness. Accordingly, summary judgment will not be granted on the ground that claims 5 and 15 of the '080 patent are indefinite.

F. Lost Profits

DFH argues that it is entitled to summary judgment that Kaneka may not recover lost profits from DFH's sales of the accused products. The Federal Circuit has made clear that in order to be entitled to lost profits, the patentee must show that the lost profits "come from the lost sales of a product or service the patentee itself was selling." *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 778 F.3d 1365, 1376 (Fed. Cir. 2015), *vacated on other grounds*, *Medtronic Sofamor Danek USA, Inc. v. NuVasive, Inc.*, 577 U.S. 1099 (2016). DFH contends that Kaneka itself does not sell any relevant product, and that Kaneka's theory of lost profits seeks to improperly recover the lost profits of its subsidiary, Kaneka North America LLC ("KNA").[4]

Various courts have addressed the situation presented by this case, in which a corporate parent seeks to recover the lost profits of its wholly owned subsidiary. In general, "a patentee may not claim, as its own damages, the lost profits of a related company." *Id.* at 1375. Several courts have departed from that general rule in cases in which the subsidiary's profits "flow[] inexorably" to the parent company. *See, e.g.*, *Schwendimann v. Arkwright Advanced Coating, Inc.*, 220 F. Supp. 3d 953, 973–74 (D. Minn. 2016); *Advanced Fiber Techs. (AFT) Tr. v. J & L Fiber Servs.,*

[4] Kaneka argues that DFH has waived the defense that Kaneka is not entitled to lost profits by failing to raise that defense in its answer or during discovery. Dkt. No. 123 at 31–34. It is generally true that affirmative defenses are waived if not raised in the pleadings. Fed. R. Civ. P. 8(c)(1); *Moody v. Atl. City Bd. of Educ.*, 870 F.3d 206, 218 (3d Cir. 2017). However, DFH's argument regarding lost profits is a "general defense," as it amounts to a contention that Kaneka has failed to present a prima facie case that it is entitled to lost profits. *See Elliott & Frantz, Inc. v. Ingersoll-Rand Co.*, 457 F.3d 312, 321 (3d Cir. 2006). The failure to raise a general defense in the pleadings does not result in a waiver as it would in the case of an affirmative defense. *Id.* Kaneka's waiver argument is therefore unpersuasive.

Inc., No. 1:07-cv-1191, 2015 WL 1472015, at *25 (N.D.N.Y. Mar. 31, 2015); *In re Biogen '755 Pat. Litig.*, No. 10-cv-2734, 2018 WL 3586271, at *19 (D.N.J. July 26, 2018); *see also Callaway Golf Co. v. Acushnet Co.*, 691 F. Supp. 2d 566, 575 (D. Del. 2010) (concluding that an award of lost profits may be appropriate "where the profits of a wholly-owned subsidiary flow up to the parent").

To be sure, the Federal Circuit has not expressly recognized that lost profits can be awarded when those profits flow inexorably from a subsidiary to the patentee. *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1367 (Fed. Cir. 2008) (declining to decide "whether a parent company can recover on a lost profits theory when profits of a subsidiary actually *do* flow inexorably up to the parent"); *see also Copperhead Indus., Inc. v. Changer & Dresser, Inc.*, No. 1:18-cv-01228, 2020 WL 429485, at *2 (N.D. Ala. Jan. 28, 2020) (recognizing that "the Federal Circuit has not adopted the inexorable flow theory"). I find the weight of district court authority on that point to be persuasive, however, and I hold that Kaneka may be entitled to lost profits if it can establish that KNA's profits flowed inexorably to Kaneka.[5]

In this case, Kaneka has pointed to sufficient evidence to establish a triable issue with respect to whether KNA's profits flowed inexorably to Kaneka. It is true that Kaneka licenses the

