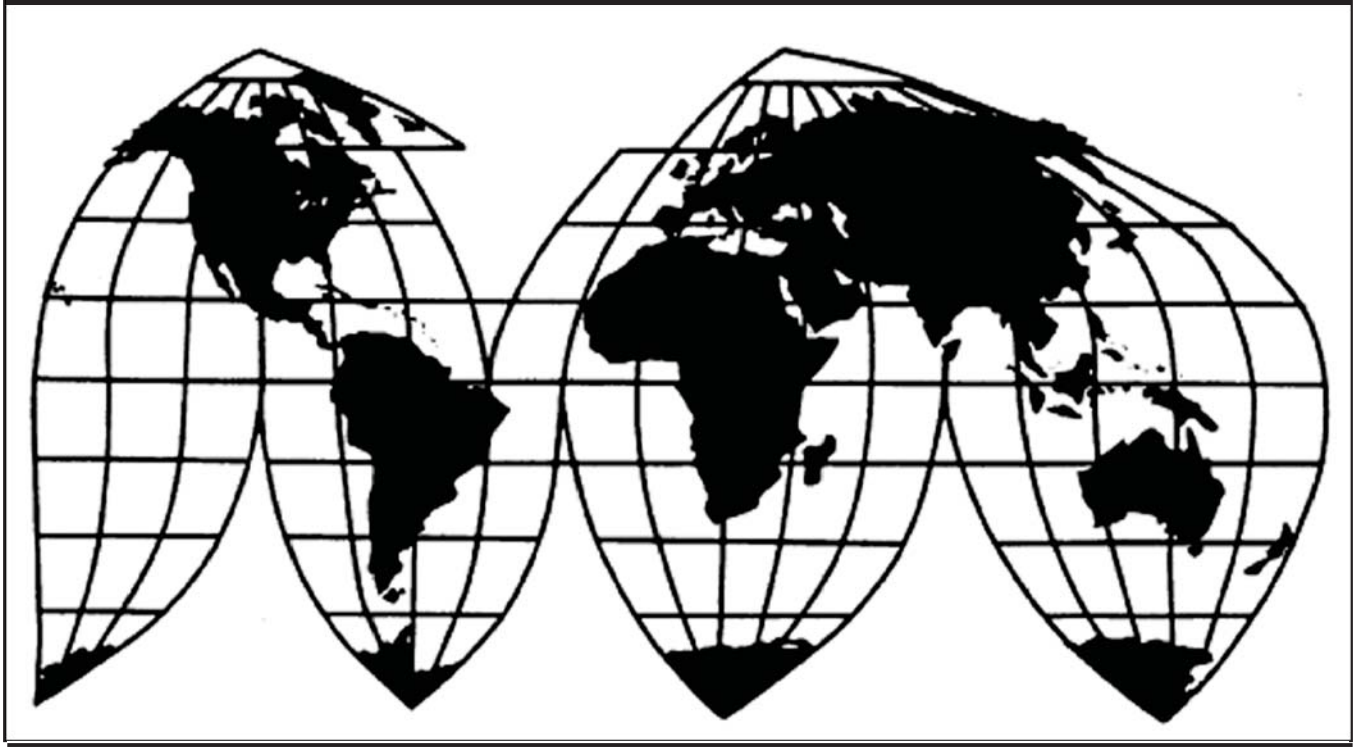
In the Matter of

Certain Coenzyme Q10 Products and Methods of Making Same

Investigation No. 337-TA-790

Publication 4407 **July 2013**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

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In the Matter of

Certain Coenzyme Q10 Products and Methods of Making Same

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN COENZYME Q10 PRODUCTS AND METHODS OF MAKING SAME	**Inv. No. 337-TA-790**

NOTICE OF COMMISSION DETERMINATION (1) TO REVIEW AND AFFIRM WITH RESPECT TO TWO ISSUES, (2) TO REVIEW AND VACATE WITH RESPECT TO ONE ISSUE, AND (3) NOT TO REVIEW THE REMAINDER OF THE FINAL INITIAL DETERMINATION OF THE ADMINISTRATIVE LAW JUDGE; TERMINATION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined the following: (1) to review and affirm (a) the finding that Mitsubishi Gas Chemical Co., Inc. ("MGC") does not satisfy the 70 mole % limitation, and (b) the claim construction of "inert gas atmosphere" with respect to the asserted claims of U.S. Patent No. 7,910,340 ("the '340 patent"); (2) to review and vacate the finding that certain asserted claims of the '340 patent are not invalid under the new matter prohibition of 35 U.S.C. § 132; and (3) not to review the remainder of the final initial determination of the administrative law judge ("ALJ") in the above-captioned investigation. This action terminates the investigation.

FOR FURTHER INFORMATION CONTACT: James A. Worth, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3065. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on July 19, 2011, based on a complaint filed on June 17, 2011, by Kaneka Corp. of Osaka, Japan ("Kaneka"), and supplemented on June 24 and 27, 2011. 76 *Fed. Reg.* 42729 (July 19, 2011).

The complaint alleged violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the sale for importation, importation, or sale after importation into the United States of certain coenzyme Q10 products by reason of infringement of certain claims of the '340 patent. The Commission's notice of investigation named as respondents Zhejiang Medicine Co., Ltd. of Zhejiang, China; ZMC-USA, LLC of The Woodlands, Texas; Xiamen Kingdomway Group Co. of Xiamen, China; Pacific Rainbow International Inc. of City of Industry, California; MGC of Tokyo, Japan; Maypro Industries, Inc. of Purchase, New York ("Maypro Inc."); and Shenzhou Biology & Technology Co., Ltd. of Beijing, China.

On January 12, 2012, the Commission issued notice of its determination not to review an ID granting a motion to amend the complaint and notice of investigation to add a new respondent, Mitsubishi Gas Chemical America, Inc. of New York, New York and to replace respondent Maypro Inc. with Maypro Industries, LLC of Purchase, New York.

An evidentiary hearing was held from July 9-13, 2012.

On September 27, 2012, the presiding ALJ (Judge Rogers) issued a final initial determination ("final ID" or "ID") finding no violation of section 337. The ALJ also issued a recommended determination on remedy and bonding.

Specifically, the ALJ found that the imported products were not shown to be manufactured by processes covered by the asserted claims. The ALJ found that Kaneka satisfied the economic prong of the domestic industry requirement but failed to satisfy the technical prong of the domestic industry requirement. The ALJ found that the asserted claims were not shown to be invalid.

On October 10, 2012, Kaneka filed a petition for review of the final ID. The Respondents and the Commission investigative attorney ("IA") filed contingent petitions for review. On October 18, 2012, each party filed a response (with Kaneka filing separate responses to the Respondents and the IA).

Having reviewed the final ID, the petitions for review, and the record in this investigation, the Commission has determined the following: (1) to review and affirm (a) the finding that MGC does not satisfy the 70 mole % limitation, and (b) the claim construction of "inert gas atmosphere" with respect to the asserted claims of the '340 patent; (2) to review and vacate the finding that the asserted claims of the '340 patent are not invalid under the new matter prohibition of 35 U.S.C. § 132; and (3) not to review the remainder of the final initial determination of the ALJ, including the ALJ's finding that certain asserted claims of '340 patent are not invalid under 35 U.S.C. § 112. This action terminates the investigation.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and of section 210.42(h) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.42(h)).

By order of the Commission.

Lisa R. Barton
Acting Secretary to the Commission

Issued: November 29, 2012

CERTAIN COENZYME Q10 PRODUCTS AND METHODS OF MAKING SAME **337-TA-790**

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, Anne Goalwin, Esq., and the following parties as indicated, on **November 30, 2012**

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN COENZYME Q10 PRODUCTS AND METHODS OF MAKING SAME**	**Inv. No. 337-TA-790**

COMMISSION OPINION

On September 27, 2012, the presiding administrative law judge ("ALJ") (Judge Rogers) issued a final initial determination ("final ID" or "ID") finding no violation of section 337 in the above-identified investigation with respect to the only asserted patent, U.S. Patent No. 7,910,340 ("the '340 patent"). The ALJ also issued a recommended determination ("RD") on remedy and bonding.

Having considered the ID, the submissions of the parties, and the relevant portions of the record, the Commission determined the following: (1) to review and affirm (a) the finding that MGC does not satisfy the 70 mole % limitation, and (b) the claim construction of "inert gas atmosphere" with respect to the asserted claims of the '340 patent; (2) to review and vacate the finding that the asserted claims of the '340 patent are not invalid under the new matter prohibition of 35 U.S.C. § 132; and (3) not to review the remainder of the final initial determination of the ALJ, including the ALJ's finding that certain asserted claims of '340 patent are not invalid under 35 U.S.C. § 112. This opinion addresses those findings which the Commission has determined to review.[1]

[1] The final initial determination of the ALJ becomes the determination of the Commission for those findings which the Commission has determined not to review. 5 U.S.C. § 557; 19 C.F.R. § 210.42.

I. BACKGROUND

A. Procedural History

The Commission instituted this investigation on July 19, 2011, based on a complaint filed on June 17, 2011, by Kaneka Corp. of Osaka, Japan ("Kaneka"), and supplemented on June 24 and 27, 2011. 76 *Fed. Reg.* 42729 (July 19, 2011). The complaint alleged violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the sale for importation, importation, or sale after importation of certain coenzyme Q10 products by reason of infringement of claims 1-45 of U.S. Patent No. 7,910,340. The Commission's notice of investigation named as respondents Zhejiang Medicine Co., Ltd. of Zhejiang, China; ZMC-USA, LLC of The Woodlands, Texas ("ZMC"); Xiamen Kingdomway Group Co. of Xiamen, China ("XKGC"); Pacific Rainbow International Inc. of City of Industry, California ("PRI"); Mitsubishi Gas Chemical Co., Inc. of Tokyo, Japan ("MGC"); Maypro Industries, Inc. of Purchase, New York ("Maypro Inc."); and Shenzhou Biology & Technology Co., Ltd. of Beijing, China ("Shenzhou").

On January 12, 2012, the Commission issued notice of its determination not to review an ID granting a motion to amend the complaint and notice of investigation to add a new respondent, Mitsubishi Gas Chemical America, Inc. of New York, New York and to replace respondent Maypro Inc. with Maypro Industries, LLC of Purchase, New York.

On June 29, 2012, the Commission issued notice of its determination not to review an ID (Order No. 42) that ZMC does not infringe claims 2, 5-8, 12, 16-19, 23, 26-28, 32, 34, 38-40, or 45.

On July 9, 2012, the ALJ ordered, pursuant to a stipulation from the parties, that no evidence be presented with respect to Maypro. Tr. at 10:21-12:21.

An evidentiary hearing was held from July 9-13, 2012.

On September 27, 2012, the presiding administrative law judge ("ALJ") (Judge Rogers) issued a final initial determination ("final ID" or "ID") finding no violation of section 337. The ALJ also issued a recommended determination ("RD") on remedy and bonding.

Specifically, the ALJ found that the imported products were not shown to be manufactured by processes covered by the asserted claims of the '340 patent. In this connection, the ALJ examined the evidence relating to the manufacturing processes of the four groups of respondents. The ALJ found that the accused Shenzhou products do not infringe claims 1, 3-4, 6, 8-11, 13-15, 17, 19-22, 24-25, 27, 29-33, 35-37, 39, or 41-45. The ALJ found that the accused XKGC and PRI products do not infringe claims 1, 4-6, 9, 11, 15-17, 20, 22, 25, 27, 29, 30, 33, 37-39, 41, 43, or 45. The ALJ found that the accused ZMC products do not infringe claims 1, 3, 4, 9-11, 13-15, 20-22, 24, 25, 29-31, 33, 35-37, or 41-44. The ALJ found that the accused MGC products do not infringe claims 1, 2, 4, 9-12, 14-15, 20-23, 25, 27, 29-31, 33-34, 36-37, 41-43, or 45.[2]

The ALJ found that Kaneka satisfied the economic prong of the domestic industry requirement but failed to satisfy the technical prong of the domestic industry requirement.

The ALJ found that the asserted claims were not shown to be invalid, as follows. The ALJ found that claims 1-4, 8-15, 20-25, 29-37, and 41-44 were not shown to be invalid by reason of an on-sale bar under 35 U.S.C. § 102(b). The ALJ found that claims 1-3, 6-14, and 17-21 of the '340 patent were not shown to be anticipated under 35 U.S.C. § 102(a). The ALJ found that claims 1-4, 8-15, 20-25, 29-37, and 41-44 were not shown to be invalid by reason of obviousness under 35 U.S.C. § 103. The ALJ found that claims 1, 11, 22, and 33 were not shown to be

[2] The ALJ also found that the accused Maypro products do not infringe any of the claims, pursuant to a stipulation by the parties.

invalid as unpatentable under 35 U.S.C. § 101. The ALJ found that claims 22-45 were not shown to be invalid for lack of an adequate written description under 35 U.S.C. § 112 ¶1 or new matter prohibition under 35 U.S.C. § 132. The ALJ found that claims 1-45 were not shown to be invalid by reason of derivation under 35 U.S.C. § 102(f).

On October 10, 2012, Kaneka filed a petition for review of the final ID. The Respondents and the Commission investigative attorney ("IA") filed contingent petitions for review. On October 18, 2012, each party filed a response (with Kaneka filing separate responses to the Respondents and the IA).

The Commission has determined as follows: (1) to review and affirm (a) the finding that Mitsubishi Gas Chemical Co., Inc. ("MGC") does not satisfy the 70 mole % limitation of the asserted claims the '340 patent, and (b) the claim construction of "inert gas atmosphere" in the asserted claims of the '340 patent; (2) to review and vacate the finding that the asserted claims of the '340 patent are not invalid under the new matter prohibition of 35 U.S.C. § 132, and (3) not to review the remainder of the final initial determination of the administrative law judge, including the ALJ's finding that the asserted claims of '340 patent are not invalid under 35 U.S.C. § 112.

B. The Patent

The '340 patent[3], entitled "Processes for Producing Coenzyme Q10," assigned to Kaneka Corporation, was issued on March 22, 2011, based on application number 11/981,181[4] filed on July 17, 2008, by Kazuyoshi Yajima, Akihisa Kanda, Shiro Kitamura, and Yasuyoshi Ueda. This application was filed as a divisional of application no. 10/500,249, filed as application no. PCT/JP02/13766, on December 27, 2002, claiming priority from Japanese application no. 2001-

[3] JX-1.
[4] JX-3.

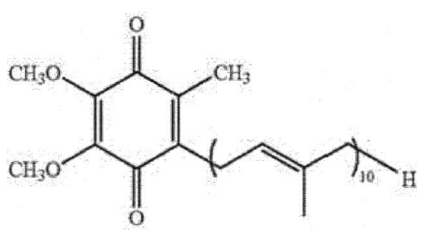
398545, filed on December 27, 2001. The '340 patent is directed to processes for producing oxidized coenzyme Q10 according to the following steps: (1) producing reduced coenzyme Q10 at a ratio of not less than 70 mole % by fermentation in microorganisms; (2) optionally disrupting the microorganism's cells; and (3) oxidizing the coenzyme Q10 before or after extraction from the cells. Col. 3, lines 47-67. The process thus results in reduced coenzyme Q10 which is then oxidized to the oxidized form of coenzyme Q10. Col. 17, lines 1-17. The patent claims a process conducted on an "industrial scale."

