APPENDIX

APPENDIX A — JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, FILED MAY 13, 2019

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2018-1892

KANEKA CORPORATION,

Plaintiff-Appellant,

v.

XIAMEN KINGDOMWAY GROUP COMPANY, PACIFIC RAINBOW INTERNATIONAL INC.,

Defendants-Appellees,

MITSUBISHI GAS CHEMICAL COMPANY, INC., MAYPRO INDUSTRIES, LLC, ZHEJIANG MEDICINE CO., LTD., ZMC-USA L.L.C., MAYPRO INDUSTRIES, INC., SHENZHOU BIOLOGY AND TECHNOLOGY CO., LTD., SOJITZ CORPORATION OF AMERICA, ROCHEM INTERNATIONAL, INC.,

Defendants.

Appeal from the United States District Court for the Central District of California in No. 2:11-cv-02389-SJO-SS, Senior Judge James S. Otero.

Appendix A

JUDGMENT

THIS CAUSE having been heard and considered, it is ORDERED and ADJUDGED:

PER CURIAM (REYNA, BRYSON, and STOLL, *Circuit Judges*).

AFFIRMED. See Fed. Cir. R. 36.

ENTERED BY ORDER OF THE COURT

May 13, 2019
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

APPENDIX B — FINAL JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA, FILED APRIL 20, 2018

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CASE NO.: 11-cv-02389 SJO (SSx)

KANEKA CORPORATION,
A JAPANESE CORPORATION,

Plaintiff,

v.

XIAMEN KINGDOMWAY GROUP COMPANY, A CHINESE CORPORATION, PACIFIC RAINBOW INTERNATIONAL INC., A CALIFORNIA CORPORATION, SHENZHOU BIOLOGY & TECHNOLOGY CO., LTD., A CHINESE CORPORATION, SOJITZ CORPORATION OF AMERICA, A NEW YORK CORPORATION, AND ROCHEM INTERNATIONAL, INC., A NEW YORK CORPORATION,

Defendants.

Hon. S. James Otero

STIPULATED FINAL JUDGMENT OF NON-INFRINGEMENT BY KANEKA CORPORATION

Appendix B

Pretrial Conference: April 12, 2018
Time: 9:00am
Trial Date: April 17, 2018
Courtroom: 10C

FINAL JUDGMENT OF NON-INFRINGEMENT

Before the Court is the Stipulation For Entry Of Final Judgment Of Non-Infringement filed by Plaintiff Kaneka Corporation ("Kaneka"). Based on Kaneka's stipulation, and good cause appearing, Kaneka's stipulation is APPROVED and SO ORDERED. Accordingly, IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:

1. Final Judgment of Non-Infringement of U.S. Patent No. 7,910,340 is entered against Kaneka and for declaratory judgment Defendants Xiamen Kingdomway Group Company ("Kingdomway") and Pacific Rainbow International Inc. ("Pacific Rainbow"); and

2. All other claims, counterclaims, defenses, or other matters which have been asserted (except for any claim(s) or motion(s) relating to an "exceptional case" determination pursuant to 35 U.S.C. § 285 or other bases for the award of attorneys' fees and/or costs, the timing of which is governed by Fed. R. Civ. P. 54(d)(1) and (2), and Fed. R. Civ. P. 58(e)) are hereby DISMISSED WITHOUT PREJUDICE.

DATED: April 20, 2018 By: /s/_____
Hon. S. James Otero
United States District Judge

APPENDIX C — JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA, FILED APRIL 10, 2018

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CASE NO.: 11-cv-02389 SJO (SSx)

KANEKA CORPORATION,
A JAPANESE CORPORATION,

Plaintiff,

v.

XIAMEN KINGDOMWAY GROUP COMPANY, A CHINESE CORPORATION, PACIFIC RAINBOW INTERNATIONAL INC., A CALIFORNIA CORPORATION, SHENZHOU BIOLOGY & TECHNOLOGY CO., LTD., A CHINESE CORPORATION, SOJITZ CORPORATION OF AMERICA, A NEW YORK CORPORATION, AND ROCHEM INTERNATIONAL, INC., A NEW YORK CORPORATION,

Defendants.

Hon. S. James Otero
Pretrial Conference: April 12, 2018
Time: 9:00am
Trial Date: April 17, 2018
Courtroom: 10C

Appendix C

Plaintiff Kaneka Corporation ("Kaneka"), by and through their undersigned counsel, hereby stipulates and agrees, subject to the approval of the Court, as follows:

1. On March 22, 2011, Kaneka filed its original Complaint for patent infringement against Defendants Xiamen Kingdomway Group Co. ("Kingdomway") and Pacific Rainbow Int'l. Inc. ("Pacific Rainbow") (collectively "Defendants") for infringing Kaneka's U.S. Patent No. 7,910,340 (the "'340 Patent"). *See* Doc. 1, and as amended, Docs. 220, 412, 420-1.

2. On April 13, 2011, April 14, 2011, and July 6, 2011, Defendants answered Kaneka's Complaint. *See* Docs. 13, 18 & 48, respectively, and as amended, Docs. 140, 238, 239, 427, 428.

3. On July 24, 2014, the Court issued its Claim Construction Order (Doc. 155) construing the "70 mole %" and "sealed tank"[1] limitations of the '340 Patent.

4. On June 10, 2015, the Court of Appeals for the Federal Circuit reversed the District Court's construction of "sealed tank,"[2] construed the "sealed tank" limitation to mean "a tank that prevents exposure of the tank's contents

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1. Doc. 155 at 9 ("a tank that is closed to prevent the entry or exit of materials.")

2. The Federal Circuit also construed the "oxidizing limitation" of the '340 patent, but this limitation is not part of the planned appeal as Defendants have withdrawn their position that Kaneka must show a baseline rate for passive oxidation. Doc. 636.

to the atmosphere," and remanded the case back to the District Court. *Kaneka Corp. v. Xiamen Kingdomway Group Co.*, 790 F.3d 1298, 1303-05 (Fed. Cir. 2015).

5. On September 16, 2016, Kaneka filed its Amended Patent Local Rule 3-1 (N.D. Cal) Disclosure of Asserted Claims and Second Amended Final Infringement Contentions (Doc. 518), asserting infringement of claims 22, 33 and 36 of the '340 Patent ("Asserted Claims"), and identified Kingdomway's "Old" and "New" manufacturing processes for producing oxidized coenzyme Q10 as infringing processes.

6. On December 19, 2016, Defendants moved for summary judgment of non-infringement on both the "sealed tank" and "70 mole %" limitations. Docs. 559 & 561-1.

7. On January 6, 2017, Defendants moved *in limine* under *Daubert* and Fed. R. Evid. 702 to exclude Kaneka's July 2016 testing regarding the 70 mole% limitation in Kingdomway's manufacturing processes and Kaneka's expert witness' (Dr. David Sherman) opinions relating to the same. Doc. 598.

8. On February 22, 2017, the Court issued its Minute Entry Order (Doc. 696) (under seal) on pending *Daubert* motions. Among other things, the Court held that a "sealed tank" "must prevent exposure of its contents to the atmosphere *for the entire duration of the extraction step, or else the contents of the tank could be exposed to the atmosphere for at least a portion of the extraction*

step." Doc. 696 at 11. (*emphasis added*). The Court further "**PRECLUDE[D]** the parties and their experts from testifying or opining that extraction can be performed in a 'sealed tank' even if the contents of the tank are exposed to the atmosphere for a portion of the extraction step." *Id.* (*emphasis in original*).

9. In its February 22, 2017 Minute Entry Order (Doc. 696), the Court also excluded "Kaneka's July 2016 testing of whether [] XKGC's manufacturing processes practice the 70 mole % limitation" under Fed. R. Evid. 702, and "**PRECLUDE[D]** Kaneka and its witnesses from testifying and offering opinions regarding the results of their testing of the 70 mole % limitation." Doc. 696 at 16 (emphasis in original). The Court further stated, "This ruling does not, however, bar Kaneka from introducing evidence or argument at trial regarding testing of the 70 mole% performed by others, such as Shenzhou and Chemir, using the Pharma Forensics Protocol as Defendants have not demonstrated that the protocol, if followed, is unreliable." Doc. 696 at 16.

10. On September 1, 2017, Defendants filed a supplemental brief (Doc. 767) in support of their summary judgment motion. Doc. 559. Defendants' supplemental brief modified their original motion to a no-evidence motion based upon the Court's Minute Entry Order (Doc. 696) excluding Kaneka's July 2016 testing.

11. On September 11, 2017, Kaneka responded to Defendants' supplemental brief (Doc. 767) and provided evidence to validate its July 2016 testing. Doc. 770-1.

12. On March 5, 2018, Kaneka moved the Court to reconsider the additional limitations it placed upon the Federal Circuit's construction of "sealed tank." Doc. 819.

13. On April 5, 2018, the Court issued its Minute Entry Order (Doc. 838) (under seal), which, among other things:

(1) denied Kaneka's motion to reconsider the Court's construction of "sealed tank" (Doc. 838 at 41);

(2) maintained the Court's construction of "sealed tank" as a "tank to prevent exposure of its contents to the atmosphere for the entire duration of the extraction step" (Doc. 838 at 41), including that:

(a) "While it does conclude that the tank must be sealed during the entirety of the extraction process, it requires only that the contents of the tank not be exposed to the atmosphere—not that the atmosphere be protected from the contents of the tank" (Doc. 838 at 39);

(b) "the use of a seal pot or some other one-way check valve that allows gas to escape the container while the tank is being filled, but does not allow atmospheric oxygen to enter, is sufficient to render a tank 'sealed' for purposes of the '340 patent" (Doc. 838 at 39);

(c) "valves 'close to prevent any potential drawing in of atmospheric air exposed to the hexane'" (Doc. 838 at 41);

(d) "Exposing the tank's contents to the atmosphere at any point during the extraction process would introduce oxygen into the tank and thereby frustrate this goal [preventing oxidation]" (Doc. 838 at 40);

(3) denied Defendants' motion for summary judgment regarding "sealed tank" for literal infringing, stating:

(a) "On the present record, the Court cannot say whether . . . XKGC's old or new processes use industrial extraction tanks subjected to the continuous exchange of liquids and gases." (Doc. 838 at 42); and

(b) "XKGC's new and old processes extract CoQ_{10} in a 'sealed tank' because although these processes include relief valves that can expose the tank's contents to the atmosphere, XKGC's SOP, coupled with the purpose of the relief valve—to prevent the build-up of the solvent hexane, which can create an explosion if too pressurized—reveal that the valves 'close to prevent any potential drawing in of atmospheric air exposed to the hexane ...'" (Doc. 838 at 41);

(4) granted Defendants' motion for summary judgment regarding "sealed tank" under the doctrine of equivalents based upon its finding of prosecution history estoppel (Doc. 838 at 42-44);

(5) denied Kaneka's request to reconsider (Doc. 770-1) the Court's Fed. R. Evid. 702 exclusion of Kaneka's July 2016 testing (Doc. 696) (Doc. 838 at 37-38);

(6) denied Defendants' motion for summary judgment regarding "70 mole %" for Kingdomway's "old manufacturing process" (Doc. 838 at 36);

(7) granted Defendants' motion for summary judgment regarding "70 mole %" for Kingdomway's "new manufacturing process" "because Kaneka has introduced no admissible evidence showing there is a genuine dispute as to whether XKGC's new manufacturing process practices the 70 mole % limitation." (Doc. 838 at 38).

14. Subject to Plaintiff's right to appeal on all issues and grounds for appeal, Kaneka stipulates and agrees that, in light of the Court's Minute Entry Orders (Docs. 696 and 838), the Accused Methods of Producing Oxidized Coenzyme Q10 have not infringed and currently do not infringe the Asserted Claims of the '340 Patent for at least the following reasons:

(1) The Court's modification and/or addition of requirements to the Federal Circuit's construction of the "sealed tank" limitation; and

(2) The Court's grant of Defendants' no-evidence summary judgment motion regarding the "70 mole %" limitation with respect to Kingdomway's

new manufacturing process based upon the Court's exclusion of Kaneka's July 2016 testing and expert witness opinions.

15. Kaneka, therefore, stipulates to entry of a final judgment that the Accused Methods have not infringed and currently do not infringe the Asserted Claims of the '340 Patent.

16. Kaneka further stipulates that the Court may enter judgment of non-infringement as to the '340 Patent to conserve judicial resources and to avoid the time and expense of further and duplicate litigation. Upon entry of such judgment, Kaneka intends to appeal the Court's judgment of non-infringement.

17. Kaneka further stipulates that Rule 54(b) authorizes a District Court to "direct entry of a final judgment as to one or more, but fewer than all, claims ... if the court expressly determines that there is no just reason for delay." Fed. R. Civ. P. 54(b). In view of the Court's claim construction and preclusive evidentiary rulings, as described above, and because the non-infringement issue is separable from the remaining counterclaims, in the interest of sound judicial administration, there is no just reason for delaying the entry of final judgment of non-infringement as to the '340 patent, and final judgment of non-infringement, subject to the Court's approval, is hereby requested pursuant to Fed. R. Civ. P. 54(b).

18. Kaneka stipulates to the dismissal without prejudice of all other claims and defenses (except for

any post judgment claim(s) or motion(s) relating to an "exceptional case" determination pursuant to 35 U.S.C. § 285 or other bases for the award of attorneys' fees and/or costs, the timing of which is governed by Fed. R. Civ. P. 54(d)(1) and (2)), subject to Kaneka's right to revive any such claim, counterclaim, and/or defenses, in the event of a remand from the Federal Circuit Court of Appeals.

19. Notwithstanding the foregoing, Kaneka specifically objects to the Court's construction of the phrases "sealed tank" and "70 mole %", and the Court's exclusion of Kaneka's July 2016 testing evidence and Dr. David Sherman's expert opinions relating to the same. The parties reserve their rights to challenge the construction of these terms or any other construction of the disputed claim terms on appeal. Kaneka reserves all appellate rights arising from this action including, but not limited to, the right to appeal the Minute Entry Orders (Docs. 696 and 838) and Order Regarding Claims Construction (Doc. 155) to the United States Court of Appeals for the Federal Circuit.

20. A proposed final judgment reflecting Kaneka's stipulation is submitted herewith.

IT IS SO STIPULATED.

DATED: April 10, 2018

Appendix C

Respectfully submitted,

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APPENDIX D — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA, DATED APRIL 5, 2018

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CV 11-02389 SJO (SHSx)

KANEKA CORP.

v.

ZHEJIANG MEDICINE CO., LTD. *et al.*

April 5, 2018, Decided
April 5, 2018, Filed

PRESENT: THE HONORABLE S. JAMES OTERO,
UNITED STATES DISTRICT JUDGE.

CIVIL MINUTES - REDACTED

PROCEEDINGS (IN CHAMBERS): ORDER (1) GRANTING IN PART AND DENYING IN PART PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT ON DEFENDANTS' CLAIMS OF PATENT INVALIDITY UNDER 35 U.S.C. §§ 101, 102, & 112, ¶ 2 [DOCKET NO. 556]; (2) GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AS TO INVALIDITY AND NONINFRINGEMENT OF U.S. PATENT NO. 7,910,340 [DOCKET NO.