[5] In the *Copperhead* case, the district court declined to award lost profits on an "inexorable flow" theory, claiming that "binding Federal Circuit precedent" compelled it to reject that theory. 2020 WL 429485, at *2 & n.2. Although the Federal Circuit has articulated a general rule that "a patentee may not claim, as its own damages, the lost profits of a related company," *Warsaw*, 778 F.3d at 1375, I do not read that statement as foreclosing an award of lost profits on an "inexorable flow" theory, particularly in light of the court's explicit decision not to answer that question in *Mars*, 527 F.3d at 1367. The Federal Circuit's decision in *Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305 (Fed. Cir. 2010), also cited by the *Copperhead* court, is not to the contrary. In that case, the court held that the patentee was not entitled to its subsidiaries' lost profits because the patentee itself did not sell any products. *Spine Sols.*, 620 F.3d at 1319. However, the patentee in that case does not appear to have argued that the subsidiaries' profits flowed inexorably to the patentee, and therefore the court did not need to address that possibility. *See id.*; *Spine Sols.*, No. 2009-1538, Appellees' Br. 55–62 (Fed. Cir. Apr. 8, 2010).

asserted patents to KNA for a three-percent royalty rate, and that such an arrangement without more is insufficient to justify an award to the parent of its subsidiary's lost profits. *See Mars*, 527 F.3d at 1367 (holding that a "traditional royalty-bearing license agreement" between the parent company and the subsidiary, absent record evidence that the parent "ever received or recognized any form of profit or revenue from [the subsidiary] apart from the[] royalty payments," did not establish an entitlement to the subsidiary's lost profits). However, Kaneka has pointed to evidence that its profits from KNA are not limited to the royalties it receives under the license to the '044 and '080 patents.

Specifically, Kaneka has proffered a declaration from Ronald Martin, a Senior Business Director at Kaneka Nutrients, a subsidiary of KNA. Dkt. No. 126. In that declaration, Mr. Martin stated that "profits from Kaneka Nutrients' sales of reduced [coenzyme Q_{10}] ultimately are transferred to Kaneka by way of a yearly dividend paid to Kaneka by Kaneka Americas Holdings [KAH]."[6] *Id.* ¶ 6. Mr. Martin further explained that "each year[,] all of Kaneka Nutrient[s'] net income is consolidated to [KAH's] net income, and fifty percent of [KAH's] net income is paid to Kaneka as a dividend." *Id.* ¶ 7. For that reason, Mr. Martin asserted, "any decline in Kaneka Nutrient[s'] profits directly affects the amount of the yearly dividend paid to Kaneka." *Id.* ¶ 9.

DFH contends that Mr. Martin's declaration does not create a genuine dispute of material fact on the issue of inexorable flow for three reasons. First, DFH argues that the declaration focuses on the accounting treatment of Kaneka's various subsidiaries, and it cites several cases for the proposition that "the corporate structure or accounting treatment for a parent and subsidiary does not establish the inexorable flow of profits to the parent." Dkt. No. 133 at 19. Those cases,

[6] As Mr. Martin notes in his declaration, KAH is a wholly owned subsidiary of Kaneka. *Id.* ¶ 3. KAH in turn has a number of subsidiaries, including KNA. *Id.* ¶ 6 n.1.

however, do not support DFH's position. Rather, they stand merely for the proposition that the corporate structure of the parent and the subsidiary cannot by itself establish inexorability; the plaintiffs in those cases offered no affirmative "evidence of inexorability, either contractual, structural or historical," but instead sought to prove inexorable flow through "mere ownership and control" of the subsidiary. *Illinois Tool Works, Inc. v. Seattle Safety, LLC*, No. 07-2061, 2010 WL 11523620, at *14 (W.D. Wash. Oct. 13, 2010) (quoting *Kowalski v. Mommy Gina Tuna Res.*, 574 F. Supp. 2d 1160, 1163 (D. Haw. 2008)). Here, Mr. Martin has offered evidence of "inexorable flow," specifically noting that Kaneka routinely receives a dividend in the amount of 50 percent of the profits earned by its subsidiaries. Dkt. No. 126 ¶ 7.