There are four different independent claims, claims 1, 11, 22, and 33. The four categories of claims are based on whether there is a cellular disruption step (or not) and based on whether the oxidation step precedes (or follows) the extraction step.

C. Technology: Coenzyme Q10's Formation, Composition, and Uses

Coenzyme Q10 is a naturally occurring compound found in the membranes of animal cells, including human cells, and in yeast and in some bacteria. Tr. at 12 (Tutorial). Coenzyme Q10 is part of the electron transport chain used in aerobic fermentation, where it alternates between an oxidized form (known as ubiquinone) and a reduced form (known as ubiquinol) and back again, as it accepts electrons from NADH and donates the electrons to oxygen (O_2), forming water and creating the gradient necessary to store chemical energy as ATP. *See* Tr. at 13-15 (Tutorial).

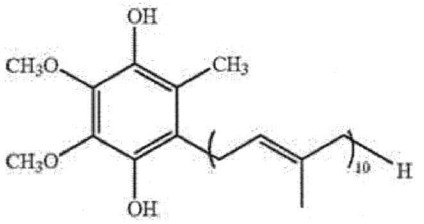
The chemical structure of oxidized coenzyme Q10 is:



CoQ10 (ox.)

'340 patent, Formula II, col. 1, lines 29-40.

The chemical structure of reduced coenzyme Q10 is:



CoQ10 (red.)

'340 patent, Formula I, col. 1, lines 16-28.

As relevant to this investigation, coenzyme Q10 is sold as a dietary supplement and as an ingredient in cosmetics and in oral care products. Tr. at 17 (Tutorial).

II. STANDARD OF REVIEW

A party may petition the Commission for review of an ID on one or more of the following bases:

> that a finding or conclusion of material fact is clearly erroneous; that a legal conclusion is erroneous, without governing precedent, rule or law, or constitutes an abuse of discretion; or that the determination is one affecting Commission policy.

19 C.F.R. § 210.43. Commission review is granted "when at least one of the participating Commissioners votes for ordering review." *Id.* § 210.43(d)(3). The Commission may review an ID on its own motion based on the same standard. *Id.* § 210.44.

Once the Commission has decided to review the decision of the ALJ, then according to statute, the agency has all of the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule. 5 U.S.C. § 557(b); *Certain Acid-Washed Garments and Accessories*, Inv. No. 337-TA-324, USITC Pub. 2576, Comm'n Op. at 3 (Nov. 1992). Commission Rule 210.45(c) implements 5 U.S.C. § 557(b). In other words, once the Commission decides to review the decision of the ALJ, the Commission may conduct a review of the findings of fact and conclusions of law presented by the record under a *de novo* standard.

III. DISCUSSION

A. Whether MGC Satisfies the 70 Mole % Limitation (Independent Claims 1, 11, 22, and 33)

The ALJ found that Kaneka failed to prove by a preponderance of the evidence that MGC satisfies the "70 mole %" limitation. ID at 323. The ALJ explained that Kaneka relied upon a document produced by MGC, CX-106C, to assert that this limitation is met. *Id.* CX-106C discloses that MGC performed a test which showed ratios of [[ ]] reduced coenzyme Q10. *Id.* However, the ALJ found that Kaneka has not tied these tests to products imported by MGC into the United States rather than being for products produced for other markets. *Id.* at 323-24.

Analysis

Kaneka argues that there is no record that MGC manufactures oxidized coenzyme Q10 at any plant other than in Niigata, Japan, and that this must be the source of the oxidized coenzyme Q10 imported into the United States. Complainant Kaneka Corporation's Petition for Review Pursuant to 19 C.F.R. §210.43 ("Kaneka Pet.") at 38.

The Respondents argue that Kaneka failed to show that MGC's process infringes the 70 mole % limitation. The Respondents argue that Kaneka does not rely on its own testing of MGC's products, but rather relies on expert testimony about an MGC document, CX-106C. Respondents' Reply to Complainant Kaneka Corporations's Petition for Review Pursuant to 19 C.F.R. §210.43 ("Resp. Rep.") at 61. The Respondents argue that Kaneka's petition focuses on the lack of connection to imported products and fails to address the following: (1) that CX-106C does not demonstrate the mole % reduced coenzyme Q10 at the end of fermentation; (2) that CX-106C lacks important details about the sampling, handling, and analysis of samples; (3) that there

is no evidence of the time delay between sampling and testing; and (4) there is no evidence concerning the analysis method used. *Id.* at 62-63.

The IA argues that experts, such as XKGC's expert, Dr. Spormann, and the prior art teach that depriving samples of oxygen can cause an increase in the ratio of reduced coenzyme Q10 and that this shift can occur in 1-2 minutes. Response of the Office of Unfair Import Investigations to Petitions For Review of the Initial Determination on Violation of Section 337 ("IA Rep.") at 16 (citing RX-623C at p.56 and Qs. 217, 212-221; RX-646; RX-645; RX-25; RX-644).[5]

The Commission affirms the ALJ's finding that Kaneka has not proven that MGC satisfies the 70 mole % limitation. First, the Commission affirms the ALJ's finding that Kaneka has not tied MGC's tests to products imported by MGC into the United States rather than products produced for other markets. ID at 323-24. Second, as an additional basis in support of the ALJ's finding, the Commission finds that Kaneka has not proven that MGC's products satisfy the "70 mole %" limitation for the same reasons as for the other respondents, *i.e.*, the oxygen-deprived environment in which the samples were stored may have been responsible for any increase in the reduced coenzyme Q10. *See* Tr. 191-194; *see also* ID at 228-29 (discussing storage of samples in the context of the testing of Respondent Shenzhou's process). The exhibit relied on, CX-106C, has a chart:

Step	first analysis	second analysis
immediately after culturing CD	[[ ]]	[[ ]]
after [ ]] (before®)	[[ ]]	[[ ]]
before entering extraction step @([[ ]])	[[ ]]	[[ ]]

[5] The record evidence indicates that a person of ordinary skill in the art would either test the samples right away, or would freeze them (and would test them right away upon thawing, making sure not to leave them in an oxygen-deprived atmosphere). *See* RX-348 at Q.269 (Taylor).

However, when the chart lists: "immediately after culturing," the word "immediately" appears to refer to the point in the fermentation process when the sample is taken, *i.e.*, before [[

]], rather than to the amount of time between the taking of the sample and the testing of the sample. On the contrary, CX-106C indicates that the samples were taken at the Niigata factory but were tested at the Niiagata Research Center, almost ensuring that 1-2 minutes elapsed between the time the samples were taken and the time the samples were tested. *Id.* The sitting samples may therefore have caused an artificial increase in reduced coenzyme Q10. See Tr. 191-94; *see also* ID at 228-29 (discussing Kaneka's testing of Shenzhou's samples). Thus, in relying on MGC's test results of the samples shown in CX-106C, Kaneka has not proven that MGC's testing is probative for the same reason as for Kaneka's testing with respect to other respondents' accused products.

B. Construction of "Inert Gas Atmosphere"

The ALJ construed "inert gas atmosphere" to mean "an atmosphere of inert gas (such as nitrogen, carbon dioxide, helium, argon, or hydrogen) that is free or substantially free of oxygen," for the reasons set forth in the ID at 34-37. The ALJ found, *inter alia*, that the specification clearly indicates that the "inert gas atmosphere" of the claims is a way to create a "deoxygenized atmosphere." ID at 35.

Kaneka argues that the construction of inert gas atmosphere was erroneous because it improperly incorporates the "free or substantially free of oxygen" limitation. Kaneka Pet. at 19. Kaneka reasons that "inert" refers to safety, not to prevention of oxidation. *Id.* at 19-21 (citing the '340 patent, col. 17, lines 20-25). Kaneka argues that the portion of the specification relied upon by the ALJ describes an entirely different invention. *Id.* at 21. Kaneka argues that the

U.S. District Court for the Southern District of Texas has construed "inert gas atmosphere" consistent with its proposed construction. Kaneka Pet. at 19 n.3 and 22.[6]

The Respondents argue that the ALJ did not err in construing "inert gas atmosphere." Resp. Rep. at 10. The Respondents assert that "inert gas atmosphere" does not describe a different invention because it appears only one time in the patent, that it is necessary to extraction of reduced coenzyme Q10, and that the patentee added "inert gas atmosphere" as a claim limitation in order to gain allowance of the claims. *Id.* at 11-12 (citing MGC00122087-108, MGC00122115-16). The Respondents argue that no skilled artisan would ever use hydrogen with oxygen present because it is explosive, and the inclusion of hydrogen gas bolsters the ID's finding that the inert gas atmosphere is "free or substantially free of oxygen" regardless of whether the purpose is to protect from oxidation or combustion. *Id.* at 12.

The IA states that in her post-hearing brief she argued that inert gas is a gas which does not cause oxidation of coenzyme Q10 but that the ID's construction of an inert gas as "free or substantially free of oxygen" is not erroneous. IA Rep. at 11. The IA argues that the gases listed in the specification are ones that do not oxidize Q10, whether or not they are combustible. *Id.* (citing Tr. at 274:12-23; 271:17-20).

The Commission has determined to review and affirm the ALJ's construction. The Commission thus adopts the claim construction and reasoning of the ALJ, set forth in the ID at 34-37.[7]

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[6] Kaneka appears to refer to the Order in *Zhejiang Medicine Co. v. Kaneka*, No. H-11-1052 (S.D. Tex.) (August 23, 2012) (Gilmore, J.) (construing claims).

[7] Although they concur in the result, Commissioners Pinkert and Broadbent would rely on the plain meaning of the term "inert gas atmosphere," which requires that the atmosphere of inert gas be "free or substantially free of reactive gases."

C. Invalidity Under 35 U.S.C. § 132

The Respondents argued that claims 22-45 are invalid for inadequate written description and new matter in violation of 35 U.S.C. § 112 and § 132.

The ALJ found that the use of "sealed tank" in the '340 patent does not violate either the written description requirement of 35 U.S.C. § 112 or the new matter prohibition of 35 U.S.C. § 132. ID at 190. The ALJ found that performing an extraction in a "sealed tank" when using solvents was obvious to a person having ordinary skill in the art at the time of the invention of the '340 patent, and would have been reasonably conveyed. *Id.* at 189-90. Further, the ALJ found that Example 7 of the specification, as originally filed, describes a process that requires disruption in a pressure homogenizer sealed with nitrogen gas. *Id.* at 189. The ALJ found that the disrupted solution was then subjected to extraction with no mention of removing the cells from the sealed homogenizer, and one embodiment discloses disruption and extraction at the same time. *Id.* (citing JX-2.044, lines 11-23; the '340 patent, col. 9, lines 17-21). Moreover, the ALJ cited expert testimony concerning the understanding of persons skilled in the art at the time of the invention regarding the use of inert gases and sealed tanks when handling organic solvents. *Id.* at 190.

The Commission has determined not to review the ALJ's finding that claims 22-45 are not invalid by reason of 35 U.S.C. § 112 but to review the ID with respect to § 132. Violations of the new matter prohibition of 35 U.S.C. § 132 may lead to invalidation under 35 U.S.C. § 112 ¶ 1, but 35 U.S.C. § 132 does not itself provide a basis for rejection or invalidation. *See, e.g.*, *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1348 (Fed. Cir. 2010)(*en banc*) ("But § 132 is an examiner's instruction, and unlike § 282 of the Patent Act, which makes the failure to comply with § 112 a defense to infringement, § 132 provides no statutory penalty for a

breach."); *see also* MANUAL OF PATENT EXAMINATION AND PROCEDURE § 2163.06, *Relationship of Written Description Requirement to New Matter* (8th ed., Latest Revision August 2012) ("If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph – written description requirement"). Therefore, we vacate the ALJ's finding on review with respect to 35 U.S.C. § 132.

IV. CONCLUSION

For the foregoing reasons, the Commission has determined, on review (1) to affirm (a) the finding that MGC does not satisfy the 70 mole % limitation and (b) the claim construction of "inert gas atmosphere" with respect to the asserted claims of the '340 patent and (2) to vacate the finding that the asserted claims of the '340 patent are not invalid under the new matter prohibition of 35 U.S.C. § 132.

By order of the Commission.

Lisa R. Barton
Acting Secretary to the Commission

Issued: January 11, 2013

CERTAIN COENZYME Q10 PRODUCTS AND METHODS OF MAKING SAME **337-TA-790**

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served by hand upon the Commission Investigative Attorney, Anne Goalwin, Esq., and the following parties as indicated, on **January 14, 2013**

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN COENZYME Q10 PRODUCTS AND METHODS OF MAKING SAME**	**Inv. No. 337-TA-790**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge Robert K. Rogers, Jr.

(September 27, 2012)

Appearances:

For Complainant Kaneka Corporation:

Joseph J. Zito, Esq.; Craig McLaughlin, Esq.; Benjamin Deming, Esq.; David Tseng, Esq.; James Ahn, Esq.; Sonia Figueroa, Esq. of DNL Zito, Los Angeles, California

For Respondents Zhejiang Medicine Co., Ltd. & ZMC-USA, L.L.C.:

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For Respondents Xiamen Kingdomway Group Company & Pacific Rainbow International Inc.:

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For Respondent Shenzhou Biology & Technology Co., Ltd.:

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For Respondent Maypro Industries, LLC:

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For Respondents Mitsubishi Gas Chemical Co., Inc. & Mitsubishi Gas Chemical America, Inc.:

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For the Commission Investigative Staff:

Lynn I. Levine, Esq., Director; Anne M. Goalwin, Esq., Supervisory Attorney; Aarti Shah, Esq., Investigative Attorney; of the Office of Unfair Import Investigations, U.S. International Trade Commission, of Washington, DC

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PUBLIC VERSION

Pursuant to the Notice of Investigation and Rule 210.42 of the Rules of Practice and Procedure of the United States International Trade Commission, this is the Administrative Law Judge's Final Initial Determination in the matter of Certain Coenzyme Q10 Products & Methods of Making Same, Investigation No. 337-TA-790.

The Administrative Law Judge hereby determines that a violation of Section 337 of the Tariff Act of 1930, as amended, has not been found in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain coenzyme Q10 products and methods of making same, in connection with U.S. Patent No. 7,910,340 ("the '340 patent").

The following abbreviations may be used in this Initial Determination:

CPX	Complainant's physical exhibit
CDX	Complainant's demonstrative exhibit
CX	Complainant's exhibit
CIB	Complainant's initial post-hearing brief
CRB	Complainant's reply post-hearing brief
RPX	Respondents' physical exhibit
RDX	Respondents' demonstrative exhibit
RX	Respondents' exhibit
RIB	Respondents' initial post-hearing brief
RRB	Respondents' reply post-hearing brief
SIB	Commission Investigative Staff's initial post-hearing brief
SRB	Commission Investigative Staff's reply post-hearing brief
Dep.	Deposition
JSRCC	Joint Statement Regarding Claim Construction
JSCI	Joint Stipulation of Contested Issues
JX	Joint Exhibit
Tr. at	Transcript
CPHB	Complainant's pre-hearing brief
RPHB	Respondents' pre-hearing brief
SPHB	Commission Investigative Staff's pre-hearing brief

I. BACKGROUND

A. Procedural History

On July 14, 2011, the Commission issued a Notice of Investigation in this matter to determine:

> [W]hether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain coenzyme Q10 products and methods of making same that infringe one or more of claims 1–45 of the '340 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

(*See* Notice of Investigation.) The investigation was instituted upon publication of the Notice of Investigation in the *Federal Register* on July 19, 2011. *See* 76 Fed. Reg. 42729-30 (2011); 19 CFR § 210.10(b).