Appendix D

559]; (3) DENYING PLAINTIFF'S MOTION FOR RECONSIDERATION OF THE COURT'S MODIFICATION OF THE FEDERAL CIRCUIT'S INTERPRETATION OF "SEALED TANK" [DOCKET NO. 819]

This matter is before the Court on (1) Plaintiff Kaneka Corporation's ("Kaneka" or "Plaintiff") Motion for Partial Summary Judgment on Defendants' Claims of Patent Invalidity Under 35 U.S.C. §§ 101, 102, & 112, ¶ 2 ("Kaneka Motion"); and (2) Defendants Shenzhou Biology and Technology Co., Ltd. ("Shenzhou"), Xiamen Kingdomway Group Company ("XKGC"), Pacific Rainbow International, Inc. ("PRI"), Sojitz Corporation of America ("Sojitz"), and Rochem International, Inc.'s ("Rochem") Motion for Summary Judgment as to Invalidity and Noninfringement of U.S. Patent No. 7,910,340 ("Defendants' Motion"), both filed December 19, 2016. Defendants opposed Kaneka's Motion for Summary Judgment ("Def.'s Opposition") and Kaneka opposed Defendants' Motion for Summary Judgment ("Kaneka Opposition") on January 9, 2017. The parties filed reply briefs in support of their summary judgment motions ("Kaneka Reply" and "Def.'s Reply," respectively) on January 16, 2017. On September 11, 2017, at the invitation of the Court, Plaintiff filed a Supplemental Brief In Opposition to XKGC's Motion for Summary Judgment ("Pl.'s Supplemental Brief") to which Defendants responded ("Def.'s Supplemental Reply") on March 9, 2018. Also before the Court is Plaintiff's Motion for Reconsideration of the Court's Modification of the Federal Circuit's Interpretation of "Sealed Tank" ("Motion for Reconsideration"), filed March 5, 2018.

Defendants opposed Kaneka's Motion for Reconsideration ("Def.'s Opp'n to Mot. For Reconsideration") on March 9, 2018 and Kaneka filed its reply brief ("Pl.'s Reply ISO Mot. For Reconsideration") on March 13, 2018. Since the filing of the parties' summary judgment motions, Plaintiff has dismissed its claims with respect to all but two Defendants, XKGC and PRI (together, the "Defendants"). The Court found these matters suitable for disposition without oral argument and vacated the hearing set for January 30, 2017. *See* Fed. R. Civ. P. 78(b). For the following reasons, the Court **GRANTS IN PART** and **DENIES IN PART** the Kaneka Motion and Defendants' Motion and **DENIES** Plaintiff's Motion for Reconsideration.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. The '340 Patent

This is a patent infringement action involving U.S. Patent No. 7,910,340 (the "'340 Patent"), titled "Processes for Producing Coenzyme Q_{10}." Coenzyme Q_{10} ("CoQ_{10}") exists in animal cells, which use CoQ_{10} to produce adenosine triphosphate ("ATP"), which aids cellular respiration. CoQ_{10} assists ATP production through redox reactions, in which the coenzyme gives up and gains electrons. Both oxidized and reduced CoQ_{10} are sold as dietary supplements.

The '340 Patent, which is owned by Kaneka, contains forty-five (45) process claims, of which four—claims 1, 11, 22, and 33—are independent. (*See* Decl. Lei Mei in Supp. Defs.' Mot. for Summ. J. ("Mei Opening Decl."), Ex. A

("'340 Patent") col. 23, l. 55-col. 26, l. 65, ECF No. 559-2; *see also* Defs.' Statement of Genuine Disputes of Material Fact in Response to Pl. Kaneka Corp.'s Statement of Uncontroverted Facts and Conclusions of Law ("Defs.' Response") ¶ 1, ECF No. 604-1.) Independent claim 22, which is asserted against Defendants, recites:

> A process for producing on an industrial scale the oxidized coenzyme Q_{10} represented by the following formula . . . which comprises culturing reduced coenzyme Q_{10}-producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorous source and a micronutrient to obtain microbial cells containing reduced coenzyme Q_{10} at a ratio of not less than 70 mole % among the entire coenzymes Q_{10},
>
> disrupting the microbial cells to obtain reduced coenzyme Q_{10}; and
>
> oxidizing thus-obtained reduced coenzyme Q_{10} to oxidized coenzyme Q_{10} and then extracting the oxidized coenzyme Q_{10} by an organic solvent in a sealed tank.

('340 Patent col. 25, ll. 31-54.) Independent claim 33, which is also asserted against Defendants, is identical to claim 1, except that (1) it does not contain a "disrupting" step; and (2) the extraction step is recited before the oxidation step. ('340 Patent col. 26, ll. 13-36 ["extracting the reduced coenzyme Q_{10} by an organic solvent in a sealed tank, and

oxidizing the extracted reduced coenzyme Q_{10} to oxidized coenzyme Q_{10}."].) Dependent claim 36, the final asserted claim, recites "[t]he process according to claim 33, further comprising disrupting the microbial cells." ('340 Patent col. 26, ll. 42-43.) Claims 22, 33, and 36 are collectively referred to as the "asserted claims."

B. The Defendants

XKGC and Shenzhou (the "Manufacturing Defendants") are entities Kaneka accuses of directly infringing the asserted claims. (*See generally* Second Am. Compl. ("SAC"), ECF No. 412.) Defendants PRI, Sojitz, and Rochem (the "Distributor Defendants") are distributors of CoQ_{10} produced by XKGC's manufacturing processes. (*See, e.g.*, SAC ¶ 19.) They do not separately move for summary judgment on any issue. (*See generally* Defs.' Mot., ECF No. 559.) After the motions for summary judgment were filed, Kaneka settled its dispute with Shenzhou, Sojitz, and Rochem.[1]

C. Procedural History

The procedural history of this case is long and tortured. On March 22, 2011, Kaneka filed the instant

1. Of the Original Defendants, only XKGC and PRI remain as defendants in the instant action. (*See* Order Re: Transfer, ECF No. 39; Order Severing and Transferring Claims, ECF No. 47; Stipulated Settlement and Dismissal Order Between Kaneka and MGC, ECF No. 154; Order of Dismissal Between Kaneka and Maypro, ECF No. 287; Stipulated Settlement and Dismissal Between Kaneka and Shenzhou, ECF No. 784; Stipulated Settlement and Dismissal of Sojitz and Rochem, ECF No. 787.)

action, which was initially assigned to Judge Mariana R. Pfaelzer, asserting infringement of the '340 Patent against XKGC, PRI, Shenzhou, Zhejiang Medicine Co., Ltd. ("Zhejiang"), ZMC-USA, L.L.C. ("ZMC"), Maypro Industries, Inc. ("Maypro"), and Mitsubishi Gas Chemical Company, Inc. ("MGC") (collectively, "Original Defendants"). (*See* Compl., ECF No. 1.) One day earlier, however, Zhejiang and ZMC filed a declaratory judgment action with respect to the '340 Patent in the United States District Court for the Southern District of Texas (the "Texas Litigation"). *See* Compl., *Zhejiang Med. Co. et al. v. Kaneka Corp.*, No. 4:11-cv-01052 (S.D. Tex. Mar. 21, 2011), ECF No. 1. On October 4, 2013, Kaneka filed an Amended Complaint against the Original Defendants. (*See* Am. Compl., ECF No. 220.) Defendants filed separate Answers to the Amended Complaint on October 18, 2013. (*See* Answers to Am. Compl., ECF Nos. 238-240.)

On June 17, 2011, Kaneka filed a Section 337 Petition in the United States International Trade Commission ("ITC") involving the same claims of the '340 Patent. *See* Certain Coenzyme Q_{10} Products and Methods of Making Same, Inv. No. 337-TA-790, USITC Pub. 4407 (Sept. 27, 2012) (Final) (the "ITC Proceeding"). Judge Pfaelzer stayed the instant action pending resolution of the ITC proceeding. (Orders and Corrected Order re Stipulation to Stay District Court Action, ECF Nos. 59-61.) The ITC issued a decision finding no infringement by any of the respondents. (*See* Joint Status Report, ECF No. 70.) The parties stipulated that all discovery taken in the ITC proceeding could be used in this case. (Joint Rule 26(f) Report 9, ECF No. 92; Stip. Protective Order, ECF No. 97.)

Appendix D

On February 7, 2013, Judge Pfaelzer lifted the stay in the instant action, (*see* Joint Status Report), and on July 24, 2013, issued a Claim Construction Order, construing the following five terms:

Claim Term	Claim Construction
"inert gas atmosphere"	a gas atmosphere that is free or substantially free of oxygen and reactive gases"
"sealed tank"	"a tank that is closed to prevent the entry or exit of materials"
"culturing reduced coenzyme Q_{10} producing microganisms . . . to obtain microbi cells containing reduced coenzymeQ_{10} at a ratio of not less than 70 mole % among the entire coenzymes Q_{10}."	"culturing reduced coenzyme Q_{10} producing microorganisms to obtain microbial cells containing reduced coenzyme Q_{10} at a ratio of not less than 70 mole % among the entire coenzymes Q_{10} at a time prior to the extraction, oxidation, or disruption steps and as determined by the assay described at col. 5, line 8 to line 43, and Example 1 of the '340 Patent."

"oxidizing thus-obtained reduced coenzyme Q_{10} to oxidized coenzyme Q_{10}"	"actively converting all or substantially all of the reduced coenzyme Q_{10} obtained from the disruption step to oxidized coenzyme Q_{10} in a step before beginning the extraction step"
"oxidizing the extracted reduced coenzyme Q_{10} to oxidized coenzyme Q_{10}"	actively converting all or substantially all of the extracted reduced coenzyme Q_{10} obtained from the disruption step to oxidized coenzyme Q_{10} in a separate step after the extraction step has been performed"

(*See* Claim Construction Order, ECF No. 155) Shortly thereafter, on August 27, 2013, XKGC, PRI, and Shenzhou moved for summary judgment of noninfringement based upon the Court's constructions and discovery taken in the ITC Proceeding. (Defs.' Mots. for Summ. J. as to Noninfringement, ECF Nos. 158, 188.) Kaneka, meanwhile, moved for summary judgment with respect to validity and to certain of XKGC's counterclaims on November 12, 2013. (Pl.'s Mots for Summ. J., ECF Nos. 265-266.)

Judge Pfaelzer granted in part XKGC, PRI, and Shenzhou's summary judgment motions on December

6, 2013, finding that no genuine dispute of material fact existed as to whether Movants' "cell paste drying step," "biomass drying step," and "alkali wash" practice the limitations of the independent claims, or whether Shenzhou's process includes an oxidation step after the extraction step as required by Claims 11 and 33. (Orders Granting in Part Defs.' Mots. for Summ. J., ECF Nos. 310-311.) On February 24, 2014, Judge Pfaelzer denied Kaneka's motion for summary judgment regarding validity but granted its motion with respect to XKGC's third through ninth counterclaims. (Order Granting in Part and Den. in Part Pl.'s Mots. for Summ. J., ECF Nos. 313-314.)

On March 27, 2014, Judge Pfaelzer entered judgment in favor of XKGC, PRI, and Shenzhou, and dismissed without prejudice these defendants' counterclaims for declaratory judgment of invalidity and unenforceability. (Judgment, ECF No. 322.) This judgment was appealed by Kaneka to the United States Court of Appeals for the Federal Circuit, which issued an opinion affirming in part, vacating in part, and remanding the action to the district court on June 10, 2015. *See Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298 (Fed. Cir. 2015) ("Opinion"). In particular, the Federal Circuit (1) upheld Judge Pfaelzer's grant of summary judgment of noninfringement of independent claims 1 and 11 and dependent claims 8-9 and 19-20; and (2) vacated Judge Pfaelzer's grant of summary judgment of noninfringement of independent claims 22 and 33 and associated depending claims. *See generally* Opinion. With respect to the latter conclusion, the Federal Circuit held (1) that Judge

Pfaelzer's construction of the term "sealed tank" conflicted with the intrinsic record, and construed the term to mean "a tank that prevents exposure of the tank's contents to the atmosphere," *id.* at 1305; and (2) that the oxidizing step "requires some action that results in oxidation but does not require oxidation of 'all or substantially all' of the coenzyme Q_{10},'" and that "it is not required that any one step be carried out separately or independently of any other step," *id.* at 1307.

The instant action was remanded and subsequently reassigned from Judge Pfaelzer to Judge Cristina A. Snyder. (*See* Notice of Reassignment of Case, ECF No. 354.) XKGC and PRI then filed a second motion for summary judgment ("Second XKGC Motion") on October 26, 2015. (*See* Mot. for Summ. J. as to Invalidity and Noninfringement, ECF No. 355.) On January 6, 2016, the parties consented to having the action referred to the Patent Pilot Program ("PPP") pursuant to General Order No. 11-11. (Joint Notice of Consent to Referral to the PPP, ECF No. 394.) On March 15, 2016, this Court issued a minute order in which it (1) set a scheduling conference; and (2) denied without prejudice the Second XKGC Motion in light of the need for additional discovery given the Federal Circuit's construction of certain terms and the passage of time. (*See* Order Setting Scheduling Conference, ECF No. 399.) At the scheduling conference, the Court imposed deadlines regarding the filing of amended pleadings, the exchange of final infringement and final invalidity contentions, and the filing of dispositive motions. (*See* Minutes of Scheduling Conference, ECF No. 405.)

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Kaneka filed its SAC on May 2, 2016, naming Sojitz and Rochem as additional defendants. (*See* SAC.) On September 16, 2016, Kaneka served its final infringement contentions on Defendants, asserting infringement of claims 22, 33, and 36. (*See* Pl. Kaneka Corp.'s Am. Patent L.R. 3-1 (N.D. Cal) Disclosure of Asserted Claims and Second Am., Final Infringement Contentions ("Kaneka's FICs"), ECF No. 518.) The parties' cross-motions for summary judgment followed.

On February 22, 2017, the Court ruled on three of the parties' four *Daubert* Motions, (1) denying Kaneka's Motion in Limine No. 1 to Preclude Admission of Portions of the Expert Report and Testimony of Shirley Webster, (2) granting-in-part and denying-in-part Kaneka's Motion in Limine No. 2 to Preclude Admission of Portions of Reports on Defendants' Infringement and Invalidity Experts and Related Testimony, and (3) granting-in-part and denying-in-part Defendants' Motion in Limine No. 1 to Exclude the Testimony of David Sherman, PhD. (Minute Order ("*Daubert* Order"), ECF No. 696.) Following the entry of this Order, but before the Court ruled on the pending cross-motions for summary judgment, the parties entered into a period of settlement negotiations during which the action was stayed. On October 5, 2017, Kaneka, XKGC, and PRI informed the Court that they were unable to reach a settlement and the Court set a trial date. (Joint Motion for Pretrial Conference Date, ECF No. 780; Order Granting Joint Motion, ECF No. 781.)

II. LEGAL FRAMEWORK

A. Overview of the Parties' Arguments

Defendants first move for summary judgment of invalidity, contending (1) the asserted claims are indefinite under 35 U.S.C. section 112 ¶ 2 ("Section 112 ¶ 2") because the '340 Patent does not teach, and persons skilled in the art did not know, how to properly collect and handle samples for testing the mole percentage; and (2) the asserted claims are invalid under 35 U.S.C. section 101 ("Section 101") for claiming a natural phenomenon combined with conventional steps. (*See* Mem. of Ps & As in Supp. Defs.' Mot ("Defs.' Mem.") 9-24, ECF No. 561-1.) Defendants also move for summary judgment of noninfringement, arguing no Defendant infringes any of the asserted claims, either literally or under the doctrine of equivalents ("DOE"), because (1) Defendants do not culture "reduced coenzyme Q_{10}-producing microorganisms," which cannot be photosynthetic bacteria; (2) Kaneka's own test results show XKGC does not produce reduced CoQ_{10} at a ratio of "not less than 70 mole %" at the end of the "fermentation" or "culturing" step; (3) Defendants do not use a "sealed tank" during extraction; and (4) Defendants' processes do not perform an active "oxidizing" step prior to extraction. (*See* Defs.' Mem. 25-35.)

Kaneka, meanwhile, moves for summary judgment of validity, arguing the asserted claims (1) are not indefinite under Section 112 ¶ 2; (2) are patent-eligible under Section 101; and (3) are not anticipated by any of Defendants' cited prior art references under 35 U.S.C. section 102 ("Section

102"). (*See generally* Mem. of Ps & As in Supp. Kaneka Mot. ("Kaneka Mem."), ECF No. 556-1.)