DFH's second point is that Mr. Martin "does not cite to or attach any documents supporting the alleged payment of dividends." Dkt. No. 133 at 19 n.11. That argument is unpersuasive. Mr. Martin's testimony provides a sufficient evidentiary basis from which to conclude that such a dividend is generally paid. That testimony, standing alone, would be sufficient to create a jury issue at trial. If at trial Kaneka should produce no corroborating evidence of those payments, the point could be raised on cross-examination of Mr. Martin, but in the absence of any contrary evidence on the issue, the absence of corroborating documentation would not itself be a reason for excluding his testimony. It is thus not a sufficient reason for denying summary judgment on this issue.

DFH's third point is that, in any event, Mr. Martin states that only 50 percent of KAH's net income is paid to Kaneka as a dividend. Federal Circuit law is clear that a patentee may claim only its own lost profits as damages. *See Warsaw*, 778 F.3d at 1375. Thus, even under an inexorable flow theory of lost profits, the patentee would be entitled to recover only the portion of the profits that flow to it from the subsidiary. Accordingly, if the evidence at trial shows that only

50 percent of the profits from KNA flow inexorably to Kaneka, then the appropriate damages award would be limited to 50 percent of KNA's profits. The fact that Mr. Martin does not represent that the entirety of KNA's profits flowed inexorably to Kaneka does not compel a grant of summary judgment that Kaneka is entitled to no lost profits whatsoever.

In summary, I conclude that Mr. Martin's declaration creates a genuine dispute of material fact regarding whether the profits from Kaneka's subsidiaries flow inexorably to Kaneka. Accordingly, DFH's motion for summary judgment that Kaneka is not entitled to lost profits is denied.

G. Injunctive Relief

DFH argues that Kaneka is not entitled to injunctive relief for infringement of the '044 patent because the '044 patent has expired. DFH is clearly correct on this point.

The law is clear that a permanent injunction is not available for infringement of an expired patent. *Douglas Dynamics, LLC v. Buyers Prod. Co.*, 717 F.3d 1336, 1339 (Fed. Cir. 2013); *Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 681 n.1 (Fed. Cir. 1990). Moreover, Kaneka does not challenge DFH's arguments on this point in its responsive brief, so Kaneka is deemed to have conceded that it is not entitled to injunctive relief for infringement of the '044 patent. *See In re Wilmington Trust Sec. Litig.*, 2017 WL 2467059, at *2 (D. Del. June 7, 2017) ("When a responding party fails to defend against an issue which is the subject of a motion, courts consistently construe the failure to respond as an abandonment of the issue or a concession that the moving party is correct."); *see also GeoComply Sols. Inc. v. Xpoint Servs. LLC*, No. 22-1273, 2023 WL 1927393, at *20 (D. Del. Feb. 10, 2023); *Noramco LLC v. Dishman USA, Inc.*, No. 21-1696, 2022 WL 2817876, at *5 (D. Del. July 19, 2022); *Blakeman v. Freedom Rides, Inc.*, No. 12-

0416, 2013 WL 3503165, at *13 (D. Del. July 10, 2013). Thus, DFH will be granted summary judgment that Kaneka is not entitled to injunctive relief for infringement of the '044 patent.

H. Testimony of Dr. Myerson

DFH next seeks to exclude the expert testimony of Dr. Myerson under the Supreme Court's decision in *Daubert* and Federal Rule of Evidence 702. DFH argues that there are four grounds on which the court should exclude Dr. Myerson's testimony: (1) Dr. Myerson bases his opinions on an improper construction of the term "hydrocarbon"; (2) Dr. Myerson bases his opinions on laboratory testing that did not contain sufficient indicia of reliability; (3) Dr. Myerson offers inconsistent opinions in his opening and reply reports; and (4) Dr. Myerson's rebuttal report on the issue of invalidity applies incorrect legal standards.