The complainant is Kaneka Corporation, 3-2-4 Nakanoshima, Kita-ku, Osaka 530-8288, Japan ("Kaneka"). The respondents are Zhejiang Medicine Co., Ltd., Zhejiang, China; ZMC-USA, L.L.C., The Woodlands, Texas (collectively "ZMC"); Xiamen Kingdomway Group Company ("XKGC"), Xiamen, China; Pacific Rainbow International ("PRI"), City of Industry, California; Mitsubishi Gas and Chemical Company, Tokyo, Japan; Mitsubishi Gas Chemical America, Inc. New York City, New York, (collectively "MGC"); Maypro Industries, LLC ("Maypro"), Purchase, New York; Shenzhou Biology and Technology Co., Ltd. ("Shenzhou"), Beijing, China. The Commission Investigative Staff of the Office of Unfair Import Investigations ("Staff") is also a party in this investigation.

On December 22, 2011, I issued Order No. 10, an Initial Determination granting complainants' motion to amend the complaint and notice of investigation to add a new respondent, Mitsubishi Gas Chemical America, Inc. and to replace respondent Maypro

Industries, Inc. with Maypro Industries, LLC. On January 12, 2012, the Commission issued a Notice indicating that it would not review Order No. 10.

On February 14, 2012, I issued Order No. 13, adopting material undisputed facts pursuant to Commission Rule 210.18(e), finding that Material Fact No. 4, which stated {

} was established.

On June 4, 2012, I issued Order No. 37, finding that there was no genuine dispute of material fact that {

} satisfying the "sale" prong of the on-sale bar.

On June 12, 2012, I issued Order No. 42, an Initial Determination that ZMC does not infringe claims 2, 5-8, 12, 16-19, 23, 26-28, 32, 34, 38-40, and 45. On June 29, 2012, the Commission issued a Notice indicating that it would not review Order No. 42.

On July 9, 2012, I granted Respondents Motion In Limine No. 3, precluding Kaneka from arguing infringement under the doctrine of equivalents. (Tr. at 23:23-24.)

On July 9, 2012, without opposition from the parties, I ordered that no evidence be presented with respect to Maypro. (Tr. at 10:21-12:12.)

An evidentiary hearing in this investigation was held on July 9-13, 2012.

B. The Private Parties

1. Kaneka

Kaneka is a corporation organized and existing under the laws of Japan with its principal place of business at 3-2-4, Nakanoshima, Kita-ku, Osaka 530-8288, Japan. (Amended Complaint at ¶ 5.) Prior to September 2004, Kaneka was known as Kanegafuchi Chemical Industry Co., Ltd. (*Id.*)

2. Shenzhou

Shenzhou is a Chinese corporation with its principal place of business at No. 61 Zhichun Road, Haidan District, Beijing, 100190, China. (Shenzhou Resp. to Amended Complaint at ¶ 15.)

3. XKGC

XKGC is a Chinese corporation with its principal place of business at No. 33-35 Xinchang Road, Haicang, Xiamen 361022, China. (XKGC and PRI Resp. to Amended Complaint at ¶ 10.)

4. ZMC Respondents

Zhejiang Medicine Company, Ltd. is a Chinese corporation with its principal place of business at No. 268 Dengyun Road, Gongshu District, Hangzhou, Zhejiang 310011, China. (ZMC Resp. to Amended Complaint at ¶ 8.) ZMC USA L.L.C. is a Texas corporation with its principal place of business at 1776 Woodstead Court, Suite 215, The Woodlands, Texas 77380. (*Id.* at ¶ 9.) ZMC USA L.L.C is a subsidiary of ZMC that was established to serve the North American market. (*Id.*)

5. Maypro

Maypro Industries, L.L.C. is a New York corporation with its principal place of business at 2975 Westchester Avenue, Purchase, New York, 10577. (Maypro Resp. to Amended Complaint at ¶ 14.)

6. MGC

Mitsubishi Gas and Chemical Company is a Japanese corporation with its principal place of business at Mitsubishi Building, 5-2, Marunouchi 2-chome Chiyoda-ku, Tokyo 100-8324, Japan. (MGC Resp. to Amended Complaint at ¶ 12.) Mitsubishi Gas Chemical America, Inc. is

a Delaware corporation with its principal place of business at 655 Third Avenue, 24th Floor, New York, NY 10017. (Amended Complaint at ¶ 13; MGC Resp. to Amended Complaint at ¶ 13.)

7. PRI

PRI is a California corporation with its principal place of business at 19905 Harrison Ave., City of Industry, California 91789. (XKGC and PRI Resp. to Amended Complaint at ¶ 11.)

C. Overview Of The Patent At Issue

U.S. Patent No. 7,910,340 is entitled "Processes for producing coenzyme Q10." (JX-1.) It lists Kazuyoshi Yajima, Takahisa Kato, Akihisa Kanda, Shiro Kitamura, and Yasuyoshi Ueda as the inventors. (*Id.*) It was filed on October 31, 2007 and issued on March 22, 2011. (*Id.*) The Abstract of the '340 patent states:

> The present invention relates to a process for producing reduced coenzyme Q10 which comprises obtaining microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10, optionally disrupting the cells and recovering thus-produced reduced coenzyme Q10. The present invention also relates to a process for producing oxidized coenzyme Q10 which comprises either recovering oxidized coenzyme Q10 after oxidizing the above-mentioned microbial cells or disrupted product thereof, or recovering reduced coenzyme Q10 from the above-mentioned microbial cells or disrupted product thereof to oxidize thus-obtained reduced coenzyme Q10 thereafter. According to the processes of the present invention, reduced coenzyme Q10 and oxidized coenzyme Q10 can be produced simply on the industrial scale.

(JX-1 at Abstract.)

D. Products At Issue

Kaneka accuses the following ZMC products of infringing claims 1, 3, 4, 9-11, 13-15, 20-22, 24, 25, 29-31, 33, 35-37, and 41-44 of the '340 patent: coenzyme Q10 (ubidecarenone);

coenzyme Q10 powder 10%/20%/40% CWS; coenzyme Q10 powder 50% TAB; coenzyme Q10 98%; and oxidized coenzyme Q10, in bulk form. (CIB at 9.)

Kaneka accuses the following XKGC products of infringing claims 1, 4-6, 9, 11, 15-17, 20, 22, 25, 27, 29, 30, 33, 37-39, 41, 43, and 45 of the '340 patent: coenzyme Q10 nano-emulsion 1%, 5%, and 10%; coenzyme Q10 40% CWS food grade; pharmaceutical grade coenzyme Q10; coenzyme Q10 powder, USP; coenzyme Q10 powder, water soluble powder 10%; United States pharmaceutical grade coenzyme Q10; coenzyme Q10 10% CWS food grade; and coenzyme Q10 20% CWS food grade. (CIB at 10.)

Kaneka accuses the following MGC products of infringing claims 1, 2, 4, 9, 10-12, 14-15, 20-23, 25, 29-31, 33-34, 36-37, 41-43, and 44 of the '340 patent: Bio Q10; BioQ10 coenzyme Q10 ubidecarenone; microactive CoQ10; PureSorbQ10; BioQ10 EX; BioQ10 SA; bulk ubidecarenone (coenzyme Q10); natural coenzyme Q10; BIO Q10 emulsifiable concentrate 10% - discontinued prior to 3/22/2011; BioQ10 WD powder 10%; BIOQ10 beads 40%; BIOQ10 CD Complext; and coenzyme Q10 MIX. (CIB at 10.)

Kaneka accuses the following Shenzhou products of infringing claims 1, 3-4, 6, 8-11, 13-15, 17, 19-22, 24-25, 27, 29-33, 35-37, 39, and 41-45 of the '340 patent: bulk ubidecarenone (coenzyme Q10); and coenzyme Q10. (CIB at 10.)

II. JURISDICTION

A. Subject Matter Jurisdiction

The complaint alleges that Shenzhou, XKGC, ZMC, Maypro, MGC, and PRI have violated Subsection 337(a)(1)(B) by the importation and/or sale of products produced by methods that infringe the asserted patent. With a single exception, Respondents do not contest

that the accused coenzyme Q10 products are imported and do not contest that the Commission has subject matter jurisdiction in this investigation. (RIB at 7-8.)

Regarding the one exception, Kaneka has relied upon a stipulation from ZMC-USA and the parties' joint stipulation of contested issues that was filed on May 15, 2012 to assert that the accused ZMC products are imported into the United States. (CIB at 9 and 152.) The joint stipulation of contested issues provides that the issues of "Sale for Importation" and "Importation and Sale after Importation" are "not contested." (JSCI at 2.) ZMC did not address this issue in its pre-trial brief. (*See* RPHB.) ZMC cannot now contest an issue it said was "not contested" in the joint stipulation of contested issues and did not address in the pre-hearing brief. (Ground Rules 8.2-8.3.)

Assuming *arguendo* that ZMC had not waived its right to contest importation of certain products, ZMC does not contest the statements in the February 17, 2012 stipulation by ZMC-USA that {

} and {

} Because "oxidized Coenzyme Q10, in bulk form" is an accused product, Kaneka has shown importation of an accused ZMC product.

Based on the foregoing, I find that the Commission has subject matter jurisdiction over this investigation under Section 337 of the Tariff Act of 1930. *See Amgen, Inc. v. United States Int'l Trade Comm'n*, 902 F.2d 1532, 1536 (Fed. Cir. 1990).

B. Personal Jurisdiction

Shenzhou, XKGC, ZMC Respondents, Maypro, MGC, and PRI each responded to the complaint and notice of investigation, participated in the investigation, made an appearance at the hearing, and with the exception of Maypro, submitted joint post-hearing briefs. Thus, I find

that Shenzhou, XKGC, ZMC Respondents, Maypro, MGC, and PRI submitted to the personal jurisdiction of the Commission. *See Certain Miniature Hacksaws*, Inv. No. 337-TA-237, Initial Determination, 1986 WL 379287 (October 15, 1986).

C. In Rem Jurisdiction

With a single exception, the Respondents do not contest that the accused coenzyme Q10 products are imported into the United States. I rejected ZMC's opposition to jurisdiction in Section II.A, *supra*. In view of the foregoing, I find that the Commission has *in rem* jurisdiction over the products at issue by virtue of the finding that accused products have been imported into the United States. *See Sealed Air Corp. v. United States Int'l Trade Comm'n*, 645 F.2d 976, 985 (C.C.P.A. 1981).

III. CLAIM CONSTRUCTION

A. Applicable Law

"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 (1996) (citation omitted). Claim construction "is a matter of law exclusively for the court." *Id.* at 970-71. "The construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims." *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000). "[O]nly those [claim] terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Claim construction focuses on the intrinsic evidence, which consists of the claims themselves, the specification, and the prosecution history. *See generally Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). The Federal Circuit in *Phillips* explained that in construing terms, courts must analyze each of these components to determine the "ordinary and customary meaning of a claim term," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313.

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Id.* at 1312 (citations omitted). "Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Id.* at 1314. For example, "the context in which a term is used in the asserted claim can be highly instructive," and "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term." *Id.*

"[T]he 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.'" *Id.* (citation omitted). "The longstanding difficulty is the contrasting nature of the axioms that (a) a claim must be read in view of the specification and (b) a court may not read a limitation into a claim from the specification." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004). The Federal Circuit has explained that there are certain instances when the specification may limit the meaning of the claim language:

> [O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs. In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct

> claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive.

Phillips, 415 F.3d at 1316.

In addition to the claims and the specification, the prosecution history should be examined if in evidence. "The prosecution history…consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent. Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Id.* at 1317 (citation omitted). "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

If the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence may be considered. Extrinsic evidence consists of all evidence external to the patent and the prosecution history, including dictionaries, inventor testimony, expert testimony and learned treatises. *Id.* at 1317. Extrinsic evidence is generally viewed "as less reliable than the patent and its prosecution history in determining how to read claim terms[.]" *Id.* at 1318. "The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

"Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one. However, such a result can ensue when the method steps implicitly require that they be performed in the order written." *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001) (citing *Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d

1313, 1322 (Fed.Cir.1999)) (internal citations omitted). This determination requires a two-part test to decide whether or not the steps of a method claim that do not otherwise recite an order must be performed in the order in which they are written. *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369-1370 (Fed. Cir. 2003) (citing *Interactive Gift* 256 F.3d at 1342-43).

First, I must look to the claim language to determine if logic or grammar requires they be performed in the order written. *Id.* (citing *Interactive Gift* 256 F.3d at 1343). In *Loral Fairchild Corp. v. Sony Electronics Corp.*, the Federal Circuit held that the claim language required the steps be performed in their written order because the second step required the alignment of a second structure with a first structure that was formed by the first step. 181 F.3d 1313, 1321 (Fed.Cir.1999); *see also Altiris, Inc. v. Symantec Corp.*, 318 F.3d at 1370. If the first part of the test is not met, I must look to the rest of the specification to determine whether or not it directly or implicitly requires the steps be performed in the order written. *Altiris, Inc. v. Symantec Corp.*, 318 F.3d at 1370 (citing *Interactive Gift* 256 F.3d at 1343). If the second part of the test also is not met, the sequence in which such steps are written is not a requirement. *Altiris, Inc. v. Symantec Corp.*, 318 F.3d at 1370.

B. The '340 patent

1. Level of Ordinary Skill in the Art

Kaneka contends that one of ordinary skill in the art would have a bachelor's degree in microbiology, biology, chemistry, chemical engineering or the equivalent, along with 2 to 5 years of experience working in the field of industrial microbiology or biotechnology preferably as it relates to industrial bioprocesses. (Citing CX-653C, Q. 18; RX-129C, Q. 5-5; RX-367C, Q. 130; RX-435C, Q. 192.) Respondents contend that a person of ordinary skill in the art would have had an advanced degree, such as a master's degree or Ph.D., in biology, microbiology,

biochemistry, chemistry, chemical engineering, biochemical engineering, bioengineering, agricultural sciences, or a related discipline, or, in the alternative, less education and approximately five or more years of relevant industry experience. (Citing RX-623C, Q. 63; RX-367C, Q. 130; RX-435C, Q. 192.) Staff contends that the differences between the private parties' positions are not so significant that they impact the analysis of claim construction or invalidity.

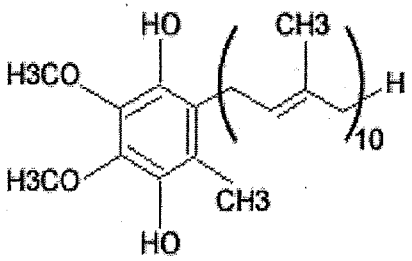
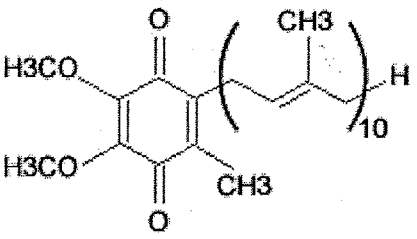
The '340 patent addresses specific and detailed aspects of producing coenzyme Q10, not just coenzyme Q10 in general. Specifically, the '340 patent focuses on distinctions between two different forms of coenzyme Q10—reduced and oxidized—and ways to manipulate the presence of each. (JX-1 at 1:66-2:8, 2:24-27, 3:15-30, 3:33-39.) In discussing the prior art, the '340 patent says that "microbial cells containing reduced coenzyme Q10 at high ratio have not been reported yet." (JX-1 at 16-17.) Moreover, the '340 patent does not address producing coenzyme Q10 on merely a laboratory scale; rather, the '340 patent concerns the process for safe and efficient production of coenzyme Q10 on an industrial scale. (*See* JX-1 at 3:33-4:36.) In discussing the prior art, the '340 patent says that a fermentation production of reduced coenzyme Q10 on an industrial scale "has not been known." (JX-1 at 3:17-24.)