B. Relevant Legal Standards

1. Summary Judgment

Federal Rule of Civil Procedure 56(a) mandates that "[t]he 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). The moving party bears the initial burden of establishing the absence of a genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). "When the party moving for summary judgment would bear the burden of proof at trial, it must come forward with evidence which would entitle it to a directed verdict if the evidence went uncontroverted at trial. In such a case, the moving party has the initial burden of establishing the absence of a genuine issue of fact on each issue material to its case." *C.A.R. Transp. Brokerage Co. v. Darden Rests., Inc.*, 213 F.3d 474, 480 (9th Cir. 2000) (citations omitted). In contrast, when the nonmoving party bears the burden of proving the claim or defense, the moving party does not need to produce any evidence or prove the absence of a genuine issue of material fact. *See Celotex*, 477 U.S. at 325. Rather, the moving party's initial burden "may be discharged by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case." *Id.* "Summary judgment for a defendant is appropriate when the plaintiff

'fails to make a showing sufficient to establish the existence of an element essential to [his] case, and on which [he] will bear the burden of proof at trial.'" *Cleveland v. Policy Mgmt. Sys. Corp.*, 526 U.S. 795, 805-06, 119 S. Ct. 1597, 143 L. Ed. 2d 966 (1999) (quoting *Celotex*, 477 U.S. at 322).

Once the moving party meets its initial burden, the "party asserting that a fact cannot be or is genuinely disputed must support the assertion." Fed. R. Civ. P. 56(c)(1). "The mere existence of a scintilla of evidence in support of the [nonmoving party]'s position will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmoving party]." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986); *accord Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986) ("[O]pponent must do more than simply show that there is some metaphysical doubt as to the material facts."). Further, "[o]nly disputes over facts that might affect the outcome of the suit . . . will properly preclude the entry of summary judgment [and f]actual disputes that are irrelevant or unnecessary will not be counted." *Liberty Lobby*, 477 U.S. at 248. At the summary judgment stage, a court does not make credibility determinations or weigh conflicting evidence. *see id.* at 249. A court is required to draw all inferences in a light most favorable to the nonmoving party. *Matsushita*, 475 U.S. at 587.

2. Definiteness Under Section 112 ¶ 2 and *Nautilus v. Biosig*

"The Patent Act requires that a patent specification 'conclude with one or more claims **particularly pointing**

out and distinctly claiming the subject matter which the applicant regards as [the] invention.'" *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 134 S. Ct. 2120, 2124, 189 L. Ed. 2d 37 (2014) (emphasis in original) (quoting 35 U.S.C. § 112, ¶ 2 (2006 ed.)). In *Nautilus*, the United States Supreme Court overturned the Federal Circuit's formulation that a patent claim passes muster under 35 U.S.C. § 112 ¶ 2 ("Section 112 ¶ 2") so long as the claim is "amenable to construction," and the claim, as construed, is not "insolubly ambiguous," concluding that such a test "does not satisfy the statute's definiteness requirement." *Id.* (quoting *Biosig Instruments, Inc. v. Nautilus, Inc.*, 715 F.3d 891, 898-99 (Fed. Cir. 2013), *judgment vacated*, 572 U.S. 898, 134 S. Ct. 2120, 189 L. Ed. 2d 37).

Instead, the Supreme Court held that 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." *Id.* Definiteness is measured from the viewpoint of a person skilled in the art at the time the patent was filed. *Id.* at 2128. The definiteness requirement must take into account the inherent limitations of language, as "[s]ome modicum of uncertainty . . . is the 'price of ensuring the appropriate incentives for innovation.'" *Id.* (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* (*"Festo VIII"*), 535 U.S. 722, 732, 122 S. Ct. 1831, 152 L. Ed. 2d 944 (2002)). Notwithstanding these inherent limitations, "a claim is indefinite if its language 'might mean several different things and no informed and confident choice is available among the contending definitions.'" *Media Rights Techs.*,

Inc. v. Capital One Fin. Corp., 800 F.3d 1366, 1371 (Fed. Cir. 2015) (quoting *Nautilus*, 134 S. Ct. at 2130 n.8).

Indefiniteness is a question of law that may be decided at the summary judgment stage. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015); *Eidos Display, LLC v. AU Optronics Corp.*, 779 F.3d 1360, 1364 (Fed. Cir. 2015).

3. Patent-Eligibility Under Section 101

"Section 101 defines the subject matter that may be patented under the Patent Act." *Bilski v. Kappos*, 561 U.S. 593, 601, 130 S. Ct. 3218, 177 L. Ed. 2d 792 (2010). Section 101 reads in its entirety: "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 therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. "Section 101 thus specifies four independent categories of inventions or discoveries that are eligible for protection: processes, machines, manufactures, and compositions of matter." *Bilski*, 561 U.S. at 601.

Although acknowledging that "[i]n choosing such expansive terms . . . Congress plainly contemplated that the patent laws would be given wide scope," the Supreme Court long ago identified three exceptions to Section 101: "laws of nature, physical phenomena, and abstract ideas." *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09, 100 S. Ct. 2204, 65 L. Ed. 2d 144 (1980). Although these exceptions are not required by the statutory text, they

are consistent with the idea that certain discoveries "are part of the storehouse of knowledge of all men" and are "free to all men and reserved exclusively to none." *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130, 68 S. Ct. 440, 92 L. Ed. 588, 1948 Dec. Comm'r Pat. 671 (1948). Thus, "the concern that drives this exclusionary principle [is] one of pre-emption." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354, 82 L. Ed. 2d 296, 189 L. Ed. 2d 296 (2014). Consequently, the Supreme Court has required that "[i]f there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end." *Funk Bros.*, 333 U.S. at 130. These principles have been held to apply with equal force to product and process claims. *Gottschalk v. Benson*, 409 U.S. 63, 67-68, 93 S. Ct. 253, 34 L. Ed. 2d 273 (1972).

The Supreme Court has articulated a two-part test for distinguishing patents that claim one of the patent-ineligible exceptions from those that claim patent-eligible applications of those concepts. *See Alice*, 134 S. Ct. at 2354. "Step one asks whether the claim is 'directed to one of [the] patent-ineligible concepts.'" *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1047 (Fed. Cir. 2016) (quoting *Alice*, 134 S. Ct. at 2354). "If the answer is no, the inquiry is over: the claim falls within the ambit of § 101." *Id.* "If the answer is yes, the inquiry moves to step two, which asks whether, considered both individually and as an ordered combination, 'the additional elements "transform the nature of the claim" into a patent-eligible application.'" *Id.* (quoting *Alice*, 134 S. Ct. at 2354). Step two is described "as a search for an 'inventive concept.'" *Alice*, 134 S. Ct. at 2354 (quoting *Mayo Collaborative*

Servs. v. Prometheus Labs, Inc., 566 U.S. 66, 72, 132 S. Ct. 1289, 182 L. Ed. 2d 321 (2012)). "At step two, more is required than 'well-understood, routine, conventional activity already engaged in by the scientific community,' which fails to transform the claim into 'significantly more than a patent upon the' ineligible concept itself." *CellzDirect*, 827 F.3d at 1047 (quoting *Mayo*, 566 U.S. at 73). "While patent eligibility is ultimately a question of law . . . [w]hether something is well-understood, routine, and conventional to a skill artisan at the time of the patent is a factual determination." *Berkheimer v. HP, Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018).

4. Anticipation and Section 102(b)'s Public Use/On-Sale Bar

Under 35 U.S.C. Section 102(a) ("Section 102(a)"), "[a] person shall be entitled to a patent unless . . . the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention. . . ." 35 U.S.C. § 102(a)(1). "It is well settled that a claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998) (citing *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 715 (Fed. Cir. 1984)).

Under 35 U.S.C. Section 102(b) ("Section 102(b)"), "[a] person shall be entitled to a patent unless . . . the invention was in public use or on sale in this country, more than one

year prior to the date of the application for patent in the United States. . . ." 35 U.S.C. § 102(b). "When the asserted basis of invalidity is a public use or on-sale bar, the court should determine 'whether the subject of the barring activity met each of the limitations of the claim, and thus was an embodiment of the claimed invention.'" *Dana Corp. v. Am. Axle & Mfg., Inc.*, 279 F.3d 1372, 1375-76 (Fed. Cir. 2002) (citing *Scaltech Inc. v. Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1383 (Fed. Cir. 1999)); *see also In re Crish*, 393 F.3d 1253, 1256 (Fed. Cir. 2004).

5. Literal Infringement

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). "To establish liability for direct infringement of a claimed method or process under 35 U.S.C. § 271(a), a patentee must prove that each and every step of the method or process was performed." *Move, Inc. v. Real Estate Alliance Ltd.*, 709 F.3d 1117, 1122 (Fed. Cir. 2013) (citing *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1307 (Fed. Cir. 2012) (en banc)). To establish literal infringement of a process claim, the enumerated steps must "all be practiced as recited in the claim . . ." *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007). "[A]ny deviation from the claim precludes a finding of literal infringement." *Jardin v. Datallegro,*

Inc., No. 08-CV-1462-IEG (WVG), 2011 U.S. Dist. LEXIS 36665, 2011 WL 1311732, at *3 (quoting *Litton Sys. Inc. v. Honeywell, Inc.*, 140 F.3d 1449, 1454 (Fed. Cir. 1998), *abrogated by Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 234 F.3d 558 (2000)).

The patentee bears the ultimate burden of proving infringement by a preponderance of the evidence, *see Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005), and as a result, summary judgment of noninfringement requires a showing by the accused infringer that "no reasonable jury could have found infringement on the undisputed facts or when all reasonable factual inferences are drawn in favor of the patentee," *Network, LLC v. Centraal Corp.*, 242 F.3d 1347, 1353 (Fed. Cir. 2001).

6. Infringement Under the "Doctrine of Equivalents"

A process that does not literally infringe a patent claim may nevertheless be found to infringe under the "doctrine of equivalents." *See Duramed Pharms., Inc. v. Paddock Labs., Inc.*, 644 F.3d 1376, 1380 (Fed. Cir. 2011). "To find infringement under the doctrine of equivalents, any differences between the claimed invention and the accused product must be insubstantial." *Brilliant Instruments, Inc. v. GuideTech, LLC*, 707 F.3d 1342, 1346 (Fed. Cir. 2013) (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608, 70 S. Ct. 854, 94 L. Ed. 1097, 1950 Dec. Comm'r Pat. 597 (1950)). "One way of proving infringement under the doctrine of equivalents is

to show, for each claim limitation, that the accused product 'performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product.'" *Id.* at 1347 (quoting *Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 559 F.3d 1308, 1312 (Fed. Cir. 2009)). This is a question of fact. *Id.* (citations omitted).

The DOE contains a number of inherent limitations. For example, "[i]f the claimed and accused elements are recognized by those of skill in the art to be opposing ways of doing something, they are likely not insubstantially different." *Id.* at 1347-48. Moreover, "the doctrine of prosecution history estoppel prevents a patent owner from recapturing through the doctrine of equivalents subject matter surrendered to acquire the patent." *Duramed*, 644 F.3d at 1380. If the patentee narrowed the scope of the asserted patent's claims in response to a prior art rejection, a presumption of prosecution history estoppel applies, which may be rebutted by showing, *inter alia*, the "alleged equivalent would have been 'unforeseeable at the time of the amendment and thus beyond a fair interpretation of what was surrendered.'" *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* ("*Festo IX*"), 344 F.3d 1359, 1369 (Fed. Cir. 2003) (quoting *Festo VIII*, 535 U.S. at 738). This is commonly referred to as "argument-based estoppel." *See Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006). Similarly, a patentee's argument to the patent examiner distinguishing a claim from the prior art—referred to as "amendment-based estoppel"—can curtail the application of the DOE. *Id.*

III. DISCUSSION

A. Whether the "70 Mole %" Limitation Is Indefinite Under Section 112 ¶ 2

1. The Parties' Arguments

Defendants first contention is that "culturing" step recited in the asserted claims—"culturing reduced coenzyme Q_{10} producing microorganisms . . . to obtain microbial cells containing reduced coenzyme Q_{10} at a ratio of not less than 70 mole % among the entire coenzymes Q_{10}" (the "70 mole % limitation")—is indefinite under Section 112 ¶ 2 and *Nautilus*. (Defs.' Mem. 9-16.) In particular, Defendants contend the record makes clear that those skilled in the art, such as the parties' technical experts, did not know, with reasonable certainty, how the molarity of the pre-extracted sample should be measured during the ITC Proceeding. (Defs.' Mem. 10-12.) The parties agree that measurement of the mole % ratio requires several steps—first **collecting** a sample, then **handling** (e.g., storing) the sample, and finally **testing** the sample. (*See* Kaneka's Response to Defs.' Statement of Uncontroverted Facts and Conclusions of Law ("Kaneka's Response") ¶ 13, ECF No. 608-1.) Defendants argue that although the '340 Patent identifies a preferred **testing** method in the specification, it is silent as to how the sample should be **collected** and **handled** before being tested in a lab, and submit that the parties' experts' disagreements regarding how to collect and handle samples during the ITC Proceeding highlight the indefiniteness of this limitation. (Defs.' Mem. 10-12.) In particular, Defendants point to

language in the Claim Construction Order indicating that, during the ITC proceeding, "[e]ach party argued that the other party's method of testing [molarity] was erroneous," supporting the conclusion that those skilled in the art did not know the scope of the asserted claims with reasonable certainty. (Defs.' Mem. 11-12 [citing Claim Construction Order at pgs. 12, 12 n.3].)

Kaneka, in turn, contends that Defendants should be barred, both procedurally and as a matter of law, from arguing the 70 mole % limitation is indefinite, characterizing this effort as "an improper request for reconsideration of this court's *Markman* ruling." (Kaneka Mem. 8.) Kaneka further submits that Defendants' own experts testified before the ITC that a person of ordinary skill in the art would understand the proper methods of sample collection, preservation, and testing, and therefore Kaneka should be entitled to summary judgment on this issue. (Kaneka Mem. 10-12.)

2. The Challenged 70 Mole % Claim Limitation

In her Claim Construction Order, Judge Pfaelzer construed the 70 mole % limitation as follows:

> culturing reduced coenzyme Q_{10} producing microorganisms to obtain microbial cells containing reduced coenzyme Q_{10} at a ratio of **not less than 70 mole %** among the entire coenzymes Q_{10} **at a time prior to the extraction, oxidation, or disruption steps**

> and **as determined by the assay described** at **col. 5, line 8 to line 43**, and **Example 1** of the '340 Patent.

(Claim Construction Order 13 [emphasis added].) In construing the 70 mole % limitation in this manner, Judge Pfaelzer noted that "any requirement as to the **timing** of the mole percent determination or the method of mole percent determination must be considered carefully and incorporated [into the claims from the specification] only if justified from the claim itself." (*Id.* at 11 [emphasis added].) She then found that although the "claims do not explicitly state a timing requirement for the mole percent determination . . ., due to the structure of the claims, there is an implicit limitation . . . [that] requires that the steps be performed in the order listed," and therefore "the mole percent of reduced CoQ_{10} must be determined at a time prior to the execution of any of the subsequent steps of the claims." (*Id.* at 11-12.)

Judge Pfaelzer further noted that although the claims "do not explicitly state a **specific method of testing** to determine the percent of the reduced CoQ_{10}," the method of testing is "**critical** . . . to the **determination of infringement.**" (*Id.* at 12 [emphasis added].) Judge Pfaelzer then acknowledged that the 70 mole % limitation was not construed in the ITC proceeding, and found that Kaneka's position taken during claim construction that no construction of the term is necessary would "leave[ ] the claim so ambiguous that a person of ordinary skill in the art at the time of the invention could not understand it." (*Id.* at 12-13.) Judge Pfaelzer "resolve[d] this ambiguity" by

taking guidance from the specification, which "provides a 'demonstrated' method to 'standardize' the determination of the ratio of reduced CoQ_{10}." (*Id.* at 13.) In taking such guidance, Judge Pfaelzer expressly relied on the Federal Circuit's decision in *Biosig*. (*Id.* at 13.) Judge Pfaelzer did not find the 70 mole % limitation to be indefinite in her Claim Construction Order.