1. "Hydrocarbon"

DFH first argues that Dr. Myerson's infringement opinion rests on an improper construction of the term "hydrocarbon." Claim 1 of the '044 patent requires the reduced coenzyme Q_{10} recited in the claim to be crystallized using a solvent "selected from the group consisting of hydrocarbons, fatty acid esters, ethers and nitriles." '044 patent, cl. 1. In his report, Dr. Myerson offered the opinion that "MCT Oil," which is present in DFH's products, is a "hydrocarbon" within the meaning of claim 1. Dkt. No. 110-1, Exh. 6 ¶ 92. In his reply report, however, Dr. Myerson acknowledged that MCT ("medium chain triglyceride") oil is not a hydrocarbon but instead is a "fatty acid ester." Dkt. No. 125-5 ¶ 1. Dr. Myerson then argued that his mischaracterization was inconsequential, as fatty acid esters and hydrocarbons are both covered by claim 1 of the '044 patent, and therefore the MCT oil in DFH's products falls within the scope of claim 1.

DFH asserts that it was prejudiced by Dr. Myerson's failure to identify Kaneka's true theory of infringement until his reply report. Dkt. No. 133 at 16. Although it is clear that Dr.

Myerson erred in his opening report by referring to MCT oil as a "hydrocarbon," I am not persuaded that his error resulted in any prejudice to DFH. Indeed, in his own report on invalidity, Dr. Taylor referred to a "medium chain triglyceride," such as MCT oil, as a "fatty acid ester," which is one of the group of solvents listed in claim 1 of the '044 patent along with hydrocarbons. Dkt. No. 110-1, Exh. 3 ¶ 83. It is therefore unclear whether the parties even disagree regarding the merits of Dr. Myerson's correction in his reply report.

In any event, courts have noted that "there is no prohibition in the Federal Rules on the submission of replies correcting errors in the expert's original report or responding to a critique of that report." *Palatkevich v. Choupak*, No. 12-cv-1681, 2014 WL 5463371, at *2 (S.D.N.Y. Oct. 22, 2014); *Mass. Mut. Life Ins. Co. v. DB Structured Prod., Inc.*, No. 11-cv-30039, 2015 WL 12990692, at *3 (D. Mass. Mar. 31, 2015) (same). And whatever prejudice might result from Dr. Myerson's correction on this narrow point can be alleviated by the fact that DFH will be free to use Dr. Myerson's opening report in "any way [it] see[s] fit, whether to impeach the . . . expert or for any other purpose, including raising questions about the general reliability of [Kaneka's] case." *See Palatkevich*, 2014 WL 5463371, at *2.

Accordingly, Dr. Myerson's testimony will not be excluded on the basis that he originally referred to MCT oil as a "hydrocarbon" in his opening report, and then corrected his opinion in reply to state that MCT oil is a "fatty acid ester."

2. Laboratory Testing

DFH next argues that Dr. Myerson relied on laboratory testing that did not provide sufficient indicia of reliability. In order to establish that the accused products contained crystallized reduced coenzyme Q_{10}, as required by the asserted claims of the '044 patent, Dr. Myerson directed the completion of "experimental studies" at a laboratory operated by "Curia

Indiana." Dkt. No. 125-3 ¶¶ 92–93. Exhibit F of Dr. Myerson's report, which can be found at Dkt. No. 140-6, contains the results of the testing conducted by Curia and a general overview of the procedures followed to obtain those results. DFH argues that two aspects of those laboratory tests were unreliable: (1) the use of "microcentrifugation" and (2) the use of "polar solvents." Dkt. No. 112 at 35–36.

With respect to microcentrifugation, Exhibit F of Dr. Myerson's report explains that in creating the samples for the Curia tests, the contents of DFH's accused products were "micro-centrifuged and the liquid supernatant [was] removed and discarded." Dkt. No. 140-6 at 5. DFH asserts that the use of microcentrifugation in preparing the test samples "could have skewed the amount of [coenzyme Q_{10}] in the samples." Dkt. No. 112 at 35.