Because the '340 patent addresses specific and detailed aspects of producing coenzyme Q10 on an industrial scale, I find that a bachelor's degree alone is insufficient for one to possess ordinary skill in the art related to the invention of the '340 patent. Dr. Taylor explained that a person with an advanced degree (such as a master's degree with two or more years of experience or a Ph.D.) would have familiarity with common industrial safety practices such as use of inert gases and metal tanks for handling organic solvents. (RX-367C, Q. 130.) Based on this testimony (and the complex nature of the '340 patent), I find that one of ordinary skill in the art

at the time of the '340 patent would have had an advanced degree (either a master's degree or a Ph.D.) in biology, microbiology, biochemistry, chemistry, chemical engineering, biochemical engineering, bioengineering, agricultural sciences, or a related discipline plus at least two years of experience working in the field of industrial microbiology or biotechnology preferably as it relates to industrial bioprocesses. Alternatively, a person of ordinary skill in the art could have less education, i.e. only a bachelor's degree, with at least five years of work experience.

2. Agreed-Upon Constructions

The parties have agreed on the following constructions:

Term	Construction
coenzyme Q10	a substance that comes in two forms, reduced coenzyme Q10 and oxidized coenzyme Q10
reduced coenzyme Q10	a chemical compound having the structure: 
oxidized coenzyme Q10	a chemical compound having the structure: 
oxidizing agent	a reagent other than ambient air that is used to oxidize the reduced coenzyme Q10

These agreed-upon constructions shall be applied in this Initial Determination.

3. "Reduced Coenzyme Q10-Producing Microorganisms"

The phrase "reduced coenzyme Q10-producing microorganisms" appears in asserted claims 1, 11, 22, and 33.

Kaneka's Position: Kaneka contends that "reduced coenzyme Q10-producing microorganisms" should be given its plain and ordinary meaning, which is "microorganisms capable of producing reduced coenzyme Q10."

Kaneka asserts there is no other supported meaning for this claim language. Kaneka argues that the 70 mole % limitation imposed by Respondents and Staff is improper and redundant, as the claims already include such language. (Citing JX-1 at Claims 1, 11, 22, 33.) Kaneka states that the inclusion of a limitation concerning a 10ml experimental sample found in the specification would improperly import limitations from the specification, and is not consistent with the industrial scale of the claimed processes.

Respondents' Position: Respondents contend that "reduced coenzyme Q10-producing microorganisms" means "microorganisms that produce reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzyme Q10 when cultured and assayed under the standard conditions set forth at col. 4, line 51 to col. 5, line 43 and Example 1 of the '340 patent."

Respondents assert that the specification set forth a screening method to determine whether or not a microorganism qualifies as a "reduced coenzyme Q10-producing microorganism." (Citing JX-1 at 4:51-5:43.) Respondents state that Example 1 in the specification applies this screening method to 68 different microorganisms. (Citing JX-1 at 17:45-67, 18:1-20:33; Tr. at 337:21-342:3, 1170:2-1175:25.) Respondents therefore claim that one of ordinary skill in the art would understand that "reduced coenzyme Q10-producing

microorganisms" are microorganisms capable of producing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10 under the standard screening methods of the '340 patent. (Citing RX-435C, Q. 283; RX-473C, Qs. 52, 58.)

Respondents argue that Kaneka's proposed construction would make the expressions "coenzyme Q10-producing microorganism" and "reduced coenzyme Q10-producing microorganism" identical in scope because coenzyme Q10-producing microorganisms will always be capable of producing reduced coenzyme Q10. (Citing RX-473C, Q. 57; Tr. at 335:1-336:20.) Respondents assert that Dr. Connors admitted that Kaneka's construction would read the term "reduced" out of the claim. (Citing Tr. at 335:1-336:20.)

Respondents claim that there is no recognized method for assaying the ratio of reduced coenzyme Q10, and the assay itself can affect the ratio. (Citing RX-435C, Qs. 289-290; RX-473C, Qs. 70-76.) Respondents state that given the dependence of the ratio on the culturing conditions and assay methods, the claims would be indefinite in the absence of some disclosure of a way to ascertain the ratio. (Citing RX-473C, Qs. 61-62; Tr. at 174:14-182:7, 187:16-200:24, 310:14-21.)

Staff's Position: Staff contends that "reduced coenzyme Q10-producing microorganisms" means "microorganisms that produce reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzyme Q10 when cultured and assayed under the standard conditions set forth at col. 4, line 51 to col. 5, line 43 and Example 1 of the '340 patent."

Staff claims that the evidence shows that almost all microorganisms produce, or are capable of producing, reduced coenzyme Q10. (Citing RX-348C, Qs. 206, 210.) According to Staff, these facts render Kaneka's proposed construction virtually meaningless.

Staff states that the amount and proportion of reduced coenzyme Q10 produced by microorganisms is highly dependent upon the conditions of culture. (Citing RX-348C, Q. 206.) Staff states that the specification describes a process for identifying whether or not microorganisms are suitable for use in the claimed processes. (Citing JX-1 at 4:50-65.) Therefore, Staff believes that the correct construction should incorporate the discussion in the specification regarding how to determine the microorganisms that may be successfully used with the claimed invention. (Citing RX-435C, Qs. 286-292; RX-348C, Q. 206.)

Construction to be applied: I find that no construction is necessary for this term.

Each of independent claims 1, 11, 22, and 33 requires "culturing reduced coenzyme Q10-producing microorganisms." The parties dispute the meaning of "reduced coenzyme Q10-producing microorganisms." Respondents and Staff contend that the term should be construed to limit the claims based on a culturing method disclosed in the '340 patent specification. (JX-1 at 4:51-5:43.) According to Respondents and Staff, this passage provides a screening method to determine which microorganisms are suitable for use in the claimed invention.

I do not concur that the claim language should be limited based on the cited passage in the specification. The passage recites in relevant part:

> How much ratio the microorganisms can produce reduced coenzyme Q10 among the entire coenzymes Q10 can be evaluated, ***for example***, by a method comprising culturing the microorganisms with shaking (amplitude: 2 cm, 310 reciprocation/min) at 25° C. for 72 hours in 10 mL of a culture medium [(glucose: 20 g, peptone: 5 g, yeast extract: 3 g, malt extract: 3 g)/L, pH: 6.0] using a test tube (inner diameter: 21 mm, entire length: 200 mm).
>
> Although the preferable culture conditions for the fermentation production on the industrial scale will be described later, ***the above-mentioned culture condition is one method for standardizing the ratio of reduced coenzyme Q10 produced***, which microorganisms have as its ability, so as to reflect the ratio within the range without having significant inaccuracies.

(JX-1 at 4:51-65) (emphasis added). It concludes with the following:

> The above-mentioned measurement method is provided for the obtained result to reflect the reduced coenzyme Q10 content and the ratio of reduced coenzyme Q10 among the entire coenzymes Q10 as accurate as possible, and to standardize the content and the ratio of reduced coenzyme Q10, which can be guaranteed at the minimum. This method has been demonstrated, by several experimentations performed by the present inventors, easy and suitable to be carried out.

(*Id.* at 5:36-43.)

I find nothing in the passage from column 4, line 51 to column 5, line 43 that demonstrates an intention on the part of the patentees to limit the meaning of the claim term "reduced coenzyme Q10-producing microorganisms." To the contrary, the above-quoted passages show that the disclosed method is exemplary, and is just "one method" that may be used. (JX-1 at 4:51-65, 5:36-43.) Limiting the claims based on such an exemplary disclosure in the specification is clearly improper. *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1287 (Fed. Cir. 2010) ("It is…important not to confuse exemplars or preferred embodiments in the specification that serve to teach and enable the invention with limitations that define the outer boundaries of claim scope.").

Kaneka's proposed construction merely seeks to re-arrange the words of the claims, and does not provide any further edification regarding the meaning of those terms. Further, Kaneka's proposed construction adds capability language that is not found in the claims. Thus, I find no basis to adopt Kaneka's proposed construction.

Beyond the dispute addressed *supra*, the parties do not raise any further dispute regarding the meaning of "reduced coenzyme Q10-producing microorganisms." Because I have established that the claims are not limited by the culturing method disclosed in the specification, there is no further dispute to resolve concerning "reduced coenzyme Q10-producing microorganisms." Therefore, I conclude that no claim construction is necessary.

4. "Microorganisms"

Kaneka's Position: Kaneka contends that "microorganisms" should be afforded its plain and ordinary meaning, without further elaboration.[1]

Kaneka notes that Respondents other than MGC seek to limit the term to "non-photosynthetic bacteria or yeast." Kaneka argues that this is incorrect because the '340 patent specification clearly imposes no limitation on the type of bacteria, yeast, or fungi that may be used in the invention. (Citing JX-1 at 5:44-49.)

Kaneka claims that Respondents' argument is based on an incorrect application of prosecution history disclaimer. According to Kaneka, the portion of the prosecution cited by Respondents comes from the prosecution of the parent application to the '340 patent, at a time when the claims themselves specifically recited "non-photosynthetic bacteria or yeast." Kaneka states that the '340 patent claims do not include any such limitation. Kaneka states that it would improper to import arguments from a different patent application, related to a different claim, and different inventions.

Respondents' Position: All of the Respondents with the exception of MGC[2] contend that "microorganisms" means "non-photosynthetic bacteria or yeast."

Respondents state that during the prosecution of the '249 patent application, which is the parent application to the '340 patent, the applicants amended the sole independent claim to change "microorganisms" to "nonphotosynthetic bacteria or yeast." (Citing JX-3; RX-504 at 2, 8.) Respondents state that Kaneka relied on this amended claim to distinguish the invention from

[1] Kaneka's assertion of "plain and ordinary meaning," without further elaboration, does not rise to the level of a proposed construction. *See, e.g., O2 Micro Int'l Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008); *Maytag Corp. v. Electrolux Home Prods., Inc.*, 411 F. Supp. 2d 1008, 1037 (N.D. Iowa 2006); *Certain Semiconductor Integrated Circuits and Products Containing Same*, Inv. No. 337-TA-665, Order No. 19 (April 8, 2009).

[2] MGC would accept the plain and ordinary meaning of "microorganisms," as specified by Kaneka.

a prior art reference, which described culturing of photosynthetic bacteria of the genus *Rhodobacter*. (Citing JX-3; RX-504 at 8-9.) Moreover, Respondents note that the '249 application and the '340 patent share a materially identical specification that teaches away from the use of photosynthetic bacteria because such bacteria are not expected to produce a sufficient ratio of reduced coenzyme Q10. (Citing JX-1 at 3:1-6; RX-413 at 4:16-21.)

Respondents argue that precedent establishes that the statements made in the prosecution history of a parent application can limit the scope of claims found in later patents. Respondents assert that the statements made during the '249 patent application prosecution should apply with equal force to the claims of the '340 patent because the specifications are materially identical, the relevant claim limitation is identical in nature and scope, and the only substantive difference between the claimed processes in the '249 application and the '340 patent is irrelevant to the "microorganisms" issue.

Staff's Position: Staff contends that "microorganisms" means "non-photosynthetic bacteria or yeast."

Staff states that the '249 application was the parent to the application that resulted in the '340 patent. Staff states that during the prosecution of the '249 application, the applicants amended the first claim of the application to replace "microorganisms" with "non-photosynthetic bacteria or yeast." (Citing JX-2 at MGC00121769.) Staff states that the applicants then distinguished their invention from prior art that used photosynthetic bacteria. (Citing *id.* at MGC00121775-6.) Staff claims that the '340 patent specification further distinguishes the invention from the prior art based on the use of photosynthetic bacteria in the prior art. (Citing JX-1 at 2:50-55, 3:1-6.)

Staff argues that this disclaimer made during prosecution of the '249 application should apply to the claims of the '340 patent. According to Staff, the applications clearly and unambiguously stated that their invention did not encompass the use of photosynthetic bacteria or yeast, and did not so to overcome a prior art rejection. Staff believes that Kaneka cannot try to recapture what it gave up to avoid a prior art rejection. Staff argues that this is supported by the specification of the '340 patent, which again distinguishes the invention from prior art which used photosynthetic yeast. (Citing JX-1 at 3:1-6.)

Discussion and Conclusions: The parties do not materially dispute the construction of "microorganisms," other than arguing whether or not it includes a limitation requiring "non-photosynthetic bacteria or yeast." I decline to include such a limitation in the construction for the reasons set forth below.

The '340 patent uses the term "microorganisms" in multiple claims. For example, claims 1, 11, 22, and 33 each require "culturing reduced coenzyme Q10-producing microorganisms in a culture medium...."

The '340 patent issued from an application that was a division of application No. 10/500,249 ("the '249 application"), which was later abandoned. (JX-1.) Respondents and Staff argue that statements made during the prosecution of the '249 application limit the meaning of "microorganisms" in the '340 patent. Specifically, Respondents and Staff seek to limit the term to mean "non-photosynthetic bacteria or yeast."

During prosecution of the '249 application, the applicants amended the claim language in claim 1 to remove the term "microorganisms" and replace it with the more limited term "nonphotosynthetic bacteria or yeast." (JX-2 at MCG00121769.) The applicants then argued that the amended claim was allowable over the prior art. The applicants stated that "[a]ccording

to the amendment, the invention of Claim 1 is restricted to the process for producing reduced coenzyme Q10 by using nonphotosynthetic bacteria or yeast." (*Id.* at MGC00121775.) The applicants noted that the Venturoli prior art reference "discloses UQ pool analysis of *Rhodobactor*, which is a photosynthetic bacterium." (*Id.* at MGC00121776.) The applicants further stated that another prior art reference, Wakabayashi "is also improper as a reference related to the present invention drawn to the process for producing reduced coenzyme Q10 by using nonphotosynthetic bacteria or yeast." (*Id.*)

Respondents and Staff allege that prosecution disclaimer applies here, in that the term "microorganism" must be limited to "non-photosynthetic bacteria or yeast" because of the applicants' statements in the '249 application prosecution described *supra*. I do not concur. Respondents and Staff ignore the key difference between the '249 application and the '340 patent. Claim 1 of the '249 application was amended to replace "microorganism" with "nonphotosynthetic bacteria or yeast." The claims of the '340 patent use the term "microorganism," and do not include the phrase "nonphotosynthetic bacteria or yeast."

"[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003). "[P]rosecution disclaimer may arise from disavowals made during the prosecution of ancestor patent applications." *Id.* at 1333.