As noted above, however, the Supreme Court vacated the Federal Circuit's decision in *Biosig* approximately one year after Judge Pfaelzer issued her Claim Construction Order, expressly overturning the Federal Circuit's "insolubly ambiguous" standard and fashioning a new test that asks whether the 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*, 134 S. Ct. at 2124. Thus, the question the Court must decide is whether the 70 mole % limitation, as construed by Judge Pfaelzer in her Claim Construction Order, when read in light of the specification and prosecution history, fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention.

3. The ITC Proceedings

The parties do not genuinely dispute that the following events occurred during the ITC proceeding. First, each party's expert[2] admitted the amount of oxygen

2. The parties do not dispute that the experts who testified during the ITC proceeding are persons of ordinary skill in the art.

available to the cells during storage affects the ratio of reduced CoQ_{10} in a sample. (Mei Opening Decl., Ex. N ("ALJ Decision") at 227, ECF No. 561-3.) Moreover, a microorganism's ability to metabolize oxygen was found to vary depending on whether samples were refrigerated or frozen, as evidenced by Kaneka's expert's testimony that although microorganisms continue to metabolize oxygen when refrigerated, "freezing causes microorganisms' metabolisms to slow greatly, or even go into a resting state." (ALJ Decision 228.) In fact, Kaneka's expert tested the impact of these two storage methods, and concluded that "after one to one and one-half days of refrigeration," 70.5% reduced CoQ_{10} was found in samples, while the amount of reduced CoQ_{10} found in samples frozen during this same time period varied between 61.30% and 64.63%. (ALJ Decision 228-229.)

How long a sample was stored prior to measurement was also found to impact the molarity of reduced CoQ_{10} in the samples. Kaneka's expert testified that the results from tests performed "on a refrigerated sample shortly after sampling" and a second test performed 30 days later "showed an increase from 70.5% reduced [CoQ_{10}] to over 90% reduced [CoQ_{10}] over those 30 days." (ALJ Decision 228.) Moreover, Shenzhou conducted duplicative testing on its own refrigerated samples, finding that a mid-culture sample taken 63 hours into fermentation from its fermentation tanks contained 68% reduced CoQ_{10}. (ALJ Decision 229.) Shenzhou's test results were challenged by Kaneka, which argued to the ALJ that a "single mid-culture sample" cannot be used to show noninfringement. (ALJ Decision 229.) The ALJ rejected

this argument, noting that Kaneka relied upon the same sample point—63 hours, which Kaneka's expert captioned "Late Fermentation"—to show infringement. (ALJ Decision 229.)

4. The Federal Circuit's Opinions in *Dow*, *Teva*, and *Honeywell*

Defendants principally rely on three Federal Circuit opinions in support of their indefiniteness arguments: (1) *Dow Chemical Co. v. Nova Chemicals Corp. (Canada)* ("*Dow*"), 803 F.3d 620 (Fed. Cir. 2015); (2) *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.* ("*Teva*"), 789 F.3d 1335 (Fed. Cir. 2015); and (3) *Honeywell International, Inc. v. International Trade Commission* ("*Honeywell*"), 341 F.3d 1332 (Fed. Cir. 2003). (*See* Defs' Mem. 9-17.) A careful review of these decisions is critical to resolving the parties' definiteness dispute.

In *Dow*, the Federal Circuit found the claim term "slope of strain hardening coefficient" indefinite in light of (1) a lack of guidance in the claims, specification, and prosecution history as to how a person of ordinary skill in the art should calculate this coefficient; and (2) the fact that the patentee's own expert's "chosen method" for calculating this coefficient "was not even an established method but rather one developed for this particular case." *Dow*, 803 F.3d at 634-35. In *Dow*, the patentee's expert testified at trial that "one of ordinary skill in the art would know that the slope of the hardening curve would have to be measured at its **maximal value**." *Id.* at 633 (emphasis added). "[T]hree methods existed to

determine the maximum slope," however, which each provided "a different way of determining the maximum slope." *Id.* Moreover, the patentee's expert "developed yet another method—of his own invention—to calculate the slope of strain hardening." *Id.* The Federal Circuit noted that "[b]ecause the methods do not always produce the same results, the method chosen for calculating the slope of strain hardening could affect whether or not a given product infringes the claims." *Id.* at 634.

In *Dow*, the Federal Circuit compared the facts in the case before it to those in another decision, *Teva*, which had issued just two months earlier. *Dow*, 803 F.3d at 634-35. In *Teva*, the challenged claim limitation recited the term "molecular weight," but three relevant measures for molecular weight were known to exist—namely, peak average molecular weight ("Mp"), number average molecular weight ("Mn"), and weight average molecular weight ("Mw")—where each was calculated in a different manner and each typically had a different value. *Teva*, 789 F.3d at 1338. The Federal Circuit looked to "the patent record—the claims, specification, and prosecution history—to ascertain if they convey to one of skill in the art with reasonable certainty the scope of the invention claimed." *Id.* at 1341. The court found that neither the claims nor the specification contained an explicit definition of molecular weight, and also noted that the prosecution history contained inconsistent statements. *Id.* at 1342-45. The court therefore concluded that the claims were indefinite under *Nautilus*, notwithstanding the patentee's expert's testimony that someone skilled in the art could determine which method was the most appropriate. *Id.* at 1338, 1341, 1344-45.

Finally, in *Honeywell*, the Federal Circuit upheld a finding that the claim term "melting point elevation" ("MPE") was indefinite under the pre-*Nautilus* "insolubly ambiguous" standard, where neither the patent's written description nor the prior art disclosed a particular method for how to prepare a polyethylene terephthalate ("PET") yarn sample. 341 F.3d at 1337, 1340-42. Three unpublished methods of PET yarn sample preparation existed in the literature at the time the patent was filed, and a fourth, unpublished method was advanced by the plaintiff's expert. *Id.* According to the court, "because the sample preparation method is critical to discerning whether a PET yarn has been produced by the claimed process, knowing the proper sample preparation method is necessary to practice the invention." *Id.* at 1340.

5. Analysis

Whether the 70 mole % limitation is indefinite in light of the '340 Patent's silence with respect to sample collection and handling is, like the concentration of reduced CoQ_{10}, difficult to reliably ascertain. Indeed, the answer to this inquiry appears to lie at the intersection of two related, but somewhat conflicting, notions. First, "[a] claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not." *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003). That said, "[t]he test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether

the claim delineates to a skilled artisan the bounds of the invention." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1340-41 (Fed. Cir. 2005). Because a genuine dispute exists as to whether persons of skill in the art in 2001, after reading the claims, specification, and prosecution history of the '340 Patent, would have understood how to properly collect and handle a sample of cultured microorganisms, the Court cannot grant summary judgment on the issue of definiteness in favor of either party, and **DENIES** both Motions with respect to this issue.

The proceedings before the ITC and discovery taken in this action make clear that sample collection and handling are critical to determining whether a given sample accurately reflects the ratio of reduced CoQ_{10} among the entire coenzymes Q_{10} inside the fermentation tank after culturing reduced CoQ_{10}-producing microorganisms on an industrial scale. Thus, here, as in *Honeywell*, "because the sample preparation method is critical to discerning whether [oxidized CoQ_{10}] has been produced by the claimed process, knowing the proper sample preparation method is necessary to practice the invention." 341 F.3d at 1340. The '340 Patent is similar to the patent at issue in *Honeywell* in a second respect: "the claims, the written description, and the prosecution history fail to give [the Court], as the interpreter of the claim term, any guidance as to what one of ordinary skill in the art would interpret the claim to require." *Id.* None of these pieces of intrinsic evidence reveal, however, how a sample should be collected or handled prior to testing the sample using the assaying method described between lines 8 and 43 of column 5 and in Example 1 of the '340 Patent.

Appendix D

According to Kaneka, that the '340 Patent does not describe sample collection and handling methods is not fatal to the 70 mole % limitation, as experts on both sides agree that persons of skill in the art knew, even in 2001, that in order to accurately measure the ratio of reduced CoQ_{10} in a sample the metabolic activity of the cells in that sample would need to be immediately halted, and that several methods of halting such metabolic activity were known to exist. In particular, Kaneka argues that "[w]ith respect to the collection and preservation issue (pre-testing), [D]efendants' expert on invalidity (Dr. Spormann) and Shenzhou's expert on noninfringement (Dr. Lievense) testified that a person of ordinary skill in the art of the '340 [P]atent would know the proper methods of sample collection, preservation and testing." (Kaneka Mem. 10.) Defendants respond by arguing the cited testimony is taken "out of context," and point to additional testimony indicating that one skilled in the art would need to know the "variabilities" within the microorganism and the conditions "that this compound is subject to" in order to take an accurate sample. (*See* Kaneka Opp'n 8-9.) Defendants also argue that "Kaneka's cited testimony does **not** establish that one skilled in the art would know how to stop metabolic activity of the microorganisms 'within a second.'" (Kaneka Opp'n 9.)

Based on the testimony of both parties' experts, the Court finds that a person of ordinary skill in the art in 2001 would have understood the **need to immediately stop** the metabolic activity of the reduced CoQ_{10}-producing microorganisms in order to obtain accurate test results, and also finds that several **methods for stopping** a

microorganism's metabolic activity were known at that time. Defendants' invalidity expert, Dr. Alfred Spormann, testified that in 2001, a person of ordinary skill in the art would have understood, even without reading the '340 Patent, that he or she should "immediately" refrigerate or freeze a sample to obtain the best test results, because "the purpose of the refrigeration or the freezing is to stop metabolic activity." (Decl. Robert M. Bowick in Supp. Defs.' Opp'n ("Bowick Opp'n Decl."), Ex. 3 at 112:17-113:20, ECF No. 608-5.) Similarly, Shenzhou's noninfringement expert, Dr. Jefferson C. Lievense, testified that freezing would be one of several options to "immediate[ly] stop[ ] metabolic activity," and that he "would look for guidance from the literature in selecting candidate methods to do that." (Bowick Opp'n Decl., Ex. 4 at 128:7-13, ECF No. 608-6.) Dr. Lievense further testified that "[i]n the case of freezing, the sample would go directly into a container, which would be placed in liquid nitrogen[,]" and that "if the volume is small enough, the time it takes to do that could be on the order of one second." (Bowick Opp'n Decl., Ex. 4 at 129:8-18.) Moreover, Dr. Lievense testified that other methods of immediately stopping metabolic activity would include "immediately add[ing] acid" or "add[ing] some sort of solvent or solvent mixture." (*Id.*) Finally, Kaneka's expert, Dr. David H. Sherman, testified that, in his own research, he either freezes or adds solvents to "essentially immediately" kill all the cells that have been fermented. (Bowick Opp'n Decl., Ex. 5 at 20:5-8, 23:10-15, ECF No. 608-7.)

In light of the above-cited expert testimony, the Court finds there to be no dispute that persons of skill in the art

in 2001 both (1) understood the importance of immediately stopping a microorganism's metabolic activity in order to obtain an accurate sample; and (2) knew that several methods—including freezing, refrigeration, and adding acid or solvents—existed to quickly stop a microorganism's metabolic activity. What is genuinely disputed, however, is whether persons of skill in the art, after reading the claims, specification, and prosecution history of the '340 Patent, would have known, with reasonable certainty, **which** of these methods could be used to collect and store samples in order to practice this limitation. Similarly, there is a genuine dispute regarding the **duration** samples can be stored prior to testing using the assaying method described in the specification of the '340 Patent.

Takeda Pharmaceutical Co. v. Zydus Pharmaceutical USA, Inc., a decision from the Federal Circuit decided prior to *Nautilus*, is instructive. In *Takeda*, the defendant argued the asserted Patent was indefinite because it did not specify the method of measurement that should be used to determine average particle diameter, which the claims required to be less than or equal to 400 micrometers. 743 F.3d 1359, 1366 (Fed. Cir. 2014). The defendant insisted several methods existed that could potentially be used to take that measurement, and that the sample could either be infringing or non-infringing depending on the measurement technique used. *Id.* Thus, according to the defendant, "the skilled artisan has no way to determine whether his or her product infringes the [ ] patent based on the information provided in the specification." *Id.*

The Federal Circuit disagreed, noting that although "evidence from both parties' experts [showed] there

are several possible ways to measure average particle diameter" and although the "experts agreed that different measurement techniques could indeed produce different results," the claims were not indefinite, both because "the evidence established that **both** methods of measurement accurately report average particle diameter" and because "there is no evidence that the differences between these techniques are in fact significant[.]" *Id.* at 1366-67 (emphasis in original). "[I]ndeed, there was no evidence in this case that different measurement techniques in fact produced significantly different results for the same sample." *Id.* at 1367. "Any theoretical minor differences between the two techniques are therefore insufficient to render the patent invalid." *Id.* (citing *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1563 (Fed. Cir. 1996), which found no indefiniteness despite failure to specify which method should be used to measure ultraviolet transmittance because all conventional methods produced "essentially identical results").

The court in *Takeda* distinguished *Honeywell*, on which Defendants rely, noting that in that case, "[b]ecause the specification did not discuss which sample preparation method should be used, and the particular method chosen was 'critical to discerning whether [an infringing yarn] has been produced by the claimed process,' we affirmed the Commission's conclusion that the claims were indefinite." *Id.* at 1367 n. 4 (quoting *Honeywell*, 341 F.3d at 1340). "Here, by contrast, no extensive manipulation of the samples is required prior to measurement, and, as discussed above, [the defendant] did not present clear and convincing evidence that the method of measurement

is in fact outcome-determinative in the infringement analysis." *Id.*

The same distinction can be drawn in this case. Although Defendants have presented evidence obtained during the ITC Proceedings showing that refrigerating or freezing samples for different durations can lead to different mole % measurements and ratios, it is far from clear whether these differences are "outcome-determinative" when samples are refrigerated or frozen "immediately" and stored for an appropriate period of time, as determined by a person of ordinary skill in the art. It is for the trier of fact to determine what sample collection and handling methods a person of skill in the art would have understood to be appropriate given the claims, specification, and prosecution history of the '340 Patent. Neither party has demonstrated that there are no genuine disputes as to this issue.

In light of the above, the Court finds *Teva* and *Dow* to be distinguishable. In *Teva*, the claims required that a copolymer have a specific molecular weight "of about 5 to 9 kiladaltons," which could be calculated using one of three known measurement methods. 789 F.3d at 1338. Unlike the '340 Patent, none of these measurement methods were disclosed in the *Teva* patent, and thus a person of ordinary skill in the art would not have known which method to use in order to arrive at the claimed molecular weight. *Id.* at 1341, 1344-45. This was critical, because each of the three known measurement methods yielded different results. *Id.* at 1338. As noted above, however, Defendants have not shown that different sample collection and handling

methods understood by persons of skill in the art to be appropriate would yield different mole % ratios. *Teva* is therefore inapposite.

In *Dow*, which was an appeal from a bench trial, the asserted claims required a "slope of strain hardening coefficient greater or equal to 1.3," which could be calculated using one of four measurement methods. 803 F.3d at 622, 624-27. The *Dow* patents, unlike the '340 Patent, failed to disclose any of these measurement methods, and the Federal Circuit noted that "[t]here is no question that each of these four methods may produce different results." *Id.* at 633. Indeed, the Federal Circuit noted that "[b]ecause the methods do not always produce the same results, the method chosen for calculating the slope of strain hardening could affect whether or not a given product infringes the claims." *Id.* at 634. Because the *Dow* patents failed to disclose which method of measurement should be used, the Federal Circuit held that a person of ordinary skill in the art would not know which method to use in order to arrive at the claimed coefficient. *Id.* at 635. Here again, by contrast, Defendants have not shown that different sample collection and handling methods understood by persons of skill in the art to be appropriate would yield different mole % ratios, and *Dow* is therefore distinguishable.