In support of that assertion, DFH cites the report of Dr. Taylor, who offered the opinion that "the sample preparation itself could have formed crystals," which would have "falsely increase[d] the likelihood" that the test would indicate "the presence of crystalline reduced [c]oenzyme [Q_{10}]." Dkt. No. 110-1, Exh. 4 ¶ 16. Dr. Taylor also challenged the choice to discard the supernatant after centrifugation, as "any dissolved [c]oenzyme [Q_{10}] or [c]oenzyme [Q_{10}] suspended in the supernatant would have been discarded and been ignored by the analysis." *Id.* ¶ 15.

Dr. Myerson responded to those challenges from Dr. Taylor in his reply report. Dr. Myerson first explained that "[f]or an amorphous solid [such as the reduced coenzyme Q_{10} in the sample that has not been crystallized], the driving force for crystallization is molecular mobility, [and] the removal of liquid and centrifugation will not impact the molecular mobility of amorphous materials." Dkt. No. 125-5 ¶ 14. Dr. Myerson then added that the choice to discard the supernatant was proper because "[t]he claim requires a specific composition in the crystalline reduced

coenzyme Q_{10}," and therefore it was correct to "only analyz[e] the solid component" of the samples. *Id.* ¶ 17.

With respect to the argument regarding polar solvents, Dr. Taylor pointed to Exhibits G and H of Dr. Myerson's report as evidence that the Curia testing involved the use of "polar solvents," which in Dr. Taylor's view "would have favored the formation of [c]oenzyme Q crystals." Dkt. No. 110-1, Exh. 4 ¶¶ 17–18.

However, Dr. Myerson's reliance on Exhibit H of his report was limited to his analysis of infringement of the '080 patent. Dkt. No. 125-3 ¶¶ 111–13 (discussing Exhibit H in the context of infringement of the '080 patent). And Dr. Myerson's report does not rely on Exhibit G in any respect. *See generally id.* As Dr. Myerson explained, the samples described in those exhibits were not used "for the detection of crystalline solids" and therefore are "not relevant" to his analysis of DFH's alleged infringement of claims 1 and 13 of the '044 patent. Dkt. No. 125-5 ¶¶ 18–19.

After weighing the parties' competing presentations, I am satisfied that Kaneka has established by preponderant evidence that Dr. Myerson's analysis of the Curia test results is the product of a reliable application of the relevant principles and methods. *See* Fed. R. Evid. 702; *Sardis*, 10 F.4th at 283–84. Dr. Taylor's criticisms of Dr. Myerson's methodology, however, are considerations that may be raised on cross-examination or in rebuttal, as those concerns are relevant to the weight of Dr. Myerson's testimony. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

3. Inconsistencies in Opening and Reply Reports

DFH next argues that Dr. Myerson offered opinions in his reply report that "directly contradict" statements he made in his opening report. Dkt. No. 112 at 37. In particular, DFH

points to paragraphs 43, 44, 45, and 51 of Dr. Myerson's report as being inconsistent with his opening report. *Id.* DFH also argues that Dr. Myerson offered new theories of infringement in paragraphs 14, 29, 40, 43, 44, 49, 50, 51, 53, and 57 of his reply report. *Id.*

With respect to the asserted inconsistencies between Dr. Myerson's opening and reply reports, DFH has not identified the statements in Dr. Myerson's opening report that purportedly conflict with the statements made in his reply report. Nonetheless, I have reviewed the contents of Dr. Myerson's two reports and I do not agree with DFH that the reports are inconsistent.

In paragraph 43 of his reply report, Dr. Myerson offered the opinion that "[t]he crystalline solids present in the sample [tested by Curia] can only be ascorbyl palmitate and ubiquinol." Dkt. No. 125-5 ¶ 43. Dr. Myerson's opening report is not inconsistent with that statement. Indeed, he expressed essentially the same opinion in paragraph 95 of his opening report, in which he stated that "[l]ooking at the results [of the Curia tests] it is clear that the only crystalline materials in this group are ubiquinol and ascorbyl palmitate." Dkt. No. 125-3 ¶ 95. The remainder of paragraph 43 is directed to "DSC results" from the Curia report, which Dr. Myerson "did not rely on" in his opening report. Dkt. No. 125-5 ¶ 43. That material is responsive to Dr. Taylor's rebuttal report and therefore does not reflect an inconsistency with Dr. Myerson's opening report.