The Federal Circuit has explained that "the doctrine of prosecution disclaimer generally does not apply when the claim term in the descendant patent uses different language." *Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1182 (Fed. Cir. 2006). In *Ventana*, the plaintiff argued that prosecution history disclaimer applied when the alleged disclaimer occurred

in an ancestor application to the patent-in-suit. The Federal Circuit found that the allegedly disclaiming statements were made in reference to a claim limitation that was not present in the patent-in-suit, and therefore rejected the prosecution disclaimer argument. *Id.*; *see also Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1078 (Fed. Cir. 2005) ("[T]he prosecution of one claim term in a parent application will generally not limit different claim language in a continuation application."). Because the alleged disclaiming statement concerns more narrow claim language found in the '249 application that is not present in the '340 patent, I find no basis to conclude that the prosecution history of the '249 application limits the meaning of "microorganism" in the '340 patent.

Respondents and Staff also point to the specification of the '340 patent. I find nothing in the '340 patent specification that amounts to a "clear disavowal" of claims scope regarding the term "microorganisms." *See Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366-1367 (Fed. Cir. 2012) (describing the "exacting" standard for finding a disavowal of claim scope in the specification).

The specification states that "[i]n terms of the culture easiness and productivity, bacteria (preferably nonphotosynthetic bacteria) and yeast are preferred." (JX-1 at 6:9-11.) Stating a preference for nonphotosynthetic bacteria does not amount to a clear disclaimer of photosynthetic bacteria. *See Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380-1381 (Fed. Cir. 2009) (noting that a list of "preferred animals" described in the specification does not serve to limit claim scope).

The specification also includes a section addressing the prior art. The specification describes the following prior art reference:

> (1) An example describing that at lowest 5 to 10% by weight and at highest 30 to 60% by weight of reduced coenzyme Q10 are present among the entire

> coenzymes Q10 in culture cells of photosynthesis bacteria (Japanese Kokai Publication Sho-57-70834).

(JX-1 at 2:50-54.) The specification explains why this prior art reference does not provide a sufficient method for producing reduced coenzyme Q10:

> Both of the above (1) and (2) aim to convert a mixture of the obtained reduced coenzyme Q10 and oxidized coenzyme Q10 or the obtained reduced coenzyme Q10 into oxidized coenzyme Q10 by further oxidation. Thus, reduced coenzyme Q10 is only described as an intermediate substance in producing oxidized coenzyme Q10.
> In the above (1), photosynthesis bacteria are used, the culture of which is complicated. Furthermore, in the microbial cells of the above-mentioned microorganisms, when the production of reduced coenzyme Q10 is aimed at, it cannot be said that the ratio of reduced coenzyme Q10 among the entire coenzymes Q10 is sufficient.

(JX-1 at 2:62-3:6.)

Respondents and Staff focus on the sentence stating that in the prior art, "photosynthesis bacteria are used, the culture of which is complicated." While that statement identifies a disadvantage of using "photosynthesis bacteria," nothing in the passage clearly indicates that the invention disavows the use of photosynthetic bacteria. The specification states that the prior art process at issue cannot generate the sufficient ratio of reduced coenzyme Q10 among the entire coenzymes Q10; but it does not clearly state that this is necessarily due to the fact that the prior art utilizes "photosynthesis bacteria." (JX-1 at 2:62-3:6.) After identifying the disadvantage regarding photosynthetic bacteria, the specification states that "[f]urthermore," a sufficient ratio cannot be reached using the prior art process. Inclusion of the word "furthermore" implies that the ratio problem is a separate issue from the photosynthetic bacteria issue.

Based on the foregoing, I find that there is no evidence in the intrinsic record to support limiting "microorganisms" to ""non-photosynthetic bacteria or yeast."

5. "Extracting"

The term "extracting" appears in asserted claims 1, 11, 19, 22, 33, and 45.

Kaneka's Position: Kaneka contends that "extracting" means "the step of removing coenzyme Q10 from the microbial cells by use of an organic solvent." (Citing CX-653C, Qs. 38-39; CX-242C at ¶¶ 67-72; CX-206C at ¶¶ 69-73; CX-184C at ¶¶ 67-71; CX-161C at ¶¶ 67-70.)

Kaneka notes that the difference between its proposed construction and Respondents' proposed construction is Kaneka's use of the term "removing" and Respondents' use of the term "separating." Kaneka states that one of ordinary skill in the art would understand that where the word "extracting" is used in conjunction with the phrase "organic solvent," the process is necessarily one where the desired target is removed from the cell. (Citing CX-653C, Q. 39.) Kaneka states that Respondents' use of "separating" connotes a purification step that is not called for by the claims of the '340 patent. (Citing *id.*)

Kaneka claims that the specification explains that the coenzyme Q10 is "recovered" by extracting. (Citing JX-1 at 10:47-49.) Kaneka asserts that the use of the word "recovered" implies the unilateral action of removal of one substance from the other. (Citing JX-1 at 16:4-5, 17:19-20, 60:15-19.)

Respondents' Position: Respondents contend that "extracting" means "separating coenzyme Q10 from the microbial cells."

Respondents assert that Example 7 of the '340 patent explains that solvents are utilized in the extraction process to separate the coenzyme Q10 into a distinct upper layer. (Citing JX-1 at 22:13-18.) Respondents state that multiple scientific dictionaries support their proposed construction of "extracting." (Citing RX-43; RX-44.)

Respondents state that Kaneka incorrectly believes that "extracting" means "removing" coenzyme Q10 from the cell. Respondents claim that the '340 patent makes clear that extraction and disruption are separate processes, and discloses numerous "disruption" methods that would result in removing the coenzyme Q10 from the cell. (Citing JX-1 at 9:32-10:7.) Respondents claim that the prior art similarly makes distinctions that show that "extracting" is not synonymous with "removing." (Citing RX-66 at 2:32-35, 2:60-3:14; RX-69 at 1:22-28.)

Staff's Position: Staff contends that "extracting" means "separating coenzyme Q10 from the microbial cells."

Staff states that the evidence shows that in the '340 patent, the purpose of the extraction step is to isolate the coenzyme Q10 from the cell remnants and other particles. (Citing JX-1 at 10:47-16:59; RX-623C, Q. 83.) Staff states that the evidence additionally shows that after the disruption step, the coenzyme Q10 is not necessarily present in the cells, because the cells are no longer intact, and much of the coenzyme Q10 is no longer within the cells. Thus, Staff believes that "extraction" does not refer to "removing" the coenzyme Q10 from the cells but rather refers to separating out the Q10 from the cell remnants.

Construction to be applied: "recovering coenzyme Q10 from the microbial cells."

The term "extracting" is used similarly in multiple asserted claims. For example, claim 1 requires "extracting the oxidized coenzyme Q10 by an organic solvent under an inert gas atmosphere." Claim 11 requires "extracting the reduced coenzyme Q10 by an organic solvent under an inert gas atmosphere." Claim 22 requires "extracting the oxidized coenzyme Q10 by an organic solvent in a sealed tank." Claim 33 requires "extracting the reduced coenzyme Q10 by an organic solvent in a sealed tank."

While each of the independent claims requires an extraction step, only two of the four claims require a disruption step. Specifically, claims 1 and 22 require "disrupting the microbial cells to obtain reduced coenzyme Q10," and the disruption step occurs before the extraction step. (*See* JX-1 at 24:20-25, 25:51-55.) Claims 11 and 33 require extraction, but are silent with regard to disruption. The '340 patent addresses the relationship between extraction and disruption in the following manner:

> In the extraction, cells can be disrupted optionally. The cell disruption contributes to the efficient extraction of the reduced coenzyme Q10 produced and accumulated in cells. It is needless to say that the cell disruption and extraction can be carried out at the same time.
>
> Incidentally, "disruption" in the present invention may be carried out to the extent that the surface structure such as a cell wall is broken so as to make extraction of reduced coenzyme Q10 possible; therefore, it is not necessary that microbial cells are torn or fragmentated.
>
> The above-mentioned cell disruption is not necessarily required in the case of bacteria. However, in the case of yeast or fungi, the cell disruption is generally required and, when cells are not disrupted, it becomes difficult to efficiently recover the reduced coenzyme Q10 produced and accumulated in the cells.

(JX-1 at 9:17-32.) The specification therefore makes clear that disruption is optional, disruption contributes to the efficient extraction of reduced coenzyme Q10, and disruption and extraction can be carried out at the same time.

The specification also addresses extraction. The specification explains that "[r]ecovery of reduced coenzyme Q10 is carried out by extraction from the microbial cells obtained by the above-mentioned culture using an organic solvent," and that "[r]educed coenzyme Q10 can be recovered by extracting the microbial cells and disrupted product thereof obtained in such a manner by an organic solvent." (JX-1 at 9:14-16, 10:47-49.) The specification further states:

> In the case of the above-mentioned extraction operation, when reduced coenzyme Q10 is extracted from the aqueous suspension of the microbial cells or disrupted product thereof, particularly from the aqueous suspension of the disrupted

> product, further particularly the case in which the disrupted product is physically treated, by an organic solvent, emulsions tend to be partly formed because of the presence of cell components such as proteins and phase separation tends to be difficult. Therefore, it becomes important to suppress the formation of emulsions mentioned above and to efficiently carry out extraction.

(*Id.* at 15:20-30.)

The parties dispute whether "extracting" is properly characterized as "removing" coenzyme Q10 from the microbial cells, or "separating" coenzyme Q10 from the microbial cells. I find that it is best to use the term "recovering" in the construction, as the specification equates extraction with "recovery." (*See, e.g.,* JX-1 at 9:14-16, 10:47-49.) In the context of the '340 patent, "recovery" encompasses gathering or isolating the coenzyme Q10 material into a common location. (*See, e.g.,* JX-1 at 9:7-21, 15:4-34, 16:7-17:30, 20:62-21:5, 21:46-22:47, 23:17-44.)

Kaneka asserts that "extracting" means "removing." As demonstrated *supra*, I find that extraction goes beyond just "removing," and that a more appropriate term is "recovering," as that is the term used by the specification. *Phillips*, 415 F.3d at 1315 (explaining that the specification "is the single best guide to the meaning of a disputed term.") (citation omitted).

Respondents assert that "extracting" means "separating." Respondents rely on an example from the specification, Example 7, whereby the extraction is performed by separating the coenzyme Q10 from the cells. (*See* JX-1 at 21:44-22:47.) I find that restricting the term "extracting" to "separating" would amount to improperly limiting the claim language based on an example disclosed in the specification. *Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.")

Respondents additionally rely on dictionary definitions of "extraction." I find that examination of the extrinsic evidence offered by the parties is unnecessary because the intrinsic evidence is sufficient to understand the meaning of "extracting." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.").

In addition to what "extraction" itself means, there is a clear dispute between the parties regarding whether or not the extraction step must be performed before, after, or at the same time as the oxidation step. I find that the plain language of the claims requires that the claimed steps (including the extraction and oxidation steps) be performed in the order written. Claims 1, 11, 22 and 33 are method claims. Although method claims are not ordinarily construed to require a particular order of steps, here the claims require they be performed in the order written. *Interactive Gift Exp., Inc.* 256 F.3d at 1342.

Like the claims in *Loral Fairchild Corp.*, each subsequent step in the asserted claims is directed to further processing on a substance formed by the previous step. 181 F.3d at 1321. The first element of claims 1 and 22 requires "culturing reduced coenzyme Q10-producing microorganisms . . . to obtain microbial cells." (JX-1 at 23:56-24:25, 25:32-54.) The second element of claims 1 and 22 refers back to these microbial cells and requires "disrupting ***the microbial cells*** to obtain reduced coenzyme Q10." (*Id.* (emphasis added).) The third element of claims 1 and 22 refers back to the "thus-obtained reduced coenzyme Q10," and requires "oxidizing ***thus-obtained reduced coenzyme Q10*** to oxidized coenzyme Q10." (*Id.* (emphasis added).) The third element of claims 1 and 22 continues, requiring "and ***then*** extracting the oxidized coenzyme Q10 by an organic solvent" "under an inert gas atmosphere"[claim 1]/"in a

sealed tank"[claim 22]. (*Id.* (emphasis added).) There is no question that the word "then" requires extraction to be conducted after oxidation. Because each subsequent step in claims 1 and 22 necessarily requires the previous step to have been executed, I find that the claims 1 and 22 require the steps be performed in the order written.

Like claims 1 and 22, each subsequent step in claims 11 and 33 are directed to further processing on a substance formed by the previous step. The three steps in claims 11 and 33 require, *inter alia*, "culturing reduced coenzyme Q10-producing microorganisms . . . to obtain microbial cells containing reduced coenzyme Q10," "extracting ***the reduced coenzyme Q10***," and "oxidizing ***the extracted reduced coenzyme Q10*** to oxidized coenzyme Q10." (JX-1 at 24:50-25:6, 26:13-35.) Because each subsequent step in claims 11 and 33 necessarily requires the previous step to have been executed, I find that the claims 11 and 33 require the steps be performed in the order written.

6. "Disrupting the Microbial Cells to Obtain Reduced Coenzyme Q10"

The phrase "disrupting the microbial cells to obtain reduced coenzyme Q10" appears in asserted claims 1 and 22.

Kaneka's Position: Kaneka contends that "disrupting the microbial cells to obtain reduced coenzyme Q10" means "breaking the surface structure to obtain reduced coenzyme Q10."

Kaneka states that the specification expressly supports its proposed construction. (Citing JX-1 at 9:22-28.) According to Kaneka Dr. Connors agrees that the specification supports Kaneka's proposed construction. (Citing CX-242C at ¶¶ 62-66; JX-1 at 9:16-26; CX-653C, Q. 36-37.)

Kaneka believes that Respondents' proposed construction, which requires that the reduced coenzyme Q10 is released under the condition that it is protected from an oxidation reaction throughout disruption, imports unnecessary limitations into the claims. (Citing CX-48.) Kaneka argues that there is no requirement that the reduced coenzyme Q10 to be released, as the specification explains that disruption merely makes extraction possible. (Citing CX-653C, Q. 37; CX-242C.022; JX-1 at col. 9.) Moreover, Kaneka asserts that there is no basis to include a requirement regarding protection from an oxidation reaction. (Citing JX-1 at 17:20-25.)

Respondents' Position: Respondents contend that "disrupting the microbial cells to obtain reduced coenzyme Q10" means "breaking the surface structure, such as a cell wall, of the microbial cells to release reduced coenzyme Q10 under the condition that the reduced coenzyme Q10 is protected from an oxidation reaction throughout disruption."

Respondents assert that their proposed construction defines the surface structure as the cell wall, whereas Kaneka's construction does not offer a definition. Respondents claim that their proposed construction addresses the claim language requiring that the disruption takes place to obtain reduced coenzyme Q10. According to Respondents, the word "obtain" connotes that the coenzyme Q10 is released from the cells. (Citing JX-1 at 9:17-19.) Respondents state that unless the released reduced coenzyme Q10 is protected from oxidation, it will not be possible to obtain reduced coenzyme Q10 in the disruption step. Respondents claim that producing reduced coenzyme Q10 while protecting it from oxidation is a major part of the novelty of the '340 patent. (Citing JX-1 at 1:46-48, 3:59-64, 4:15-21, 4:40-50, 7:9-16.)

Staff's Position: Staff contends that "disrupting the microbial cells to obtain reduced coenzyme Q10" means "breaking the surface structure, such as a cell wall, of the microbial cells to obtain reduced coenzyme Q10."