The Court also rejects Defendants' argument that the 70 mole % limitation must be indefinite because (1) Kaneka's own expert, Dr. Sherman, found that the testing of the mole % ratio by a co-inventor of the '340 Patent was not reliable in light of a lack of description regarding

how the samples were handled between harvesting and testing; or (2) Kaneka failed to follow its own "mobile laboratory" protocol upon remand from the Federal Circuit. (*Cf.* Defs.' Mem. 10-14.) First, that a particular test conducted by one of the '340 Patent's co-inventors either was unsuccessful or used unclear or improper methods does not demonstrate that persons of skill in the art were unaware of how to properly collect and handle cell samples, and Defendants cite no authority indicating otherwise. Second, the fact that a party has developed a particular protocol for proving whether a defendant has committed infringement does not, by itself, indicate that persons of skill in the art were previously incapable of understanding how to accurately test a sample. Such an inference is particularly difficult to draw where, as here, it appears that the need to create such a "mobile laboratory" arose because of the remoteness of XKGC and Shenzhou's facilities and because these defendants did not permit Kaneka to test samples at their facilities. To the extent Defendants challenge the accuracy and reliability of the "mobile laboratory" method itself, such an argument concerns infringement, rather than indefiniteness. (*Cf.* Defs.' Mem. 13-14.)

The Court also finds occasion to recite the bedrock principle of patent law that a claim is not indefinite merely because it is difficult to determine whether one's own product infringes, for this difficulty may lie in the inadequacy of testing procedures rather than imprecision in the claim language. *See Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1346 (Fed. Cir. 2010) ("The difficulty or complexity of the infringement analysis

does not necessarily speak to whether a claim is definite or not."); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1340-41 (Fed. Cir. 2005) ("The test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention."). For example, in *Invitrogen Corp. v. Biocrest Manufacturing, L.P.*, the Federal Circuit affirmed the district court's summary judgment finding that a claim reciting the term "improved competence" was not indefinite, rejecting the accused infringer's argument that because testing was required to know whether a product infringed, the claim should be considered to be indefinite. 424 F.3d 1374, 1384 (Fed. Cir. 2005). The Federal Circuit wrote:

> Stratagene further argues that it would have had to practice the claimed process in order to determine if it was infringing, even though "[t]he primary purpose of the definiteness requirement is to ensure that the claims are written in such a way . . . that interested members of the public . . . can determine whether or not they infringe." *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1340 (Fed. Cir. 2003). Indeed, the lower court had to have separate side-by-side tests done to determine whether Stratagene infringed, and other testimony indicates that tests were necessary to determine infringement. However, Oakley goes on to explain that "a

> patentee **need not define his invention with mathematical precision** in order to comply with the definiteness requirement." *Id.* at 1341. Stratagene is really talking about the **difficulty of avoiding infringement, not indefiniteness** of the claim. "The test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1341 (Fed. Cir. 2005). This court's and the district court's constructions of the claim showed that it contained no material ambiguities, and therefore was not invalid for indefiniteness. *See All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 780 (Fed. Cir. 2002).

Invitrogen, 424 F.3d at 1384 (emphasis added). Thus, to the extent the parties' definiteness arguments turn on the tests performed on samples taken from Manufacturing Defendants' fermentation tanks, the Court cautions that methods used to determine whether Manufacturing Defendants' processes practice the 70 mole % limitation are not necessarily indicative of whether a person of skill in the art in 2001 would have understood the scope of this limitation.

For the foregoing reasons, the Court **DENIES** both Kaneka's and Defendants' Motions for Summary

Judgment on the issue of whether the asserted claims are indefinite under Section 112 ¶ 2.

B. Whether the Asserted Claims Are Patent-Eligible Under Section 101

Defendants next contend that the asserted claims are invalid under Section 101 for claiming a natural phenomenon combined with conventional steps. (Defs.' Mem. 17-24.) In particular, Defendants argue that because microorganisms are able to produce microbial cells containing "not less than 70 mole %" reduced CoQ_{10} and because the 70 mole % limitation is merely identified, the asserted claims are directed to a patent-ineligible natural phenomenon very similar to that at issue in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (*See* Defs.' Mem. 17-18.)

Kaneka responds that the asserted claims are patent-eligible because the inventors did not stop at identifying certain microorganisms with the ability to produce reduced CoQ_{10} at ratios greater than 70 mole % under specific culturing conditions, but instead used this knowledge to create a new and useful method of producing oxidized CoQ_{10} on an industrial scale. (*See* Kaneka Mem. 12-20.) Kaneka points out that PTO examiners noted that a process of culturing microorganisms to produce greater than 70 mole % reduced CoQ_{10} and then actively oxidizing the resulting culture was neither routine nor conventional, and that the patented process yields the specific benefit of creating oxidized CoQ_{10} with greater purity without (Z)-isomers and (all-E) isomers. (Kaneka Mem. 19-20.)

For the reasons that follow, the Court agrees with Kaneka that the asserted claims are patent-eligible under 35 U.S.C. Section 101. The Court therefore **GRANTS** Kaneka's Motion for Summary Judgment on this issue, and **DENIES** Defendants' Motion.

1. Step 1: Whether the Claims Are "Directed to" a Natural Phenomenon

"We begin with step one: whether the claims here are 'directed to' a patent-ineligible concept." *CellzDirect*, 827 F.3d at 1047. The Court concludes that they are not.

The asserted claims recite a "**process for producing** on an **industrial scale** the **oxidized** coenzyme Q_{10}." ('340 Patent col. 25, ll. 32-33; col. 26, ll. 13-14 [emphasis added].) The claimed processes require an artisan to carry out several steps to achieve the desired production, including (1) culturing reduced CoQ_{10}-producing microorganisms in a specific culture medium; (2) optionally disrupting the microorganisms; (3) actively oxidizing the reduced CoQ_{10}; and (4) extracting the CoQ_{10} with an organic solvent in a sealed tank. The end result of this process, according to the '340 Patent, is oxidized CoQ_{10} of a high purity produced "safely and efficiently on the industrial scale." ('340 Patent col. 3, ll. 33-35; col. 4, ll. 28-36.) Thus, according to the '340 Patent, the claimed process "achieved a notable advance over prior art techniques" for creating high-purity oxidized CoQ_{10} on an industrial scale. *CellzDirect*, 827 F.3d at 1047.

Notwithstanding that the plain claim language refers to producing oxidized CoQ_{10} on an industrial scale,

Defendants contend that the asserted claims are "directed to" the natural phenomenon that certain microorganisms have the natural ability to produce at least 70 mole % reduced CoQ_{10} under standardized culturing conditions. (*See* Defs.' Mem. 18 [citing '340 Patent col. 4, ll. 61-65].) According to Defendants, because the 70 mole % limitation discussed at length in Section III(A), *supra*, is "merely identified," the asserted claims are directed to the natural ability of these microorganisms to produce at least 70 mole % reduced CoQ_{10}. (Defs.' Mem. 18-20.)

The parties correctly note that *CellzDirect* is particularly instructive. In *CellzDirect*, the Federal Circuit found claims reciting a "method of producing a desired preparation of multi-cryopreserved hepatocytes," coupled with several concrete steps,[3] to be patent-eligible because the claims were not "directed to" the natural phenomenon that hepatocytes are capable of surviving multiple freeze-thaw cycles. 827 F.3d at 1047-50. The Federal Circuit distinguished these claims from those found to be patent-ineligible in *Mayo, Association for Molecular Pathology v. Myriad Genetics, Inc.* ("*Myriad*"), 569 U.S. 576, 133 S. Ct. 2107, 186 L. Ed. 2d 124 (2013), *Genetic Technologies, Ltd. v. Merial L.L.C.* ("*Genetic Technologies*"), 818 F.3d 1369 (Fed. Cir. 2016), *Ariosa*

3. These steps include (1) "performing density gradient fractionation on a set of previously frozen and thawed cells to separate out the viable ones;" (2) "recovering the separated viable cells;" and (3) "cryopreserving the recovered cells." 827 F.3d at 1047. A dependent claim required "the additional step of pooling hepatocytes from multiple donors," which was unconventional. *Id.* at 1049.

Diagnostics, Inc. v. Sequenom, Inc. ("*Ariosa*"), 788 F.3d 1371 (Fed. Cir. 2015), and *In re BRCA1-& BRCA2-Based Hereditary Cancer Test Patent Litigation* ("*In re BRCA*"), 774 F.3d 755 (Fed. Cir. 2014) because "the end result of the [asserted] claims is **not simply an observation or detection of the ability** of hepatocytes to survive multiple freeze-thaw cycles," but were instead "directed to a **new and useful method of preserving** hepatocyte cells." *Id.* at 1048 (emphasis added). According to the court:

> Through the recited steps, the patented invention achieves a better way of preserving hepatocytes. The '929 patent claims are like thousands of others that recite processes to achieve a desired outcome, e.g., methods of producing things, or methods of treating disease. That one way of describing the process is to describe the natural ability of the subject matter to **undergo** the process does not make the claim "directed to" that natural ability. If that were so, we would find patent-ineligible methods of, say, producing a new compound (as directed to the individual components' ability to combine to form the new compound), treating cancer with chemotherapy (as directed to cancer cells' inability to survive chemotherapy), or treating headaches with aspirin (as directed to the human body's natural response to aspirin).

Id. at 1048-49 (emphasis in original). The Federal Circuit went on to distinguish the claims before it from those at

issue in *Funk Brothers. Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 68 S. Ct. 440, 92 L. Ed. 588, 1948 Dec. Comm'r Pat. 671 (1948), by noting that "*Funk Bros.* involved product claims, and the court explicitly noted that it was not 'presented [with] the question whether the methods of selecting and testing the non-inhibitive strains are patentable." *Id.* at 1049 (citing *Funk Bros.*, 333 U.S. at 130). Thus, "[h]ere, regardless of whether the individual hepatocytes in the pool of multi-cryopreserved hepatocytes have the same effect they always had or perform in their natural way, the claims are directed to a new and useful process of creating that pool, not to the pool itself ." *Id.*

The Federal Circuit distinguished the claims before it from those at issue in *Myriad* and *Ariosa* on similar grounds. First, in *Myriad*, the Supreme Court stated that

> It is important to note what is **not** implicated by this decision. First, there are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could have possibly sought a method patent. But the processes used by Myriad to isolate DNA were well understood . . . and are not at issue in this case.

569 U.S. 576, 133 S. Ct. 2107, 2119-20, 186 L. Ed. 2d 124 (2013) (emphasis in original). In *CellzDirect*, however, "the inventors developed an innovative method of manipulating hepatocytes, a particular kind of liver cell which, prior to this invention, had been very difficult to preserve for

future use." 827 F.3d at 1049. Second, "[a]lthough the claims in *Ariosa* were also written as process claims, the court concluded that they were 'directed to' the patent-ineligible cffDNA itself." 788 F.3d at 1376.

Defendants pay mere lip service to these principles. Here, as in *CellzDirect*, the claims are "directed to" a superior method of producing a certain end product—in this case, efficiently creating oxidized CoQ_{10} on an industrial scale—rather than to the inherent properties of certain biological materials. That the asserted claims rely on the ability of certain microorganisms to produce reduced CoQ_{10} at a ratio greater than 70 mole % among the entire coenzymes Q_{10} under standard culturing conditions does not indicate the claims are "directed to" this phenomenon. "Rather, the claims of the '[340] patent are directed to a new and useful [industrial process] for [manufacturing oxidized CoQ_{10}]." *CellzDirect*, 827 F.3d at 1048. Indeed, Kaneka has identified language in the specification of the '340 Patent indicating the claimed invention provides several advances over prior art techniques for creating oxidized CoQ_{10} on an industrial scale:

> According to the processes of the present invention, reduced coenzyme Q_{10} can be produced cheaply on the **industrial scale** by considerably simple steps comprising culturing microorganisms and recovering reduced coenzyme Q_{10}. In addition, oxidized coenzyme Q_{10} can also be **produced by simple processes.** Moreover, these coenzymes Q_{10} produced by

> microorganisms **basically do not contain (Z)-isomers** thereof, and (all-E) isomers thereof can be obtained, which are same as those contained in meat, fish, etc.

('340 Patent col. 4, ll. 28-36 [emphasis added].)

In light of the above, the asserted claims are readily distinguishable from those at issue in *Genetic Technologies, Ariosa*, and *In re BRCA*. The claims in the first two cases recited methods for detecting coding regions of DNA and cffDNA, respectively, based on these regions' relationships to non-coding regions. *Genetic Techs.*, 818 F.3d at 1369, 1373-74; *Ariosa*, 788 F.3d at 1373-74, *cert. denied*, 136 S. Ct. 2511, 195 L. Ed. 2d 841 (2016). The existence and location of DNA or cffDNA is a natural phenomenon, and identifying the presence of certain regions based on the location of non-coding regions is tantamount to claiming the natural phenomenon itself. *See Ariosa*, 788 F.3d at 1376 (holding that, because the method "starts with cffDNA taken from a sample of maternal plasma or serum—a naturally occurring non-cellular DNA that circulates freely in the blood stream of a pregnant woman" and "ends with paternally inherited cffDNA, which is also a natural phenomenon [the] method therefore begins and ends with a natural phenomenon" and "the claims are directed to matter that is naturally occurring"). Here, by contrast, the claims call for culturing certain microorganisms on an industrial level in order to obtain reduced CoQ_{10} above a certain ratio, disrupting the microbial cells, and then oxidizing the reduced CoQ_{10} and extracting the resulting oxidized CoQ_{10} in a sealed tank. (*See generally* '340 Patent.) The cases are not analogous.

In re BRCA is similarly inapposite. In that case, the claims recited methods for screening human germline for an altered BRCA1 gene by comparing the target DNA sequence with a wild-type sequence. 774 F.3d at 761-62. Comparing two sequences in order to detect alterations, however, is a patent-ineligible "abstract mental process." *Id.* at 763. Thus, although the claims in this case also employed method steps, the end result of the process was a patent-ineligible concept.

Defendants decry the lack of a yield requirement in the oxidation step, arguing that without such a limitation, the oxidizing, extracting, and optional disrupting steps "simply are not required to actually make a particular amount of oxidized CoQ_{10} from the starting ratio of reduced CoQ_{10}." (Kaneka Opp'n 16.) Defendants further argue that "[t]he combination of steps cannot help given the Federal Circuit's construction" because "[s]ince the 70 mole % reduced ratio need not be maintained and the yield of oxidized [CoQ_{10}] is not limited, the mole % reduced can be either above or below 70 mole % before or after extraction and before or after oxidation." (Kaneka Opp'n 17.) Defendants cite no facts or legal authority in support of either argument. Moreover, the intrinsic record suggests there are benefits associated with using reduced CoQ_{10} created by microorganisms at a ratio of at least 70% to form oxidized CoQ_{10} on an industrial scale, including the elimination of certain problematic isomers and a higher yield of oxidized CoQ_{10} in a simple, safe, and cost-effective manner. (*See* '340 Patent col. 2, ll. 28-37; col. 3., ll. 33-46; col. 4, ll. 28-36.)

For the foregoing reasons, the Court concludes that the asserted claims are not "directed to" the natural phenomenon that certain microorganisms have the natural ability to produce at least 70 mole % reduced CoQ_{10} under standardized culturing conditions, and **GRANTS** Kaneka's Motion for Summary Judgment on this issue.

2. Step 2: Whether the Asserted Claims Contain an "Inventive Concept"

Even if the Court were to conclude that the asserted claims are "directed to" the natural phenomenon that certain microorganisms have the natural ability to produce at least 70 mole % reduced CoQ_{10} under standardized culturing conditions, it would nevertheless conclude that the remaining elements, viewed in isolation and in combination with the other non-patent-ineligible elements, are sufficient to "'transform the nature of the claim into a patent-eligible application." *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 132 S. Ct. at 1297). Step two of the Section 101 inquiry requires searching for an "inventive concept to take the claim into the realm of patent-eligibility." *In re BRCA*, 774 F.3d at 764 (citing *Alice*, 134 S. Ct. at 2355).