In paragraph 44 of his reply report, Dr. Myerson stated that "[a]morphous solids do not have melting points" and instead have "glass transition temperatures." *Id.* ¶ 44. In his opening report, Dr. Myerson did not offer an opinion regarding the melting point (or lack thereof) of an amorphous solid. His discussion of amorphous solids in the opening report was limited to four paragraphs in the background section of that report. Dkt. No. 125-3 ¶¶ 29–32. Nothing in those paragraphs is inconsistent with paragraph 44 of Dr. Myerson's reply report.

In paragraph 45 of his reply report, Dr. Myerson stated that he was "not relying on [the DSC] results," but that those results "are supportive of the presence of crystalline ubiquinol." Dkt. No. 125-5 ¶ 45. As Dr. Taylor acknowledged in his rebuttal report, Dr. Myerson "did not discuss" the DSC results from Curia, nor did he "express an opinion" on those results. Dkt. No. 110-1, Exh. 4 ¶ 43. Thus, Dr. Myerson's choice to address those results in reply was a proper rebuttal to Dr. Taylor's report, particularly given Dr. Myerson's statement that he was not relying on those results to support his opinion.

In paragraph 51 of his reply report, Dr. Myerson addressed Dr. Taylor's criticisms of the test results disclosed in Exhibit G to Dr. Myerson's opening report. Dkt. No. 125-5 ¶ 51. As Dr. Myerson explained, he "did not rely on th[o]se tests for any of [his] infringement opinions." *Id.* Indeed, Dr. Myerson's opening report did not contain a single substantive reference to Exhibit G. *See generally* Dkt. No. 125-3. Thus, it was not improper for Dr. Myerson to respond to Dr. Taylor's criticisms of that exhibit in reply. And Dr. Myerson's statements about that exhibit in paragraph 51 of his reply report do not appear to conflict with any statements he made in his opening report.

Beyond those four paragraphs, DFH asserts that Dr. Myerson "introduced new theories and analytical protocols" in paragraphs 14, 29, 40, 49, 50, 53, and 57 of his reply report. Dkt. No. 112 at 37. Each of those paragraphs is directly responsive to a criticism raised by Dr. Taylor's rebuttal report. *See* Dkt. No. 125-5 ¶¶ 14, 29, 40, 49, 50, 53, 57. They do not, as DFH suggests, "attempt[] to put forth new theories outside the scope" of Dr. Myerson's opening report. *See* Dkt. No. 112 at 37 (quoting *Huawei Techs., Co, Ltd v. Samsung Elecs. Co, Ltd.*, 340 F. Supp. 3d 934, 995 (N.D. Cal. 2018)). As responses to criticisms from Dr. Taylor, those statements by Dr. Myerson were permissible as directed to matters typically contained in reply expert reports.

For the above reasons, Dr. Myerson's testimony will not be excluded on the ground that his reply report expressed opinions that were either new or inconsistent with opinions set forth in his opening report.

4. Legal Standard Applied by Dr. Myerson

DFH next argues that Dr. Myerson's report applies an incorrect legal standard in two respects. First, DFH argues that Dr. Myerson applies the "broadest reasonable interpretation" standard for claim construction rather than the "ordinary and customary meaning" standard articulated by the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1301, 1313 (Fed. Cir. 2005) (en banc). Second, DFH argues that Dr. Myerson improperly relied on the Patent and Trademark Office's Manual of Patent Examining Procedure ("MPEP") when setting forth various legal standards in his report.