Staff asserts that Respondents' proposed construction adds a significant limitation to the plain and ordinary meaning of the claim language. Staff states that Respondents have not pointed to any portions of the intrinsic record that indicate that the inventors were acting as their own lexicographers or meant to require protection from oxidation during disruption. Staff further claims that Respondents have not alleged that the term "to obtain" is unclear. Staff states that its construction is preferable to Kaneka's because Staff's construction clearly sets forth what is broken in the disruption step.

Construction to be applied: "breaking the surface structure, such as a cell wall, of the microbial cells to obtain reduced coenzyme Q10."

Asserted claims 1 and 22 both require "disrupting the microbial cells to obtain reduced coenzyme Q10." In addressing disruption, the specification states the following:

> Incidentally, "disruption" in the present invention may be carried out to the extent that the surface structure such as a cell wall is broken so as to make extraction of reduced coenzyme Q10 possible; therefore, it is not necessary that microbial cells are torn or fragmentated.

(JX-1 at 9:22-26.)

The parties agree that this claim element requires, at least, "breaking the surface structure, such as a cell wall, of the microbial cells."[3] Respondents seek to add further limitations to the construction.

Respondents seek to replace the word "obtain" with "release" by arguing that the word "obtain" requires that coenzyme Q10 be released from the cells. This is incorrect. As explained in *Fin Control Systems Pty, Ltd., v. OAM, Inc.*, "the same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims."

[3] Kaneka's proposed construction does not expressly include "such as a cell wall," but I find that such exemplary language is consistent with the specification and provides further helpful clarification of the claim language.

256 F.3d 1311, 1318 (Fed. Cir. 2001) (citing *Phonometrics, Inc. v. N. Telecom, Inc.*, 133 F.3d 1459, 1465, 45 USPQ2d 1421, 1426 (Fed.Cir.1998)). Here, "obtain" is used twice within the same asserted claims (*See, e.g.*, JX-1 at 24:17, 24:20, 24:22.), yet Respondents seek only to replace the word "obtain" with "release" in one case. Respondents cite nothing in the specification or prosecution history that requires that the term "obtain" have a different meaning in different portions of the claims.

In the context of asserted claims 1 and 22 of the '340 patent, the term "obtain" is used twice to describe a result that arises from an act or process immediately preceding use of the term "obtain." In the first element of the asserted claims, the patent teaches "culturing reduced coenzyme Q10 producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient" to arrive at the result of "microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10."[4] The second element requires "disrupting the microbial cells" in order to achieve a specific result, which is access to and possession of the reduced coenzyme Q10 that was contained within the microbial cells. This understanding of the term "obtain" is clear from the context of its repeated and consistent use within each asserted claim.

To use the word "release" to define "obtain" in the second element as suggested by Respondents would create a conflict with use of the term in the first element of the claim, which clearly does not involve the release of anything. As detailed above, the use of the term in the first element of the claim describes the result of the culturing process, which is the creation of microbial cells containing the reduced coenzyme Q10 described therein. I find, therefore, that

[4] While only relevant to claims 1 and 22 here, I note that this first use of the term "obtain" is also contained in the same context in claims 11 and 33.

the use of the word "obtain" within the asserted independent claims refers to a result that arises from an act or process immediately preceding use of the term "obtain."

Respondents also seek to add a requirement that "the reduced coenzyme Q10 is protected from an oxidation reaction throughout disruption." This language is found nowhere in the claims, and Respondents argue that the specification makes clear that such a limitation is required because "unless the released reduced coenzyme Q10 is protected from oxidation, it will not be possible 'to obtain reduced coenzyme Q10' in the disruption step." (RIB at 19.) After a review of the portions of the specification cited by Respondents, I find nothing that dictates including the protection language proposed by Respondents. (*See* JX-1 at 1:46-48, 3:59-64, 4:15-21, 4:40-50, 7:9-16.) The cited passages instead address the culturing step and the 70 mole % requirement that appears in each of the asserted claims. (*Id.*) Moreover, Respondents cite Examples 3 and 6 in the specification for support; but such exemplary disclosures cannot serve to limit the meaning of the claims. *Kara Tech.*, 582 F.3d at 1348 ("The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.").

7. "Inert Gas Atmosphere"

The term "inert gas atmosphere" appears in asserted claims 1, 9, 11, 20, 29, and 30.

Kaneka's Position: Kaneka contends that "inert gas atmosphere" means "a gas atmosphere that is less readily reactive with the organic solvent."

Kaneka asserts that its proposed construction is consistent with the common meaning of "inert gas atmosphere" as is known in the art. (Citing CX-653C, Q. 42; RX-287 at 117:7-17; Tr. at 688:5-20, 648:24-649:9.) Kaneka claims that the specification supports its proposed construction. (Citing JX-1 at 10:60-61, 17:20-25; CX-653C, Q. 42-44, 49; RX-392C at 33:16-

20; CX-242C at ¶¶ 80-88, 93-94; CX-206C at ¶¶ 86-90, 97-98; CX-184C at ¶¶ 79-85, 92-93; CX-161C at ¶¶ 75-85, 91-92.) Kaneka states that in view of the specification, one of ordinary skill in the art would understand that the atmosphere does not need to be 100% free or even substantially free of oxygen. Kaneka believes that the specification makes clear that all is required is that the extraction should be carried out in a safe manner, *i.e.* under a gas atmosphere that is less readily reactive with the organic solvent and more conductive to safe operation.

Kaneka states that Respondents' and Staff's proposed constructions improper import extraneous language concerning oxygen into the claims. Kaneka argues that these proposed constructions contradict the intent of the '340 patent, as the purpose of the patented process it to oxidize the reduced coenzyme Q10. According to Kaneka, an atmosphere which avoids oxygen would be counter-productive.

Respondents' Position: Respondents contend that "inert gas atmosphere" means "an atmosphere of inert gas that is free or substantially free of oxygen."

Respondents state that consistent with the plain and ordinary meaning of the term "inert gas," the term "inert gas atmosphere" has the same meaning as the term "atmosphere of inert gas," which is used in the '340 patent specification. (Citing RX-650; JX-1 at 16:37-39.) Respondents state that the specification identifies exemplary inert gases used to ensure that the reduced coenzyme Q10 is protected from an oxidation reaction. (Citing JX-1 at 16:35-39.)

Respondents assert that Kaneka's proposed construction suffers from three problems. First, Respondents argue that Kaneka's construction is vague because the phrase "less readily reactive" is relative, and Kaneka has provided no baseline against which an atmosphere can be judged as "less readily reactive." Second, Respondents believe that Kaneka's construction vitiates the requirement of inert gas, rendering the meaning of those words unnecessary and

meaningless. Finally, Respondents claim that Kaneka's construction is not consistent with the claim language or specification. (Citing JX-1 at 16:35-39, 17:20-25; Tr. at 274:5-275:2.)

Staff's Position: Staff contends that "inert gas atmosphere" means "an atmosphere of gases that do not cause substantial oxidation of coenzyme Q10."

Staff concurs with Respondents that an "inert gas atmosphere" must be one that is free or substantially free of oxygen. Staff believes it is unnecessary to construe the term to require that the atmosphere be both of inert gas and substantially free of oxygen. Staff states that the '340 patent lists highly combustible gases, such as hydrogen, as "inert gases," indicating that "inert gas atmosphere" describes an atmosphere that does not oxidize rather than one that is limited to gases that are completely chemically inert, such as helium. (Citing Tr. at 274:12-23.) Staff states that all of the gases listed in the specification are ones that do not oxidize coenzyme Q10. (Citing Tr. at 271:17-20.)

Staff asserts that Kaneka's proposed construction is vague and divorced from the specification. Staff states that "less readily reactive" is a relative term, and it is not clear with what the atmosphere is being compared.

Construction to be applied: "an atmosphere of inert gas (such as nitrogen, carbon dioxide, helium, argon, or hydrogen) that is free or substantially free of oxygen."

The term "inert gas atmosphere" appears in multiple asserted claims. For example, claim 1 requires "extracting the oxidized coenzyme Q10 by an organic solvent under an inert gas atmosphere." Claim 11 requires "extracting the reduced coenzyme Q10 by an organic solvent under an inert gas atmosphere." Claims 20 and 30 require that "the inert gas atmosphere comprises nitrogen gas." Claim 29 requires that "the sealed tank is sealed under an inert gas atmosphere."

The '340 patent specification describes the following when addressing the extraction of reduced coenzyme Q10:

> ***In recovering reduced coenzyme Q10, it is preferable to be careful so that reduced coenzyme Q10 is not decomposed (e.g. so that reduced coenzyme Q10 is not oxidized to oxidized coenzyme Q10).*** For that, the above-mentioned extraction (including cell disruption) is preferably carried out under an acidic to a weakly basic condition, and more preferably under an acidic to a neutral condition. In the case where a pH is used as an index, although it depends on the contact time, the pH is generally not more than 10, preferably not more than 9, more preferably not more than 8, and still more preferably not more than 7.
>
> ***By the above-mentioned conditions, an oxidation reaction can be substantially prevented and, optionally, more strictly, the above-mentioned cell disruption and/or extraction are preferably carried out under the condition that reduced coenzyme Q10 is protected from an oxidation reaction.*** It is preferable to carry out at least the extraction under this condition, and it is more preferable to carry out the disruption and the extraction under this condition.

(JX-1 at 16:16-34 (emphasis added).) The specification then provides examples of conditions wherein reduced coenzyme Q10 is protected from an oxidation reaction: "[a]s 'the condition that reduced coenzyme Q10 is protected from an oxidation reaction' means, for example, ***a deoxygenized atmosphere (an atmosphere of an inert gas such as nitrogen gas, carbon dioxide gas, helium gas, argon gas or hydrogen gas, reduced pressure, a boiling condition***)..." (*Id.* at 16:35-39 (emphasis added).)

The above-quoted passage from the specification clearly indicates that the "inert gas atmosphere" of the claims is a way to create a "deoxygenized atmosphere." Therefore, "inert gas atmosphere" means "an atmosphere of inert gas (such as nitrogen, carbon dioxide, helium, argon, or hydrogen) that is free or substantially free of oxygen." This reasoning is further supported by the fact that the specification includes in its examples of "inert gas" certain combustible gases, such as hydrogen. I have, therefore, included in the construction the examples of "inert gas"

listed in the specification to make clear the breadth of gases that qualify as "inert gases" according to the '340 patent.

Kaneka seeks to construe "inert gas atmosphere" to mean "a gas atmosphere that is less readily reactive with the organic solvent." Kaneka's proposed construction is ambiguous, as "less readily reactive" is a relative term; but Kaneka fails to provide the baseline against which it is measured. Stated another way, it is impossible to know if the atmosphere is "less readily reactive" if one lacks knowledge about what other atmosphere is being used as a comparison. Therefore, using Kaneka's construction, we are left with a situation where one cannot determine whether or not the "inert gas atmosphere" limitation is satisfied.

Kaneka notes that the "inert gas atmosphere" limitation is found in claims, such as claim 1, that address the extraction of oxidized coenzyme Q10. Kaneka argues that an oxygen-free atmosphere is not necessary for the extraction of oxidized coenzyme, as opposed to the extraction of reduced coenzyme Q10.

In discussing the extraction of oxidized coenzyme Q10, the specification states that the protections taken for the extraction of reduced coenzyme Q10 are not necessary. Instead, the specification explains that the extraction must be carried out under conditions allowing for "general safe operation:"

> In the case where the microbial cells or disrupted product thereof are oxidized, the extraction operation of oxidized coenzyme Q10 can be carried out in the same manner as the above-mentioned extraction operation of reduced coenzyme Q10. Thereby, oxidized coenzyme Q10 can be efficiently recovered. Incidentally, ***it is not necessary to carry out the recovery of oxidized coenzyme Q10 under "the condition that reduced coenzyme Q10 is protected from an oxidation reaction", which is recommended for the recovery of reduced coenzyme Q10 and the recovery may be carried out in consideration of general safe operation and the like.***

(JX-1 at 17:15-25 (emphasis added).)

Kaneka argues that because the extraction of oxidized coenzyme Q10 does not need to be performed in an oxygen-free atmosphere, and because claim 1 requires extraction of oxidized coenzyme Q10 under an inert gas atmosphere, it cannot be the case that an inert gas atmosphere must be free or substantially free of oxygen. I do not concur with Kaneka's logic. The above-quoted passage merely states that it is "not necessary" for the extraction to be carried out under the special conditions used for extraction of reduced coenzyme Q10. It does not prohibit the extraction of oxidized coenzyme Q10 under the special conditions. Interpreting "inert gas atmosphere" to merely mean an atmosphere that is less readily reactive would read "inert gas atmosphere" out of the claims.

8. "Deoxygenized Atmosphere"

The term "deoxygenized atmosphere" appears in asserted claims 41 and 43.

Kaneka's Position: Kaneka contends that "deoxygenized atmosphere" means "an atmosphere from which some oxygen has been displaced."

Kaneka asserts that as the claims provide for a "deoxygenized atmosphere" in the context of manufacturing oxidized coenzyme Q10, the specification makes it clear that the term should be construed in light of safety considerations, and such safety considerations would not require an atmosphere of gases free or even substantially free of oxygen. (Citing CX-653C, Qs. 42-46, 49; CX-242C at ¶¶ 80-90, 93-94; CX-206C at ¶¶ 86-90, 93-94, 97-98; CX-184C at ¶¶ 79-85, 88-89, 92-93; CX-161C at ¶¶ 75-88, 91-92.)

Respondents' Position: Respondents contend that "deoxygenized atmosphere" means "an atmosphere of gases free or substantially free of oxygen."

Respondents claim that "deoxygenized atmosphere" is expressly defined in the specification as "an atmosphere of an inert gas such as nitrogen gas, carbon dioxide gas, helium

gas, argon gas or hydrogen gas, reduced pressure, a boiling condition." (Citing JX-1 at 16:35-39.) Respondents assert that in this instance, the patentee acted as his own lexicographer. Respondents states that each of the exemplary instances of a "deoxygenized atmosphere" in the written description results in an atmosphere that is free or substantially free of oxygen.

Respondents argue that Kaneka's proposed construction would encompass an atmosphere consisting mostly of oxygen so long as a minimal amount of oxygen had been displaced. According to Respondents, Kaneka's proposed construction therefore reads the term "deoxygenized" out of the claims.

Staff's Position: Staff contends that "deoxygenized atmosphere" should be given its plain and ordinary meaning.

Staff states that Respondents' proposed construction is essentially a recitation of the plain and ordinary meaning of the phrase. Staff states that it does not object if Respondents' position is adopted.

Staff disagrees with Kaneka's proposed construction. Staff argues that Kaneka's construction is indefinite because it does not clarify how much oxygen must be displaced in order to meet the limitation. Staff states that if Kaneka's construction is literally read, any amount of displacement, no matter how small, would be sufficient. Further, Staff asserts that all of the examples of a "deoxygenized atmosphere" in the specification refer to atmospheres free or substantially free of oxygen.

Construction to be applied: "an atmosphere free or substantially free of oxygen."

Claim 41 is a dependent claim, and depends from claim 33. It claims the process of claim 33 "wherein the sealed tank is sealed under a deoxygenized atmosphere." Claim 43

depends from claim 41, and requires that "the deoxygenized atmosphere comprises nitrogen gas."