Such an "inventive concept" is present here. As a starting point, as discussed above, the asserted claims require much more than identifying microorganisms capable of culturing reduced CoQ_{10} at a ratio of at least 70 mole % in a particular medium. In addition to this step, an artisan must actively oxidize the reduced CoQ_{10} to oxidized CoQ_{10} and extract the oxidized CoQ_{10} using an organic solvent in a sealed tank, and may optionally

disrupt the microbial cells to obtain the reduced CoQ_{10}. (*See generally* '340 Patent.) Although each of these steps might have been known to skilled artisans, Kaneka points to evidence indicating a process of culturing microorganisms to produce greater than 70 mole % reduced CoQ_{10} and then actively oxidizing the CoQ_{10} was far from "routine" or "conventional." Indeed, the PTO clarified during reexamination of the claims of the '340 Patent that:

> While the culturing conditions and steps for isolating coenzyme Q_{10} from microbial culture may have been conventional and well-known in the art, the **choice of specific microorganisms** having the claimed properties of reduced coenzyme Q_{10} **was not**. Particularly, as the claims as a whole are drawn to include steps for the production of oxidized coenzyme Q_{10} as a final product, there was **no motivation to choose** for the initial steps in the culturing processes microorganisms that naturally contain "reduced coenzyme Q_{10} at a ratio of not less than 70 mole % among the entire coenzyme Q_{10}."

(Bowick Opp'n Decl., Ex. 9 [emphasis added].) Thus, according to the examiner, it took some inventiveness on the part of the applicants to use reduced CoQ_{10} at a ratio of at least 70 mole % as a starting product for the industrial production of oxidized CoQ_{10}. Defendants have not pointed to any evidence indicating that creating oxidized CoQ_{10} on an industrial scale by starting with reduced CoQ_{10} of a certain ratio was not "inventive."

Thus, even if the asserted claims were "directed to" the natural phenomenon that certain microorganisms have the natural ability to produce at least 70 mole % reduced CoQ_{10} under standardized culturing conditions, the Court would nevertheless conclude that the claims contain an inventive concept that brings the claims into the realm of patent-eligibility. *Alice*, 134 S. Ct. at 2355.

C. Whether a Genuine Dispute Exists Regarding Anticipation by *Folkers* and the *Pre-2002 Process*

1. The Parties' Arguments

Kaneka next seeks summary judgment that the asserted claims are not anticipated under 35 U.S.C. Section 102. According to Kaneka, although Defendants asserted Kaneka's *Pre-2002 Process* as the sole anticipatory reference in their Final Amended Invalidity Contentions, they nevertheless added a **second** anticipatory reference—U.S. Patent No. 3,066,080 to Folkers et al. ("*Folkers*")—in the expert report and testimony of Dr. Spormann. (*See* Kaneka Mem. 3.) Kaneka first argues that any reliance on *Folkers* as an anticipatory reference is improper. (*See* Kaneka Mem. 3.) Notwithstanding whether *Folkers* is a proper reference, Kaneka further contends that Dr. Spormann has admitted that neither reference contains an "active oxidation step." (Kaneka Mem. 4-7.)

Defendants respond by arguing that they, through the opinions of Dr. Spormann and through other materials, have provided *prima facie* evidence that both *Folkers*

and the *Pre-2002 Process* satisfy the "active" oxidation limitation as construed by the Federal Circuit. (Kaneka Opp'n 2.)

2. Analysis

"Whether a patent is anticipated under section 102(b) is a question of fact." *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315 (Fed. Cir. 2002) (citing *Apple Computer, Inc. v. Articulate Sys., Inc.*, 234 F.3d 14, 20 (Fed. Cir. 2000)). "On summary judgment, all justifiable inferences are made in favor of the nonmovant, here [Defendants]." *Id.* (citing *Liberty Lobby*, 477 U.S. at 255).

Each of the asserted claims requires "oxidizing" reduced CoQ_{10} "to oxidized coenzyme Q_{10}," although the claims differ with respect to whether such oxidation begins before or after the "extraction" step. (*See generally* '340 Patent.) In its Opinion, the Federal Circuit concluded that although "oxidation requires an active step," it "does not require the use of an oxidizing agent." (Opinion 1305-06.) The Federal Circuit also required that "at least some action resulting in oxidation must be applied to the disruption step in claim 22, and the product of the extraction step in claim 33." (Opinion 1306.) In addition, the Federal Circuit "disagree[d] that the claimed order excludes passive oxidation during other process steps" and further "disagree[d] . . . that the claimed order requires that each step occur independently or separately." (*Id.*) The Federal Circuit summarized its construction as follows:

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> [T]he oxidation step requires some action that results in oxidation but does not require oxidation of "all or substantially all" of the coenzyme Q_{10}. Because the oxidation step indicates that oxidation is carried out on the product from the previous disruption step in claim 22, some action resulting in oxidation must occur after some product from the disruption step forms and before the extraction step in claim 22 begins. Similarly, some action resulting in oxidation must occur after at least some reduced coenzyme Q_{10} has been extracted in claim 33. Because the claims read on a continuous process, a process step does not need to be complete before another step begins. Thus, it is not required that any one step be carried out separately or independently of any other step.

(Opinion 1307.)

According to Kaneka's Final Infringement Contentions, two actions on the part of Defendants constitute the "active step" required for oxidation. First, there is "washing" and "drying" the biomass of reduced CoQ_{10}. (*See* Kaneka's FICs for Shenzhou at 21-22, ECF No. 518-1; Kaneka's FICs for XKGC at 20-22, ECF No. 518-2.) Second, there is "air drying." (Kaneka's FICs for Shenzhou at 24-26; Kaneka's FICs for XKGC at 22-26.) Defendants nevertheless contend that Kaneka has identified a third alleged "active" oxidation step—acid-heat treatment—although the Court cannot find support

for this argument. (*See* Kaneka Opp'n 2-3.) Defendants and their expert, Dr. Spormann, "dispute that any of these three steps satisfies the 'active' oxidation limitation of the '340 Patent," but argue that "to the extent Kaneka's contentions are adopted, *Folkers* and [the *Pre-2002 Process*] meet the 'active' oxidation limitation of Claims 22 and 33 of the '340 Patent." (Kaneka Opp'n 3.)

As a threshold matter, the Court agrees with Kaneka that Defendants should be precluded from relying on *Folkers* as an anticipatory reference, as this reference was not properly included in Defendants' Final Invalidity Contentions. Kaneka submits that "Defendants' Final Amended Invalidity Contentions (10-03-2016) only asserted Kaneka's pre-2002 Process as an anticipatory reference under 35 U.S.C. § 102[,]" providing a copy of these contentions as evidence. (*See* Pl. Kaneka Corp.'s Statement of Uncontroverted Facts and Conclusions of Law in Supp. Kaneka Mem. ("Kaneka's Facts") ¶ 10, ECF No. 556-2.) In response, Defendants do not dispute that *Folkers* was not included as an anticipatory reference in their Final Amended Invalidity Contentions, but instead submit that they stated in these contentions that they "will revise their contentions concerning the invalidity of the claims of the Asserted Patent as appropriate depending upon . . . positions that Kaneka or its expert witness(es) may take concerning claim interpretation, infringement, and/or invalidity issues." (Defs.' Response ¶ 10.) The Court made clear in its September 13, 2016 Order Granting in Part and Denying in Part Plaintiff Kaneka Corporation's Motion for Leave to Amend Its Final Infringement Contentions that it would hold both sides to the theories

provided in their final infringement and invalidity contentions. (*See* Order Granting in Part & Den. in Part Kaneka's Mot. For Leave to Amend Its FICs, ECF No. 513.) Defendants have not demonstrated "good cause" for belatedly shoehorning *Folkers* into Dr. Spormann's expert report. As such, the Court **GRANTS IN PART** Kaneka's Motion and **PRECLUDES** Defendants from arguing that *Folkers* anticipates any of the asserted claims under 35 U.S.C. Section 102. *See MyMedicalRecords, Inc. v. Walgreen Co.*, No. 2:13-cv-00631-ODW(SHx), 2013 U.S. Dist. LEXIS 179945, 2013 WL 6834639 (C.D. Cal. Dec. 23, 2013) (striking supplemental invalidity contentions that were both untimely and improperly amended without a court order and denying leave to amend for lack of good cause).

Turning to the second anticipatory reference, the Court has reviewed Dr. Spormann's expert report on invalidity ("Spormann Invalidity Report") and his December 2, 2016 deposition transcript, and finds there to be a genuine dispute as to whether Kaneka's *Pre-2002 Process* disclose an "active oxidation" step. Because the determination whether a particular process meets the "active oxidation" limitation is a question of fact, the Court **DENIES** Kaneka's Motion for Summary Judgment on the issue of whether the *Pre-2002 Process* anticipates any of the asserted claims.

First, the portions of Dr. Spormann's deposition testimony Kaneka cites in its moving papers do little more than reveal the tension between Dr. Spormann's views regarding whether the three types of "active" oxidation

(apparently) advanced by Kaneka meet the Federal Circuit's construction of the oxidizing limitation and his interpretation of Kaneka's three infringement theories. In the Spormann Invalidity Report, Dr. Spormann opines that, "applying the logic of Kaneka's tutorial and infringement contentions," (1) Kaneka's [redacted] used in the *Pre-2002 Process* meets the oxidizing limitation found in claim 22; and (2) Kaneka's [redacted] used in the *Pre-2002 Process* meets the oxidizing limitation found in claim 33. (*See* Decl. Lei Mei in Supp. Kaneka Opp'n ("Mei Opp'n Decl."), Ex. B at #x00B6;¶ 123-24, ECF No. 600-3..) Making all justifiable inferences in Defendants' favor, as the Court must when ruling on a motion for summary judgment, the Court finds there to be a genuine dispute as to whether the *Pre-2002 Process* anticipates the asserted claims.[4]

The Court finds a second basis for denying Kaneka summary judgment on the basis of anticipation: the possibility that because the *Pre-2002 Process* calls for the [redacted], it anticipates claim 33. Kaneka argues that because Dr. Spormann admitted during his deposition that the [redacted] in Kaneka's *Pre-2002 Process* occurred [redacted] the addition of this compound cannot meet the "active

4. Kaneka argues in its reply that Dr. Spormann "cannot raise an issue of fact simply by submitting an expert declaration contradicting his sworn testimony." (Kaneka Reply 3, ECF No. 610.) The Court, however, reaches its conclusion without relying on Dr. Spormann's declaration.

oxidation" limitation. (Kaneka Mem. 7.) Defendants point to evidence indicating that during the "first extraction" as part of Kaneka's *Pre-2002 Process*, Kaneka [redacted] (*See* Mei Opp'n Decl., Ex. F at KAN790ITC003770974.) In light of this evidence, the Court cannot say whether some amount of "extraction" occurs prior to the [redacted] such that the addition of this compound meets the "oxidizing" limitation. (*See* Order 13 [holding that "some action resulting in oxidation must occur after at least some reduced coenzyme Q_{10} has been extracted in claim 33"].) The Court must therefore **DENY** Defendants' Motion for Summary Judgment on this issue.

D. Whether Manufacturing Defendants' Processes Infringe the Asserted Claims

The final issue the Court must determine is whether a genuine dispute exists as to whether Manufacturing Defendants' processes infringe one or more of the asserted claims. Defendants raise the following four noninfringement arguments. First, they argue that XKGC does not culture "reduced coenzyme Q_{10}-producing microorganisms," but instead cultures photosynthetic bacteria. (Defs.' Mem. 25-29.) Second, they contend that Kaneka has no evidence that XKGC's processes meet the 70 mole % limitation, either literally or under the doctrine of equivalents. (Defs.' Mem. 29-31.) Third, they argue that XKGC does not use a "sealed tank," and that Kaneka essentially conceded that it would be impossible

to have a "sealed tank" in an industrial scale process as the term was construed by the Federal Circuit. (Defs.' Mem. 31-34.) Finally, Defendants submit the processes do not infringe claim 22, at the very least, because neither process performs an "oxidizing" step. (Defs.' Mem. 34-35.)

Kaneka responds to each of these arguments as follows. First, Kaneka argues that Defendants should be judicially estopped from attempting to narrow the construction of the culturing step, and further argues that Judge Pfaelzer previously rejected Defendants' effort to import an "end of fermentation" limitation into the "culturing" step. (*See* Mem. of Ps & As in Opp'n Defs.' Mot. ("Defs.' Opp'n") 19-24, ECF No. 608.) Kaneka also argues that the term "microorganisms" includes photosynthetic bacteria. (Defs.' Opp'n 24-31.) Kaneka next points to evidence indicating XKGC's old and new manufacturing processes practice the 70 mole % limitation. (Defs.' Opp'n 31-34.) Finally, Kaneka argues that because Defendants have pointed to no "evidence" that XKGC does not extract in "sealed tanks," Kaneka's affirmative evidence is sufficient to defeat summary judgment on this issue, both with respect to literal infringement and infringement under the DOE. (Defs.' Opp'n 34-38.)

1. Issues Related to the "Culturing" Step

Defendants begin their noninfringement arguments by raising several issues concerning the "culturing" step recited in each of the asserted claims. The Court addresses each of these arguments in turn.

Appendix D

a. Whether the "Culturing" Step Requires "Pre-Screening" Testing

First, Defendants argue Kaneka has "no proof" that XKGC cultures "reduced coenzyme Q_{10}-producing microorganisms" because Kaneka never cultured their bacteria pursuant to the assay described between column 4, line 51 and column 5, line 43 of the '340 Patent. (Defs.' Mem. 25.) Defendants contend that, as a corollary to the above, since there is a separate requirement that the microbial cells contain at least 70 mole % reduced CoQ_{10}, limiting the scope of this phrase "is needed to eliminate redundancy and give meaning to the phrase." (Defs.' Mem. 25.) Defendants then point out that they do not use any of the 63 strains of bacteria listed in Tables 1-3 of the '340 Patent. (Defs.' Mem. 26.) Finally, Defendants note that Kaneka's own testing of certain strains of bacteria demonstrates these bacteria produced microbial cells with less than 70 mole % reduced CoQ_{10} when cultured and measured pursuant to the assay described in the '340 Patent, and that Shenzhou's own tests of its strain of one of these bacteria yielded the same result. (Defs.' Mem. 26-27.)

Kaneka does not dispute that it never cultured Defendants' photosynthetic bacteria pursuant to the assay described between column 4, line 51 and column 5, line 43 of the '340 Patent. (*See* Kaneka's Response to Defs.' Statement of Uncontroverted Facts and Conclusions of Law ("Kaneka Resp.") ¶ 47, ECF No. 608-1.) Instead, Kaneka argues that the claims do not require Defendants to evaluate their bacteria according to this test-tube

assay in order to practice the "culturing" step. Moreover, Kaneka notes that until the deadline for disclosure of Defendants' expert reports on noninfringement, they had never advocated limiting this claim element to the laboratory-scale culturing experiment described between column 4, line 51 and column 5, line 43 of the '340 Patent. (*See* Defs.' Opp'n 20.)