On the issue of the claim construction standard, it is true that Dr. Myerson stated that he was informed "that the claims should be given their broadest reasonable interpretation . . . as they would be understood by a person of ordinary skill in the art." Dkt. No. 125-4 at 20. However, in the paragraph preceding that statement, Dr. Myerson articulated the correct claim construction standard, i.e., that "claims are generally construed to have their ordinary meaning to a person of ordinary skill in the art at the time of the invention." *Id.* Moreover, Dr. Myerson's report did not purport to offer opinions on the proper construction of any claim term. He expressly recognized that the parties had stipulated that "certain claim terms should be given their plain and ordinary meaning" and thus there were no pending claim construction issues. *Id.* at 20–21. To the extent that Dr. Myerson relied on a claim construction of "relative to" that differed from Dr. Taylor's construction, that issue has been resolved by this opinion. Accordingly, Dr. Myerson's erroneous

recitation of the "broadest reasonable interpretation" standard does not undermine the reliability of his testimony such that it should not be admitted.

With respect to Dr. Myerson's reliance on the MPEP, it is true that guidance from the Patent and Trademark Office (such as the MPEP) "does not carry the force of law and is not binding" on courts. *cxLoyalty, Inc. v. Maritz Holdings Inc.*, 986 F.3d 1367, 1375 n.1 (Fed. Cir. 2021) (citation omitted). However, the MPEP can serve as "an official interpretation of statutes or regulations so long as it is not in conflict therewith." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995). DFH does not offer a response to the *Molins* case in its reply brief, nor has it pointed to any statement in Dr. Myerson's report in which he relied on the MPEP for an incorrect statement of the law. Accordingly, Dr. Myerson's testimony will not be excluded on the basis that he relied on the MPEP for the articulation of certain legal standards.

I. Testimony of Mr. Rosenfarb

DFH moves to exclude the testimony of Kaneka's damages expert, Sam Rosenfarb. Dkt. No. 108. Although DFH's argument on that point is not developed in any detail in DFH's opening brief, the request to exclude Mr. Rosenfarb's testimony appears to be an alternative argument to DFH's request for summary judgment that Kaneka is not entitled to lost profits. *See* Dkt. No. 112 at 31–32 ("In the alternative, Defendants request that the Court exclude any testimony from [Mr.] Rosenfarb related to Kaneka's lost profits on the grounds that such testimony would be legally erroneous and unhelpful and confusing to a jury."). Thus, the same grounds for denying DFH's motion for summary judgment on the issue of lost profits would appear to apply to its motion to

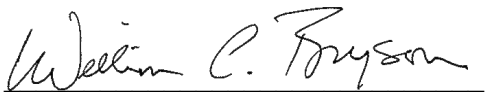
preclude the testimony of Mr. Rosenfarb.[7] Because, as noted above, summary judgment on that issue would be improper, I will also deny DFH's request to preclude Mr. Rosenfarb's testimony.

IV. Conclusion

For the reasons set forth above, DFH's motion for summary judgment is GRANTED to the extent that Kaneka will not be entitled to injunctive relief for infringement of the expired '044 patent. The motion for summary judgment is DENIED in all other respects. The motions to preclude expert testimony are also DENIED.

IT IS SO ORDERED.

SIGNED this 3rd day of March, 2023.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE

[7] DFH argues in a footnote that Mr. Rosenfarb "has not conducted a proper evidence-based lost profits analysis using the relevant legal factors." Dkt. No. 112 at 32 n.9. That argument fails for two reasons. First, arguments raised solely in footnotes are waived. *See Nw. Univ. v. Universal Robots A/S*, No. 21-149, 2022 WL 903892, at *6 & n.26 (D. Del. Mar. 28, 2022) ("[C]ourts traditionally do not consider arguments presented entirely in footnotes.") (citing cases); *see also SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006) ("[A]rguments raised in footnotes are not preserved."). Second, DFH has not explained with any specificity how Mr. Rosenfarb's analysis is insufficient, apart from DFH's contention that Kaneka is improperly seeking lost profits that would have been earned by its subsidiary, KNA.