Certain claims in the '340 patent refer to a "deoxygenized atmosphere," while other claims refer to an "inert gas atmosphere." It is presumed that these two terms have different meanings. *Tandon Corp. v. United States Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987) ("There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims."). I find that the parties have offered no evidence to rebut this presumption. As described in my discussion of "inert gas atmosphere," the term "deoxygenized atmosphere" is a broader term, and "inert gas atmosphere" is a type or subset of a "deoxygenized atmosphere." It follows that there are more ways to create a "deoxygenized atmosphere" beyond using an "inert gas atmosphere."

In addressing a "deoxygenized atmosphere," the specification states, "[a]s 'the condition that reduced coenzyme Q10 is protected from an oxidation reaction' means, for example, a deoxygenized atmosphere (an atmosphere of an inert gas such as nitrogen gas, carbon dioxide gas, helium gas, argon gas or hydrogen gas, reduced pressure, a boiling condition)." (JX-1 at 16:35-39.) I find that this disclosure is fully consistent with the above-stated plain and ordinary meaning of "deoxygenized atmosphere."

Kaneka's proposed construction -- "an atmosphere from which some oxygen has been displaced" – is impossibly broad. The construction does not explain what qualifies as "some oxygen." As both Respondents and Staff note, the construction would be satisfied if any amount of oxygen displacement, no matter how small, occurs. I find that such a broad interpretation of "deoxygenized atmosphere" is not correct and reads out the term "deoxygenized" from the claims.

Based on the foregoing, I find that a "deoxygenized atmosphere" is "an atmosphere free or substantially free of oxygen."

9. "Sealed Tank"

The term "sealed tank" appears in asserted claims 22, 29, 33, and 41.

Kaneka's Position: Kaneka contends that "sealed tank" means "a tank that substantially prevents direct exposure of its contents to the atmosphere."

Kaneka states that in the production of coenzyme Q10, the release of volatile hydrocarbons into the atmosphere surrounding the extraction tank must be avoided for safety reasons and the uncontrolled entry of materials into the extraction tank must be avoided to prevent contamination. Kaneka contends that the purpose of using a "sealed tank" is to meet these goals. Kaneka relies on the testimony of MGC's expert for support. According to Kaneka, Mr. Ebina stated that Kaneka's proposed construction for "sealed tank" correspondents to his understanding of the tanks that are generally used in the production of coenzyme Q10. (Citing Tr. at 658:13-19.)

Kaneka disagrees with Respondents' argument that a "sealed tank" must prevent the flow of gases and liquids in and out of the tank. Kaneka argues that a tank that satisfied Respondents' construction would be unusable because of the potential for dangerous levels of pressure buildup inside a tank that did not permit any gas or liquids to enter or exit, which would render the tank dangerous and inoperable. (Citing *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 275 F.3d 1371, 1376 (Fed. Cir. 2002).) According to Kaneka, Mr. Ebina testified that such a danger was well known. (Citing Tr. at 689:23-690:25.) Kaneka posits that the more reasonable conclusion is that the tank is sealed by a means of a ventilation system or pressure relief system, which was described by Mr. Ebina and others. (Citing Tr. at 689:23-690:25.) Kaneka contrasts its

construction with Respondents' proposed construction, asserting that Kaneka's construction accounts for the commercial reality of extracting fermented products using organic solvents, including the use of a venting device for relieving pressure in the tank while still preventing escape of solvent vapors to the atmosphere.

Kaneka argues that Respondents' construction excludes the preferred embodiment depicted in Figure 1 and Example 8 of the specification and claimed in dependent claims 27-28 and 39-40. Kaneka says that Figure 1 and Example 8 in the specification of the '340 patent depict a countercurrent 3-step continuous extraction using a series of tanks. (Citing JX-1 at 23:23-44; Figure 1.) According to Kaneka, the tanks in Figure 1 are not "sealed" as Respondents construe the term because solvent, solution, isopropanol, n-hexane, and residue are transferred among various tanks during extraction. Kaneka adds that the lack of a vent line in Figure 1 does not mean a sealed tank cannot have a vent line because one of skill in the art would not intend such a result. (Citing RX-294 at 144:16-145:8, 149:5-15.)

In addition to the figures and specification, Kaneka asserts that dependent claims 27-28 and 39-40 require "continuous extraction" and/or "countercurrent multistage extraction" in a "sealed tank," which requires constant flow of liquids and gases in and out of the extraction tank. Kaneka argues that such a continuous extraction could not occur under Respondents' construction of "sealed tank."

Kaneka says that the sealed pressure homogenizer discussed in examples 3, 7, and 8 of the '340 patent specification are not related to the extraction step and are therefore irrelevant. Kaneka likewise criticizes Respondents' reliance on dictionary definitions and inventor testimony that contradicts the specification and claims of the '340 patent, asserting that extrinsic evidence should not be used to contradict the intrinsic evidence.

Kaneka says that Respondents' proposed construction of "sealed tank" separates "sealed" from "tank," defines those terms based on dictionary definitions, and then combines the definitions together. Kaneka argues that, in contrast to Respondents' construction, the proper way to construe a term is to consider it as a whole in view of the purpose of the invention, the teaching of the specification, and common sense. Kaneka criticizes Respondents' construction as running afoul of the guidance provided by *Phillips v. AWH Corp.*, regarding the reliance on dictionary definitions of claim terms. (Citing 415 F.3d 1303, 1321 (Fed. Cir. 2005).)

Respondents' Position: Respondents contend that "sealed tank" means "a tank that has been closed off to protect the contents of the tank from exposure to air and otherwise prevent the entry or escape of gases during the extraction process."

Respondents say that the term "sealed tank" was first added by amendment on August 27, 2010. (Citing JX-3 at MGC122095-100, 122102-107.) Respondents continue that the only use of the word "sealed" in the specification is in the context of a pressure homogenizer, disclosing a "pressure homogenizer sealed with nitrogen gas." From this use, Respondents infer that "seal" means to prevent the microbial cells from exiting, and the outside atmosphere from entering, the pressure homogenizer. (Citing JX-1 at 20:65-21:1, 22:2-5, 23:20-23, 9:22-26, 9:33-42.)

Respondents state that the plain and ordinary meaning of "seal" is "a tight and perfect closure (as against the passage of gas or water)" and "a device to prevent the passage or return of gas or air into a pipe or container." (Citing RX-655 at XKGCITC445617; Tr. at 295:17-296:2, 657:25-658:6, 688:21-25, 773:24-774:19, 776:5-16.) Respondents assert that this plain and ordinary meaning of "seal" when combined with tank is consistent with Respondents' construction.

Respondents criticize Kaneka's construction as essentially rendering the term "sealed tank" meaningless. Respondents argue that Kaneka's construction ignores the fact that the only distinction between a "tank" and a "sealed tank" is the quality of ensuring that the contents remain inside the tank while the outside environment remains outside. According to Respondents, Kaneka's construction is actually the definition of a partially sealed tank, an incompletely sealed tank, or a vented tank. Respondents reason that such a tank does not possess the quality of being sealed at all and is erroneous as a matter of law.

Respondents also criticize Kaneka's and Dr. Connors' reliance on Figure 1 and Example 8 of the specification to support Kaneka's construction. Respondents say that Figure 1 and Example 8 describe and illustrate a "countercurrent 3-step continuous extraction apparatus," but there is nothing in the specification indicating that the apparatus uses one or more "sealed tanks." Rather, according to Respondents, the apparatus includes stirring tanks and static separation tanks that are not characterized as being sealed. (Citing JX-1 at 23:23-55, Fig. 1.) Respondents contend that Dr. Connors admitted this to be the case, and only argued that the words "isopropanol" and "n-hexane" disclose to one of skill in the art that a sealed tank must be used. (Citing Tr. at 1140:8-1141:5.)

Respondents criticize Kaneka's reliance on the testimony of Dr. Connors' as conclusory and conflicting with the testimony of the other experts and the plain and ordinary meaning of "sealed tank." Respondents say that Dr. Connors agreed, during cross examination, that the plain and ordinary meaning of "sealed" was "airtight." (Citing Tr. at 295:13-296:7.) Respondents continue that there is no intrinsic evidence assigning a special meaning to "sealed."

Respondents argue that Mr. Ebina's testimony does not support Kaneka's construction as Kaneka contends. Rather, according to Respondents, Mr. Ebina agreed that a vented tank could

be used safely in the industrial production of coenzyme Q10, but did not agree that a vented tank was a "sealed tank." (Citing Tr. at 657:25-658:6, 659:9-660:1, 660:18-661:9.) Likewise, Respondents say that Dr. Trumpower's testimony relied upon by Kaneka was actually referring to the need for a vent for a fermentation tank, not an extraction tank. (Citing Tr. at 690:23-29.) According to Respondents, Dr. Trumpower actually testified that an extraction tank with all valves closed simultaneously constituted a "sealed tank." (Citing Tr. at 696:14-25.) Respondents say that Dr. Spormann also testified that such a "sealed tank" could be used safely to extract coenzyme Q10. (Citing RX-623C, Qs. 109-112.)

Respondents say that the specification of the '340 patent does not identify the tanks in example 8 and figure 1 of the '340 patent as "sealed tanks," which Kaneka admits. Respondents argue that Kaneka cannot, therefore, rely on example 8 and figure 1 of the '340 patent to vitiate the term "sealed" in the "sealed tank" limitation.

Respondents argue that the cases relied upon by Kaneka do not support Kaneka's construction. Rather, Respondents say that in *Talbert Fuel Systems Patents Co. v. Unocal Corp.* the patentee failed to prove that the claim as construed was inoperable. (Citing 275 F.3d 1371, 1376 (Fed. Cir. 2002), *vacated*, 537 U.S. 802 (2002).) Respondents assert that Dr. Spormann testified that claims 1, 11, 22, and 33 are all operable under Respondents' construction. (Citing RX-623C, Qs. 109-112.) Respondents say that *AIA Eng'g Ltd. v. Magotteaux Int'l S/A* acknowledges that courts may not redraft claims whether to make them operable or sustain their validity. (Citing 657 F.3d 1264, 1278 (Fed. Cir. 2011).)

Staff's Position: Staff contends that "sealed tank" means "a tank that has been closed off to protect the contents of the tank from exposure to air and otherwise prevent the entry or escape of gases during the extraction process."

Staff asserts that its construction is in accordance with the plain meaning of the word "sealed," which refers to something that prevents the entry or exit of any material. Staff reasons that a tank that allows the entry of oxygen gas or exit of any potentially flammable gases would not accomplish the goals of reducing oxidation and increasing safety. Staff criticizes Kaneka's construction as focusing on whether or not the tank's contents are exposed to the atmosphere. According to Staff, Kaneka's construction would permit various gases (such as pure oxygen) or liquids to enter the tank, which fails to serve the purpose of having a sealed tank—preventing oxidation and increasing safety. (Citing RX-623C, Q. 113.)

Construction to be applied: "a tank that is closed to prevent the entry or exit of materials."

Although the term "sealed tank" appears a number of times in the claims, the intrinsic record does not disclose a special definition for that term. Claim 22 requires "extracting the oxidized coenzyme Q10 by an organic solvent in a sealed tank." (JX-1 at 25:54-55.) Claim 29 requires "wherein the sealed tank is sealed under an inert gas atmosphere." (JX-1 at 26:3-4.) Claim 33 requires "extracting the reduced coenzyme Q10 by an organic solvent in a sealed tank." (JX-1 at 26:32-33.) Claim 41 requires "wherein the sealed tank is sealed under a deoxygenized atmosphere." (JX-1 at 26:51-52.) The term "sealed tank," however, does not appear ***anywhere*** in the specification of the '340 patent. (*See* JX-1.) Although the term "sealed" does appear in the specification three times, each time it is used addresses a pressurized homogenizer that is "sealed" with nitrogen gas, not a "sealed tank" used for extraction. (JX-1 at 20:65-21:1, 22:2-5, 23:20-23.) Moreover, even when the term "sealed" does appear in the specification, the specification does not assign a special meaning to that term. (*See* JX-1 at 20:65-21:1, 22:2-5, 23:20-23.)

The remainder of the intrinsic record is also devoid of guidance regarding any special meaning of "sealed tank." Claims 22, 29, 33, and 41 were added by amendment on August 27, 2010. (JX-3 at MGC00122089-099.) The amendment provides no explanation regarding the meaning of "sealed tank," nor does it cite any support for a "sealed tank" in the specification. (*See id.* at MGC00122100-108.) The August 27, 2010 amendment was filed following a personal interview with the Examiner on July 27, 2010. Although the amendment says that it includes a "record of the substance of that interview," the amendment provides no detailed discussion regarding issues raised during the interview. (*Id.* at MGC00122100.) The Examiner's summary of the interview fails to provide details regarding what was discussed. (*Id.* at MGC00122086-088.)

Because the intrinsic record does not contain anything that would assign a special meaning to the term "sealed tank," the ordinary meaning to one of skill in the art controls. As explained in *In re Paulsen*, "'[w]here an inventor chooses to be his own lexicographer and to give terms uncommon meanings, he must set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change." 30 F.3d 1475, 1480 (Fed. Cir. 1994)(citations omitted). Here, the intrinsic record does not assign a special meaning to "sealed tank."

The next question is what one of ordinary skill in the art would understand "sealed tank" to mean. Merriam-Webster's Collegiate Dictionary, Tenth Edition, defines "seal" as "a tight and perfect closure (as against the passage of gas or water)." (RX-655 at XKGCITC0445618.) Kaneka's expert, Dr. Connors, agreed with this definition, testifying that the plain meaning of "sealed" is "airtight." (Tr. at 295:25-296:2.) His testimony was uncontroverted. Thus, the

undisputed evidence introduced at the hearing shows that "sealed" means closed to prevent the entry or exit of materials.

This definition of "sealed" comports with the use of the term "sealed" in the '340 patent specification. The '340 patent describes a pressure homogenizer that is "sealed" with nitrogen gas. (*See* JX-1 at 23:20-23.) The '340 patent further states that the pressure homogenizer operates at a pressure of 140 MPa. (JX-1 at 23:20-22.) Dr. Connors testified that for the homogenizer to operate at this high pressure, it would have to prevent the escape of materials. (Tr. at 301:21-302:2.) Combining this definition of "sealed" with "tank," it is clear that the meaning of "sealed tank" to one of ordinary skill in the art is a tank that is closed to prevent the entry or exit of materials.

Kaneka's argument that the ordinary meaning of "sealed tank" is incorrect because it would not read on Example 8 and Figure 1 of the '340 patent is not persuasive. Although figure 1 of the '340 patent shows tanks that have open inlets and outlets, the specification does not indicate that the tanks in figure 1 are "sealed tanks." (*See* JX-1 at Fig. 1; *see also* JX-1 generally.) The inclusion of Example 8 and Figure 1 does not rise to the level of an inventor acting as lexicographer, especially since the '340 patent does not refer to the tanks in Figure 1 as "sealed tanks." Moreover, the '340 patent includes four independent claims, only two of which require a "sealed tank." (JX-1 at 23:55-26:64.) A claim does not need to cover all embodiments since a patentee may draft different claims to cover different embodiments. *Intamin Ltd. v. Magnetar Technologies, Corp.*, 483 F.3d 1328, 1337 (Fed. Cir. 2007).