The Court agrees with Kaneka that taking this laboratory-scale measurement is not required under the Court's construction of the "culturing" step, and further agrees that Defendants are judicially estopped from advancing such an argument. The Court has reviewed Defendants' *Markman* briefs, and notes that Defendants themselves argued to Judge Pfaelzer that "the relevant sampling point to determine whether the 70% limitation is met is at the end of fermentation," which is "consistent with a natural reading of each independent claim, which requires **culturing** microorganisms **to obtain** microbial cells containing 70 mole % reduced coenzyme Q_{10}." (Defs.' Responsive Claim Construction Br. 22 [emphasis in original], ECF No. 146.) Judge Pfaelzer adopted Defendants' proposed construction, requiring that the assay described at column 5 between lines 8 and 43, rather than the one described between column 4, line 51 and column 5, line 43, be used to determine the ratio of reduced CoQ_{10}. (*See* Claim Construction Order 10-13.) Under the Court's construction of the term "culturing reduced coenzyme Q_{10}-producing microorganisms . . . at a ratio of not less than 70 mole % among the entire coenzymes Q_{10}," a manufacturer practices this limitation if, "at a time prior to the extraction, oxidation, or disruption steps,"

one performs the assay described at column 5 between lines 8 and 43 and in Example 1 of the '340 Patent, and the results show the microbial cells contain reduced CoQ_{10} at a ratio of not less than 70 mole % among the entire coenzymes CoQ_{10}. The manufacturers are not required to use one of the microorganisms listed in Tables 1 through 3 of the '340 Patent. Nor are they required to perform the laboratory-scale assay described between column 4, line 51 and column 5, line 43 of the '340 Patent. The Court **DENIES** Defendants' Motion to the extent it centers on these arguments.

b. Whether the Term "Microorganisms" Is Limited to "Non-Photosynthetic Bacteria or Yeast"

Defendants next argue that because Kaneka explicitly disclaimed the use of photosynthetic bacteria during prosecution of the application leading to a parent of the '340 Patent—Application No. 10/500,249 (the "'249 Application")—and because it is undisputed that XKGC uses the photosynthetic bacterium *Rhodobacter sphaeroides*, its processes do not practice the "culturing" step. (Defs.' Mem. 27.) Kaneka responds by noting that Judge Rodgers in the ITC Proceeding expressly rejected Defendants' effort to limit the "microorganism" term to nonphotosynthetic microorganisms, and also by noting that Defendants did not ask Judge Pfaelzer to so limit this term during the 2013 *Markman* proceedings. (Defs.' Opp'n 18-19.)

The Court agrees with Kaneka that the term "microorganism . . . 70 mole %" is not limited to

nonphotosynthetic microorganisms. Defendants did not ask for such a construction during the *Markman* proceedings, and Judge Pfaelzer did not construe this term as requiring that nonphotosynthetic bacteria or yeast be used. (*See* Defs.' Opening Claim Construction Br., ECF No. 139, Defs.' Responsive Claim Construction Br.; Claim Construction Order 10-13.) Judicial estoppel applies to patent claim construction, and Defendants are prohibited from abandoning their earlier, successfully advanced claim construction positions. *See Biomedical Patent Mgmt. Corp. v. Cal. Dep't of Health Servs.*, 505 F.3d 1328, 1341 (Fed. Cir. 2007); *Fitness Quest, Inc. v. Monti*, 330 Fed. App'x 904, 914 (Fed. Cir. 2009); *Mondis Tech. Ltd. v. Chimei Innolux Corp.*, 822 F.Supp.2d 639, 650 n.14 (E.D. Tex. 2011) (holding that "InnoLux is judicially estopped from agreeing to a claim construction position, which this Court accepted in its claim construction order, and then urging a different position merely weeks before trial"). Additionally, this argument is waived because it was not raised during the "claim construction phase" of this case, nor was it raised on appeal. *See Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Sols., P.C.*, 482 F.3d 1347, 1356 (Fed. Cir. 2007) ("The district court found that ACS waived any argument with respect to this term by failing to raise it during the claim construction phase. We agree.").

Even if the Court were inclined to consider statements made during prosecution of the '249 Application for the purpose of construing the term "microorganism," it would not agree with Defendants that this term should be limited to "nonphotosynthetic bacteria or

yeast." First, Defendants' own expert, Dr. Jefferson C. Lievense, testified that "because there is one example of a photosynthetic bacterium" in the specification of the '340 Patent, a person of ordinary skill in the art, when reviewing the '340 Patent, would not limit the term "microorganism" to nonphotosynthetic bacteria. (Bowick Opp'n Decl., Ex. 4 at 53:10-15.) The specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Moreover, Defendants have not shown that the proposed amendment to the abandoned '249 Parent Application, attached as Exhibit C to the Mei Opening Declaration, was even considered by the examiner, and there is thus little support for importing this limitation from the prosecution history into the claims. *see id.* at 1317 ("Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.").

The Court **DENIES** Defendants' Motion to the extent Defendants argue their processes cannot infringe because they utilize photosynthetic bacteria.

c. Whether Kaneka Has Sufficient Evidence that XKGC's Process Meets the 70 Mole % Limitation

Finally, Defendants argue summary judgment must be entered in XKGC's favor because there is no genuine dispute that XKGC's old and new manufacturing processes do not produce reduced CoQ_{10} at a ratio of not less than 70 mole % at the end of the fermentation step. (Defs.' Mem. 29.) In support of this argument, Defendants contend that a person of ordinary skill in the art "would understand that the appropriate point in the process from which to take a sample for testing the ration of reduced CoQ_{10} among the entire CoQ_{10}s in the obtained microbial cells is the fermentation tank at or close to the end of the 'culturing' (i.e. fermentation) step." (Defs.' Mem. 29.) In further support of this argument, Defendants point to (1) the testimony of one of Kaneka's experts during the ITC Proceeding; and (2) Judge Rodgers' finding during the ITC Proceeding that the correct "sampling point to determine whether or not the 70 mole % reduced CoQ_{10} ratio limitation is satisfied is at the end of culturing, which is the end of fermentation."[5] (Defs.' Mem. 29.)

Kaneka responds that Judge Pfaelzer considered and rejected Defendants' argument that this determination must be made at the "end of fermentation." (Defs.' Opp'n

5. The Court recognizes the dispositive nature of this construction in light of the exclusion of Dr. Sherman's test results. Despite the persuasive logic of Judge Rodger's conclusion, however, the Court ultimately declines to disturb Judge Pfaelzer's carefully considered ruling.

21-22.) It is true that, in their opening and responsive *Markman* briefs, Defendants advanced this argument. (*See generally See* Defs.' Opening Claim Construction Br., Defs.' Responsive Claim Construction Br.) Judge Pfaelzer recognized the parties' respective positions, noting that "[t]he primary disagreement between the parties appears to be over the [1] timing and [2] method for determining the mole percent of reduced CoQ_{10}." (Claim Construction Order 11.) Judge Pfaelzer disagreed with Defendants' position, and concluded that "[s]ince the steps must be performed in order, and the other steps of the claim affect the mole percent of reduced CoQ_{10}, the mole percent of reduced CoQ_{10} must be determined **at a time prior to** the execution of any of the subsequent steps of the claims." (Claim Construction Order 12 [emphasis added].) Both parties' experts agree that microorganisms surrounded by nutrients do not stop metabolizing simply because one "step" of the manufacturing process is determined to be complete and a second "step" is said to begin. What matters is whether the microorganisms continue to metabolize. Indeed, the specification of the '340 Patent implicitly acknowledges this reality, stating "it is preferable to supply the . . . carbon sources to the culture medium separately from other components." ('340 Patent col. 8, ll. 51-53.)

The Court first considers whether a genuine dispute exists as to whether XKGC's old manufacturing process practiced the 70 mole % limitation. Kaneka has introduced evidence that two sets of samples collected in February and March of 2012 by Alliance Technologies—both of which were "flash frozen in liquid nitrogen" and the

latter of which were stored on dry ice—demonstrated that XKGC's old plant cultured reduced CoQ_{10}-producing microorganisms such that more than 70 mole % of the entire CoQ_{10}s were reduced after assaying. (*See* Bowick Opp'n Decl., Ex. 30 at 15, 18, 20, 28 [showing results of "82.1-87.9 mole %" and between 73.5 and 74.7 mole %]; Ex. 12 at 125:14-16, 126:11-128:10, 141:15-142:13, 145:5-11, 146:12-16, 152:14-153:13.) Again, because Judge Pfaelzer's construction of the 70 mole % term does not require that testing be performed at the "end of fermentation," these samples, which were taken hours before the "end of fermentation," are seemingly sufficient to create a genuine dispute regarding whether XKGC's old process practiced the 70 mole % limitation. Moreover, disputes regarding the method of storage between collection and sampling must be resolved by the trier of fact, as the Court in ruling on summary judgment motions must make all reasonable inferences in the light most favorable to Kaneka, the nonmovant. The Court therefore concludes that a genuine issue of fact exists regarding whether XKGC's old manufacturing process practiced the 70 mole % limitation, and **DENIES** Defendants' Motion for Summary Judgment on this ground.

The Court reaches a different conclusion, however, with respect to XKGC's new manufacturing process. The only pieces of evidence Kaneka cites in support of its contention that XKGC's new process practices the 70 mole % limitation are the results of two tests conducted by PharmaForensics Labs on July 18, 2016 and July 20, 2016, respectively, that apparently resulted in ratios of reduced CoQ_{10} of 79.6% and 78.9%, respectively. (*See*

Bowick Opp'n Decl., Ex. 1 ¶ 16; Ex. 28 at KAN-CD-CAL 23689, 23692.) In its February 22, 2017 Order, the Court reviewed the methods used to conduct these tests and Dr. Sherman's opinions and testimony regarding these tests, and found the test results and Dr. Sherman's associated testimony to be inadmissible under Rule 702 of the Federal Rules of Evidence. *Daubert*, 509 U.S. at 590. Following this ruling, the Court asked the parties to file supplemental briefing regarding the impact of the Court's February 22, 2017 Order on Defendants' motion for summary judgment on non-infringement with respect to the "70 mole %" limitation. (Minute Order, ECF No. 766.) Kaneka's supplemental brief did not address this question, but instead noted the tentative nature of motions in limine and argued for the Court to reconsider its ruling. (P's Supplemental Brief, ECF No. 770-1.) In support of its request, Kaneka provided three peer-reviewed articles discussing organic solvent toxicity and a new study, conducted by Kaneka, purporting to examine the toxicity of n-hexane on *Rhodobacter sphaeroides* ("*R. Sphaeroides*"). (*See generally*, Declaration of David Sherman, PhD ISO Kaneka's Suppl. Brief in Opposition to Defendants' Motion for Summary Judgment ("Sherman Decl. ISO Suppl. Brief") Exhs. A-E, ECF No. 770-2-6.)

The journal articles proffered by Kaneka are largely unhelpful because none discuss, or even mention, the relevant bacterium—*Rhodobacter sphaeroides*. Kaneka asks the Court to conclude from this that *R. sphaeroides* has not been identified as an organic-solvent-resistant bacteria, noting that "nothing in the scientific literature suggests that *Rodobacter spheroides* can resist n-hexane

in small amounts, let along the very large amounts used by Dr. Sherman." (P's Suppl. Brief, fn. 4.) Nowhere, however, do these articles claim to present an exhaustive list of all such "extremophile" bacteria; on the contrary, they openly acknowledge that "fresh habitats need to be explored to isolate other species displaying such tolerance." (Sherman Decl. ISO Suppl. Brief, Exh. A at 267.) More importantly, while the articles identify the partition coefficient ("Log Pow") as a useful measure of solvent toxicity, none address the rate at which bacteria are disabled once they are exposed to toxic solvents and therefore do not establish that exposure to a mixture of n-hexane and isopropanol "immediately kills the microorganisms upon contact" such that refrigeration would be "unnecessary." (*Cf.* Decl. Robert M. Bowick in Opp'n Defs.' Mot. For Summ. J., Ex. 2 ("Sherman Infringement Report") ¶ 122, ECF No. 605-5.) In essence, Kaneka's articles only establish that: (1) some bacteria are resistant to organic solvents, (2) some bacteria are not resistant to organic solvents, and (3) organic solvents vary in their degree of toxicity. None of this information serves to validate Dr. Sherman's decision to deviate from his own protocol.

Presumably seeking to rectify the lack of information specific to *R. sphaeroides*, Kaneka also offers a new study—performed August 29-September 5, 2017—the stated purpose of which is to "[a]ssess the ability of *R. sphaeroides* culture to maintain viability following exposure to organic solvents." (Sherman Decl. ISO Suppl. Brief, Exh. E at 2.) The study introduced a mixture of n-hexane and 2-propanol to a sample of *R. sphaeroides* and, after a set period of time, assayed the bacteria-

solvent mixture, placed it on an agar plate and incubated it for three days. At the end of the three-day period, none of the bacteria were living, even those only directly exposed to the organic solvent for fifteen (15) seconds. (Sherman Decl. ISO Suppl. Brief, Exh. E at 4-5.)

Kaneka's study is defective both because the experimental design is flawed and because it does not purport to test the relevant question. The experiment involves withdrawing the bacteria-solvent mixture after a set period of time and depositing this mixture onto an agar plate. Simply withdrawing the assay from the larger mixture does not remove the bacteria from the solvent because the assay itself contains both. The solvent remains in contact with the bacteria until it evaporates from the plate—a time period not measured by the experiment. Thus, the bacteria was not only exposed to organic solvent for 15 seconds, it was also exposed to organic solvent for the time necessary to transfer the assay to the agar gel and the time required for the solvent to fully evaporate. This problem is further exacerbated by the fact that the agar plates are chilled to 4 degrees centigrade, slowing the evaporation rate. (Sherman Decl. ISO Suppl. Brief, Exh. E at 3.) The procedure also fails to address whether the agar plates are sealed or left open when placed into the incubator. If the plates are sealed—as is customary—the bacteria could have been exposed to organic solvent vapor for all three days of incubation. The experiment's second flaw is its failure to directly test the relevant question: whether exposure to the mixture of n-hexane and isopropanol "immediately" kills *R. sphaeroides* such that the deviation from Dr. Sherman's proposed testing

procedure is immaterial. While it does seek to test the lifespan of these microorganisms, it does not meaningfully compare this process to the PharmaForensics protocol.

As Plaintiff has failed to cure the defect identified in Dr. Sherman's report in the original *Daubert* Order, the Court **DENIES** Kaneka's request to reconsider that finding. Kaneka and its witnesses are precluded from testifying and offering opinions regarding the results of their testing of the 70 mole % limitation under Dr. Sherman's July 2016 protocol. Accordingly, because Kaneka has introduced no admissible evidence showing there is a genuine dispute as to whether XKGC's new manufacturing process practices the 70 mole % limitation, the Court **GRANTS** Defendants' Motion for Summary Judgment that XKGC's new manufacturing process does not infringe the asserted claims.

2. Whether Defendants Use a "Sealed Tank"

Defendants next challenge whether Manufacturing Defendants' processes use a "sealed tank," arguing that Kaneka "essentially conceded" in its *Markman* and earlier summary judgment papers that it would be impossible to have a "sealed tank" in an industrial-scale process as the term has been construed by the Federal Circuit. (Defs.' Mem. 31-32.) Defendants note that although Kaneka sought to construe the term "sealed tank" to mean "a tank that **substantially** prevents direct exposure of its contents to the atmosphere," the Federal Circuit rejected this proposed construction, instead construing the term as "a tank that prevents exposure of the tank's contents

to the atmosphere." (Defs.' Mem. 32.) Defendants do not cite any evidence in support of this argument, and do not reference the "relief valve" discussed at length in their initial motion for summary judgment filed after the Federal Circuit issued its mandate. (*Cf.* Mot. for Summ. J. as to Invalidity and Noninfringement, ECF No. 355.)

Kaneka responds that Dr. Spormann failed to apply the Federal Circuit's construction in providing his non-infringement opinions, creating his own interpretation of "sealed tank" by adding the qualifier "all the time." (Bowick Opp'n Decl., Ex. 12 at 161:21-162:22, 214:11-215:1.) Kaneka next points out that Shenzhou employees testified that Shenzhou's old and new extraction processes, which are described in Standard Operating Procedures ("SOPs"), are performed in tanks that are sealed. (Defs.' Opp'n 35.) Kaneka submits that this evidence, coupled with the opinions and testimony of its expert, is sufficient to defeat summary judgment.

a. The Court's Construction of "Sealed Tank" and Plaintiff's Motion for Reconsideration

In the Judge Pfaelzer's original claim construction order, the term "sealed tank" was construed to mean "a tank that is closed to prevent the entry or exit of **materials**." (emphasis added) (Claim Construction Order, 9.) On appeal, the Federal Circuit reversed this construction, finding that it improperly excluded one of the '340 Patent's preferred embodiments. (*Kaneka Corp. v. Xiamen Kingdomway Group Co.*, 790 F.3d 1298, 1304

(Fed. Cir. 2015). Instead, the Circuit determined that a "'sealed tank' should be sealed to the atmosphere, but not necessarily to other materials, such as solvents" and, based on this understanding, held that "the term 'sealed tank," means 'a tank that prevents exposure of the tank's contents to the atmosphere.'" *Id.* at 1304-5.

In its February 22, 2017 Order addressing arguments raised in the parties' *Daubert* motions, the Court referred to a portion of the Federal Circuit's ruling which held:

> In the industrial scale process of Example 8, a solution of disrupted (ruptured) cells containing reduced coenzyme Q_{10} is "sealed with nitrogen gas," i.e., sealed under an inert gas atmosphere **such that solution contents are not exposed to the atmosphere, and continuously extracted** in a manner that allows solvent to flow into and out of the extraction tanks depicted in Figure 1.

(*Daubert* Order, 11.) From this, the Court concluded that "[t]he only tenable reading of this limitation is that the tank must prevent exposure of its contents to the atmosphere for the entire duration of the extraction step, or else the contents of the tank could be exposed to the atmosphere for at least a portion of the extraction step." (*Daubert* Order, 11.) Plaintiff now challenges this conclusion as improperly adding an additional limitation to the Federal Circuit's existing construction of "sealed tank." (*See generally*, Motion for Reconsideration, ECF No. 819-1.) Kaneka asserts that the additional language "necessarily exclude[s] the preferred embodiment of

Example 8 and Figure 1 of the '340 Patent." (Declaration of David Sherman PhD ISO Mot. for Reconsideration ¶ 14, ECF No. 819-2.)

The basis for Kaneka's claim is that the industrial tanks used for extraction must, at some point, be filled with solvent, displacing any air contained within the extraction tank. (Sherman Decl. ISO Reconsideration ¶ 13.) If this air is not bled off during the filling process, the tank would become pressurized with compressed air and solvent vapor—an unworkable and highly dangerous proposition. (Sherman Decl. ISO Reconsideration ¶ 11.) The alternative solution of placing the tank under complete vacuum during the filling process is a similarly impractical, if not impossible, requirement. (Sherman Decl. ISO Reconsideration ¶ 7.) Plaintiff is therefore correct that requiring a hermetically-sealed tank during the extraction process is inconsistent with the patent specification as read by a person of ordinary skill in the art. The Court's February 22, 2017 Order, however, makes no such demand. While it does conclude that the tank must be sealed during the entirety of the extraction process, it requires only that the contents of the tank not be exposed to the atmosphere—not that the atmosphere be protected from the contents of the tank. (*Daubert* Order, 11.) Thus, the use of a seal pot or some other one-way check valve that allows gas to escape the container while the tank is being filled, but does not allow atmospheric oxygen to enter, is sufficient to render a tank "sealed" for purposes of the '340 Patent. This understanding is fully consistent with the patent specification which discloses that, at least with respect to reduced coenzyme Q_{10}, the primary

concern during the extraction step is preventing oxidation. ('340 Patent col. 16:16-54.) Exposing the tank's contents to the atmosphere at any point during the extraction process would introduce additional oxygen into the tank and thereby frustrate this goal. Because the Court's construction permits venting of air during the filling process, it does not conflict with Example 8 or Figure 1 of the '340 Patent.

The Court further notes that the case law relied upon by Plaintiff in its Motion for Reconsideration is inapposite. Kaneka cites a related case appealed from the Southern District of Texas in which the Federal Circuit rejected the lower court's construction of the term "oxidation." *Zhejiang Medicine Co., Ltd. v. Kaneka Corp.*, 676 Fed. Appx. 962, 964 (Fed. Cir. 2017). Contrary to Kaneka's assertion, however, the rejection was not because the district court further clarified the Circuit's previous construction, but rather because the lower court's construction lacked precision. *Id.* In point of fact, by arguing that a "sealed tank" may sometimes be open and sometimes be closed, Kaneka seeks to introduce exactly the type of ambiguity and imprecision that the Federal Circuit sought to avoid. If a tank that is open for 5% of the extraction process is "sealed," it begs the question whether the same logic applies to a tank that is open 25% of the time, or 95% of the time. Moreover, Plaintiff has already litigated this issue before the Federal Circuit in its initial appeal when it sought to construe "sealed tank" as "a tank that **substantially** prevents direct exposure of its contents to the atmosphere." (Brief for Plaintiff-Appellant ("Kaneka App. Brief") at 49, *Kaneka*

Corp. v. Xiamen Kingdomway Group Co., 790 F.3d 1298 (Fed. Cir. 2015).) While the Circuit accepted some of Kaneka's proposed construction, it conspicuously chose not to include "substantially" or any similarly equivocal language. This Court follows the Federal Circuit's lead and declines to add such a limitation at this time.

Plaintiff's reliance on *Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.* is similarly misplaced. 55 F.3d 615 (Fed. Cir. 1995). There, the Federal Circuit considered an asserted claim requiring a data packet to travel along a single, assigned network tree. *Id.* at 622. Because the accused system consisted of packets capable of switching, mid-course, from one tree to another, the district court concluded that there was no literal infringement. *Id.* The appellate court observed that "the record does not make it clear that [defendant]'s system *never* uses the claimed method," thereby implying that there may be situations in which the packet does not, in fact, switch network trees and therefore may literally infringe at least some of the time. *Id.* Without making an ultimate determination on the issue of infringement, the case was remanded with instructions that "an accused product that sometimes, but not always, embodies a claimed method nonetheless infringes." *Id.* Kaneka contends that this holding requires the Court to consider a tank that, for some period of time, exposes its contents to the atmosphere to nevertheless be a "sealed tank." (Mot. For Reconsideration, 8.) This argument, however, appears to be based on a misunderstanding of the biphasic nature of infringement analysis. Before a court considers a defendant's accused product, it must first determine the proper scope of the asserted claim

terms as presented in the patent and understood by a person of ordinary skill in the art. *Markman*, 52 F.3d at 976. It is only once the claim scope is understood that a court may determine if a defendant infringes those claims. *Id.* Kaneka's argument goes to the first of these steps—claim interpretation—while the court in *Bell Commc'ns* addressed the second. Had Kaneka shown, for example, that Defendants sometimes perform their process with an open tank and sometimes with a sealed tank, the principle from *Bell Commc'ns* would apply. Here, however, Plaintiff does not allege that Defendants' process differs from run to run, but rather asks the Court to alter its construction of "sealed tank."

For these reasons, the Court **DENIES** Kaneka's Motion for Reconsideration and continues to interpret the term "sealed tank" as requiring the tank to prevent exposure of its contents to the atmosphere for the entire duration of the extraction step.

b. Whether a Genuine Dispute Exists as to Manufacturing Defendants' Literal Usage of "Sealed Tanks"

Even with this understanding, the Court finds that a genuine dispute exists as to whether the old and new processes used by XKGC literally perform extraction using "sealed tanks," and accordingly **DENIES** summary judgment in favor of Defendants on this issue. Kaneka's expert, Dr. Sherman, testified and opined that XKGC's new and old processes extract CoQ_{10} in a "sealed tank" because although these processes include relief valves

that can expose the tank's contests to the atmosphere, XKGC's SOP, coupled with the purpose of the relief valve—to prevent the build up of the solvent hexane, which can create an explosion if too pressurized—reveal that the valves "close to prevent any potential drawing in of atmospheric air exposed to the hexane . . ." (Bowick Opp'n Decl., Ex. 36 at 318:15-321:20; Ex. 2 at 161-190; Exs. 37-38; Ex. 41 at 586:4-22; Exs. 46-47.) Kaneka also points to its Final Infringement Contentions, which detail why XKGC's new and old processes use "sealed tanks" relying on their SOP and certain deposition testimony. (Kaneka's FICs for XKGC at 26-31.)

Defendants do not directly challenge Dr. Sherman's testimony or opinions, nor do they offer any affirmative evidence of their own. Instead, they rely on a submission by Kaneka in a 2013 brief opposing summary judgment that a "sealed tank" in an industrial-scale process can only be "substantially" sealed "because the absolute nature of complete oxygen exclusion and/or absolute retention of all organic solvent presents certain logistical and system-based difficulties that operate contrary to known realities inherent to any industrial scale production process." (Defs.' Mem. 32; Defs.' Reply 18, ECF No. 611-1.) As a preliminary matter, the Ninth Circuit holds that "statements of fact contained in a brief may be considered admissions of the party in the discretion of the district court." *Am. Title Ins. Co. v. Lacelaw Corp.*, 861 F.2d 224, 227 (9th Cir. 1988). Given this statement was made in the context of Kaneka opposing summary judgment under a since-reversed claim construction ruling, the Court does not find the statement to be tantamount to a judicial

admission that the extraction tanks are not "sealed," as the term has since been construed by the Federal Circuit. Even if the Court were to treat this submission as a binding admission, however, it would not conclude that Kaneka has admitted Defendants' processes do not extract in "a tank that prevents exposure of the tank's contents to the atmosphere." This opinion is limited to large industrial tanks subjected to the continuous exchange of liquids and gases. (*See* Mem. Ps. & As. in Opp'n to Mot. for Summ. J. on the Issue of Non-Infringement 21, ECF No. 218.) On the present record, the Court cannot say whether Shenzhou or XKGC's old or new processes use industrial extraction tanks subjected to the continuous exchange of liquids and gases.

b. Whether a Genuine Dispute Exists as to Manufacturing Defendants' Usage of "Sealed Tanks" under the DOE

Defendants next argue that Manufacturing Defendants' processes do not meet the "sealed tank" limitation under the DOE, both because Dr. Sherman did not address any alleged infringement under this doctrine and because Kaneka is barred from asserting infringement of this claim limitation under the doctrine of prosecution history estoppel. (*See* Defs.' Mem. 33.)

As a threshold matter, the Court granted Kaneka leave to amend its Final Infringement Contentions to include infringement of the "sealed tank" limitation under the DOE. (*See* Order Granting in Part & Den. in Part Pl.'s Mot. for Leave to Amend Its FICs, ECF No.

513.) The Court therefore rejects Defendants' challenge on this ground.

The Court next addresses whether Kaneka is barred from asserting infringement under the DOE because of prosecution history estoppel. "Estoppel arises when an amendment is made to secure the patent and the amendment narrows the patent's scope." *Festo VIII*, 535 U.S. at 736. "A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art or to comply with § 112." *Id.* at 737. In *Festo*, the United States Supreme Court provided an overview of the doctrine:

> The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes. When, however, the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent. On the contrary, "[b]y the amendment [the patentee] recognized and emphasized the difference between the two phrases[,] . . . and [t]he difference which [the patentee] thus disclaimed must be regarded as material."

Id. at 733-34. "Estoppel is a 'rule of patent construction' that ensures that claims are interpreted by reference to those 'that have been cancelled or rejected.'" *Id.* at 733 (quoting *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 220-21, 61 S. Ct. 235, 85 L. Ed. 132, 1941 Dec. Comm'r Pat. 802 (1940)).

Defendants argue that, during prosecution of the application leading to the '340 Patent (Appl. No. 11/981,181), after repeated rejections of its claims by the PTO, Kaneka submitted an Amendment canceling old claims and adding new ones. (*See* Defs.' Mem. 33.) Among these new claims were claims 131 and 142, which the patentee claimed were not obvious in light of certain prior art references because these references "fail[ ] to provide any teaching or suggestion" of extraction by an organic solvent "in a sealed tank." (*See* Mei Opening Decl., Ex. K at MGC00122101-MGC00122107.) These claims ultimately issued as claims 22 and 33.

Kaneka does not cite to, much less grapple with, the doctrine of prosecution history estoppel once in its papers. (*See generally* Defs.' Opp'n.) Instead, Kaneka cites to cases discussing the role of the jury in determining infringement under the DOE and the type of evidence sufficient to establish such infringement. (*See* Defs.' Opp'n 38.) Moreover, the main authority cited by Kaneka regarding the DOE, *AquaTex Industries v. Techniche Solutions*, shows why Kaneka has failed to carry its summary judgment burden with respect to the issue of prosecution history estoppel:

> Under th[e] doctrine [of prosecution history estoppel], the surrender of subject matter during patent prosecution creates a presumption that the patentee is precluded from recapturing that subject matter through the doctrine of equivalents; this presumption can be rebutted by the patentee through a **showing** that an amendment was unrelated to patentability.

479 F.3d 1320, 1325 (Fed. Cir. 2007). Kaneka has failed to introduce any evidence or argument as to why the addition of the term "in a sealed tank" during prosecution was unrelated to patentability, particularly in light of the patentee's statements contained in the Amendment distinguishing certain prior art references. As such, the Court **GRANTS** summary judgment in favor of Defendants that XKGC's manufacturing processes do not practice the "sealed tank" limitation under the doctrine of equivalents.

3. Whether Defendants' Processes Contain an " Active Oxidation" Step

Finally, Defendants argue that they do not infringe claim 22 because Manufacturing Defendants' processes do not perform the "oxidizing" step. (Defs.' Mem. 34.) In particular, they contend that because Kaneka has not presented "a baseline rate of passive oxidation to show that the alleged pre-extraction 'oxidizing step' (i.e., washing and drying steps) is active oxidation in [] XKGC's process," summary judgment of noninfringement must be entered in their favor. (Defs.' Mem. 34.) Kaneka does not dispute that

it does not have a "baseline rate of passive oxidation," but argues it nevertheless has sufficient evidence to withstand summary judgment on this issue.

Since the filing of the parties' cross-motions for summary judgment, the Court of Appeals for the Federal Circuit has issued an opinion regarding an appeal from the Texas Litigation (the "*ZMC* Opinion"). (*See* Defs.' Second Notice of Supplemental Authority and Partial Withdrawal of Summ. J. Mot. ("Notice"), Ex. A, ECF No. 636.) In the *ZMC* Opinion, the Federal Circuit held, among other things, that the construction of the oxidizing steps does not require increased oxidation in excess of that which occurs naturally from exposure to ambient air. (Notice, Ex. A at 6.) In light of the *ZMC* Opinion, Defendants "withdraw the part of their Motion for Summary Judgment that is based on Kaneka's failure to present a baseline rate for passive oxidation to prove infringement of claim 22." (Notice 1.)

IV. RULING

For the foregoing reasons, the Court:

1. **DENIES** both Kaneka's and Defendants' Motions for Summary Judgment on the issue of whether the asserted claims are indefinite under 35 U.S.C. § 112 ¶ 2;

2. **GRANTS** Kaneka's Motion for Summary Judgment that the asserted claims are patent-eligible under 35 U.S.C. § 101;

3. **GRANTS** Kaneka's Motion for Summary Judgment that *Folkers* does not anticipate any of the asserted claims under 35 U.S.C. Section 102;

4. **DENIES** Kaneka's Motion for Summary Judgment that Kaneka's *Pre-2002 Process* do not anticipate the asserted claims under 35 U.S.C. § 102;

5. **DENIES** Defendants' Motion for Summary Judgment to the extent they seek summary adjudication that XKGC's old manufacturing does not practice one or more aspects of the "culturing" step recited in the asserted claim, but **GRANTS** Defendants' Summary Judgment that XKGC's new manufacturing process does not practice the 70 mole % limitation;

6. **DENIES** Defendants' Motion for Summary Judgment that XKGC's Defendants' processes do not literally extract CoQ_{10} in a "sealed tank," but **GRANTS** Defendants' Motion for Summary Judgment that XKGC's processes do not extract CoQ_{10} in a "sealed tank" under the doctrine of equivalents; and

7. **DENIES** Defendants' Motion for Summary Judgment that XKGC does not practice the "oxidizing" limitation of claim 22.

Appendix D

The Court is in receipt of Kaneka's Notice of Proposed Stipulation of Non-infringement based on the Court's Rulings (ECF No. 831) and Defendants' Response (ECF No. 833). Now that a decision has been rendered, the parties shall advise the Court how they wish to proceed.

IT IS SO ORDERED.