Kaneka is also wide of the mark when it argues that the ordinary meaning of "sealed tank" is incorrect because it conflicts with dependent claims 27-28 and 39-40. Kaneka's brief merely asserts, in a conclusory manner, that a "sealed tank" under the ordinary meaning of that

term "excludes the preferred embodiment from the scope of claims 27-28 and 39-40." (CIB at 37.) Kaneka has produced no evidence that a "sealed tank," under the adopted construction, cannot be used in a "continuous extraction" or a "countercurrent multistage extraction," as required by claims 27-28 and 39-40. (*See* CIB at 37; JX-1 at 25:65-26:2, 26:48-51.) Kaneka also introduces no evidence that claims 27-28 and 39-40 must read on Figure 1 of the '340 patent—the "preferred embodiment." As noted above, a claim does not need to cover all embodiments. *Intamin Ltd.*, 483 F.3d at 1337. Based upon the foregoing, Kaneka's argument fails.

Respondents contend that a "sealed tank" cannot have a vent valve for the release of pressure. To be clear, the adopted construction of "sealed tank" does not preclude the presence of a vent valve to release pressure for safety as long as the vent valve is closed during the normal extraction process. Dr. Connors explained that for safety purposes, a tank without a way to release pressure would be a safety hazard:

> Further, Respondents' construction of sealed tank transforms the extraction tank into a hazard. Closing off all valves so that no gases or liquids enter or escape the tank would lead to a build up of a dangerous amount of pressure, especially when organic solvents are present in the tank under high temperatures.
>
> It would be unreasonable to require that the claims to be limited in this manner, as espoused by MGC's own expert Mr. Ebina (pg.147-150 of transcript).

(CX-653C, Q. 52.) Mr. Ebina, an expert for MGC, agreed that vent valves are included for safety purposes:

> Q. Is it accurate to say that Kaneka's proposed definition for sealed tank would correspond to your understanding of the kinds of tanks that are used in the industrial production of CoQ10?
>
> A. In the sense of -- or in terms of safety, it does.
>
> Q. What kind of tank would you call that?
>
> A. It may be difficult if when it's -- it may be difficult for it to be understood when it's stated in Japanese, but usually, I think it may be called something like a vented tank.

(Tr. at 658:12-24.) Dr. Trumpower, Shenzhou's expert, expressed similar safety concerns regarding the need for vent valves in tanks, albeit in discussing fermentation tanks:

> Q. But that's your interpretation of what sealed tank may mean?
>
> A. I believe a common interpretation of sealed tank would be nothing goes in and out of that tank, and that would be a safety hazard in a fermentation.

(Tr. at 694:24-695:4.) Thus, three experts, two for Respondents and one for Kaneka, testified that vent valves are needed for safety purposes. Because of these safety concerns, a person of ordinary skill in the art would not understand a "sealed tank" to preclude the presence of "vent valves," as Respondents contend.

The testimony of Dr. Spormann, cited by Respondents to argue that a tank without a vent valve is not a safety hazard, does not actually rebut the testimony of the three experts. Rather, Dr. Spormann indicated that an unsafe buildup of pressure was not "necessarily" a result of using a sealed tank without a vent valve:

Question No. 112: Would performing extraction as you have stated lead to an unsafe buildup of pressure?

Answer: Not necessarily. During extraction in a sealed tank, the pressure of the gas phase can change and either increase or decrease, which typically depends on the specific conditions of phases used.

(RX-623C, Q. 112.) This is hardly a ringing endorsement that performing an extraction in a sealed tank without vent valves would be safe, or that one of ordinary skill in the art would understand a "sealed tank" to preclude the presence of vent valves. This testimony also does not rise to the level necessary to rebut the testimony of three other experts. Because a tank without vent valves raises serious safety concerns, I find that one of ordinary skill in the art would not understand a "sealed tank" to preclude vent valves.

Finally, Respondents' expert, Dr. Trumpower, confirmed this understanding, testifying that an extraction tank with a vent valve is still a "sealed tank" as long as the vent valve is closed:

> Q. If I'm running an extraction process and I close the inflow and I close the outflow and I have my vent valve, but as you said, when the vent valve is closed the tank is sealed, so don't I have a sealed tank unless or until I increase the pressure to blow the valve open, and then it becomes unsealed?
>
> A. Correct.

(Tr. at 696:14-21.)

Based on the foregoing, I find that a "sealed tank" is "a tank that is closed to prevent the entry or exit of materials."

IV. INVALIDITY

A. Applicable Law

It is the respondent's burden to prove invalidity, and the burden of proof never shifts to the patentee to prove validity. *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d

1365, 1380 (Fed. Cir. 2008). "Under the patent statutes, a patent enjoys a presumption of validity, *see* 35 U.S.C. § 282, which can be overcome only through facts supported by clear and convincing evidence[.]" *SRAM Corp. v. AD-II Eng'g, Inc.*, 465 F.3d 1351, 1357 (Fed. Cir. 2006). The clear and convincing standard was recently reaffirmed by the Supreme Court. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S.Ct. 2238 (2011) (upholding the Federal Circuit's interpretation of 35 U.S.C. § 282).

The clear and convincing evidence standard placed on the party asserting the invalidity defense requires a level of proof beyond the preponderance of the evidence. Although not susceptible to precise definition, "clear and convincing" evidence has been described as evidence which produces in the mind of the trier of fact "an abiding conviction that the truth of a factual contention is 'highly probable.'" *Price v. Symsek*, 988 F.2d 1187, 1191 (Fed. Cir. 1993) (citing *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed.Cir.1988)).

"When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job[.]" *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). Therefore, the challenger's "burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed.Cir.1990).

1. Anticipation

"A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharm., Inc.*, 339

F.3d 1373, 1377 (Fed. Cir. 2003) (citations omitted). A prior art reference may inherently disclose a claim limitation if the claim limitation is necessarily present in the prior art reference. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) ("Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art.") (citation omitted); *see also Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, (Fed. Cir. 2011) (explaining that "inherent anticipation requires more than mere probabilistic inherency[.]") A district court summed up the law of inherency by explaining:

> To establish inherency, the anticipatory feature or result must be consistent, necessary, and inevitable, not simply possible or probable, and it should be clear that it would be so recognized by persons of ordinary skill. That is, inherency may not be established by probabilities or possibilities, and the mere fact that a certain thing may result from a given set of circumstances is not sufficient to show inherency.

Allergan, Inc. v. Sandoz Inc., 818 F. Supp. 2d 974, 1003 (E.D. Tex. 2011) (citations omitted).

The sale of a product made by a patented process is sufficient to meet the requirements of the on-sale bar—the process itself need not be sold. In *D.L. Auld Co. v. Chroma Graphics Corp.*, the Federal Circuit held that "a party's placing of the product of a method invention on sale more than a year before that party's application filing date must act as a forfeiture of any right to the grant of a valid patent on the method to that party if circumvention of the policy animating § 102(b) is to be avoided in respect of patents on method inventions." 714 F.2d 1144, 1148 (Fed. Cir. 1983) (emphasis added). Likewise, in *In re Kollar*, the Federal Circuit noted that "[w]e cannot articulate in advance what would constitute a sale of a process in terms of the on-sale bar. Surely a sale by the patentee or a licensee of the patent of a product made by the claimed process would constitute such a sale because that party is commercializing the patented

process in the same sense as would occur when the sale of a tangible patented item takes place." 286 F.3d 1326, 1333 (Fed. Cir. 2002) (emphasis added).

To show that the sale of a product meets the requirements of the on-sale bar for a process claim, the party asserting invalidity must show that the product sold was actually made by the patented process. *See D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d at 1150. In *D.L. Auld Co. v. Chroma Graphics Corp.*, the Federal Circuit affirmed summary judgment of invalidity of method claims based on the on-sale bar where there was "uncontradicted evidence that other samples had been made by the claimed method and offered for sale before the critical date." *Id.* (rejecting the argument that the fact some samples were not made by the patented process raised a material issue of fact).

2. Obviousness

Section 103 of the Patent Act states:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103(a) (2008).

"Obviousness is a question of law based on underlying questions of fact." *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1379 (Fed. Cir. 2008). The underlying factual determinations include: "(1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness." *Id.* (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). These factual determinations are often referred to as the "*Graham* factors."

The critical inquiry in determining the differences between the claimed invention and the prior art is whether there is a reason to combine the prior art references. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417-418 (2007). In *KSR*, the Supreme Court rejected the Federal Circuit's rigid application of the teaching-suggestion-motivation test. The Court stated that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* at 418. The Court described a more flexible analysis:

> Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue...As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

Id.

Since *KSR* was decided, the Federal Circuit has announced that, where a patent challenger contends that a patent is invalid for obviousness based on a combination of prior art references, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, . . . and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

In addition to demonstrating that a reason exists to combine prior art references, the challenger must demonstrate that the combination of prior art references discloses all of the limitations of the claims. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010) (upholding finding of non-obviousness based on the fact that there was

substantial evidence that the asserted combination of references failed to disclose a claim limitation); *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003) (explaining that a requirement for a finding of obviousness is that "all the elements of an invention are found in a combination of prior art references").

B. Anticipation

1. Kaneka's Pre-2002 Process

Respondents' Position: {

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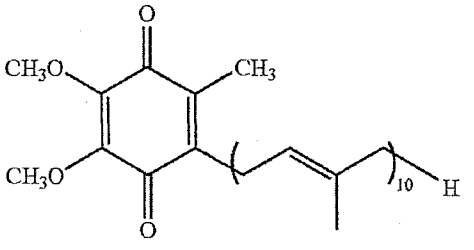
Discussion and Conclusions: {

} Here, I reaffirm those findings in Order 37 and the rationale upon which they are based. I turn to the question of whether or not the Pre-2002 process

anticipates each and every element of asserted claims 1-4, 8-15, 20-25, 29-37 and 41-44 of the '340 patent[6].

Among the asserted claims, claims 1, 11, 22 and 33 are independent claims, and the remainder of the asserted claims depend directly or indirectly from one of those independent claims. All of the asserted independent claims share an identical preamble and first element, to wit:

> A process for producing on an industrial scale the oxidized coenzyme Q10 represented by the following formula:



> which comprises culturing reduced coenzyme Q10 producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10.

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Respondents' expert, Dr. Taylor, testified on cross-examination that the {

} sample samples that were tested appear to have been taken approximately 5 days prior to testing and that he had no idea how they were stored or treated in that time. He agreed that he had no idea of whether or not the cells were still metabolizing during the interim. (Tr. at 753:3-25; 755:13-16; 756:1-760:4; RX-138C at KAN790ITC00505244.)

Respondents' burden is to provide clear and convincing evidence that the Pre-2002 culturing of coenzyme Q10 producing microorganisms described in the first element "obtains" "microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10." Respondents' expert, Dr. Taylor admitted on cross-examination, that the end of fermentation is the point at which the '340 patent describes obtaining reduced coenzyme Q10 at a ratio of not less than 70 mole %." (Tr. at 744:20-745:3.) {

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I find that the Respondents have failed to prove by clear and convincing evidence that Kaneka's Pre-2002 process for producing coenzyme Q10 practices the limitation of the first element of asserted claims 1, 11, 22 and 33 that requires one to "obtain" "microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10." Therefore, I find that Respondents have failed to meet their burden to provide clear and convincing evidence that Kaneka's Pre-2002 process reveals each and every element of asserted claims 1, 11, 22 or 33 of the '340 patent.

The second element of claims 1 and 22 teaches, "disrupting the microbial cells to obtain reduced coenzyme Q10." This step occurs immediately after fermentation and refers to the microbial cells obtained through said fermentation.

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I find that there is clear and convincing evidence that Kaneka's Pre-2002 process practiced the second element of claims 1 and 22 in the sequence required by those asserted claims.

The third element of claim 1 teaches:

> oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10 and then extracting the oxidized coenzyme Q10 by an organic solvent under an inert gas atmosphere.

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I find that respondents have failed to prove by clear and convincing evidence that Kaneka's Pre-2002 process practiced the limitation of the third element of claim 1 that oxidizing the coenzyme Q10 be performed prior to extraction.

Assuming *arguendo* that the oxidizing step is found to be performed as required by the third element of claim 1. I would find that the final limitation of that element, that extraction occur by an organic solvent under an inert gas atmosphere, is met by the Kaneka Pre-2002 process. {

} I note that the term inert gas atmosphere is construed in Section III.B.7 to mean "an atmosphere of inert gas (such as nitrogen, carbon dioxide, helium, argon, or hydrogen) that is free or substantially free of oxygen."

Based upon the foregoing, I find that the respondents have failed to prove by clear and convincing evidence that the Kaneka Pre-2002 process practiced each and every limitation of asserted independent claim 1 of the '340 patent.

The third element of claim 22 teaches:

> oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10 and then extracting the oxidized coenzyme Q10 by an organic solvent in a sealed tank.

This element of claim 22 is identical to that of claim 1 with the exception that extraction

in claim 22 is required to be accomplished in a "sealed tank." To the extent that the two claims are identical, I apply the same findings here as in claim 1. I turn to the final limitation of this element of claim 22.

In Section III.B.9, *supra*, I construed the term "sealed tank" to mean "a tank that is closed to prevent the entry or exit of materials." I explained that the adopted construction of "sealed tank" does not preclude the presence of a vent valve to release pressure as long as the vent valve is closed during the normal extraction process. Dr. Connors explained that for safety purposes, a tank without a way to release pressure would be a safety hazard, and there does not appear to be any evidence to the contrary. I did not, however, construe the term to include a tank with a vent that remains open during extraction.

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Based upon the foregoing, I find that the respondents have failed to prove by clear and convincing evidence that the Kaneka Pre-2002 process practiced each and every limitation of asserted independent claim 22 of the '340 patent.

The second element of claim 11 teaches:

extracting the reduced coenzyme Q10 by an organic solvent under an inert gas atmosphere,

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} The described process does not meet the clear requirement of the second element of claim 11.

Based upon the foregoing, I find that the respondents have failed to prove by clear and convincing evidence that the Kaneka Pre-2002 process practiced the second element of asserted independent claim 11 of the '340 patent.

The second element of claim 33 teaches:

extracting the reduced coenzyme Q10 by an organic solvent in a sealed tank,

This element of claim 33 is identical to that of claim 11 with the exception that extraction in claim 33 is required to be accomplished in a "sealed tank." To the extent that the two claims are identical, I apply the same findings here as in claim 11. I have already found, *supra*, that it has not been established by clear and convincing evidence that the Kaneka Pre-2002 process used a "sealed tank" as construed herein.

Based upon all of the foregoing, I find that the respondents have failed to prove by clear and convincing evidence that the Kaneka Pre-2002 process practiced the second element of asserted independent claim 33 of the '340 patent.

The third element of claims 11 and 33 teaches:

Oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10

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I find that Respondents have not provided clear and convincing evidence that the Kaneka Pre-2002 process performed the step of oxidizing ***the extracted reduced coenzyme Q10*** to oxidized coenzyme Q10, {

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Based upon the foregoing, I find that the respondents have failed to prove by clear and convincing evidence that the Kaneka Pre-2002 process practiced the third element of asserted independent claims 11 and 33 of the '340 patent.

Based upon all of the foregoing, I find that the respondents have failed to prove by clear and convincing evidence that Kaneka's Pre-2002 process anticipates any of asserted claims 1, 11, 22 or 33 of the '340 patent.

A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined the asserted independent claims to be anticipated and invalid, I could still find that their respective dependent claims are valid. Since, however, I have found asserted independent claims 1, 11, 22 and 33 to be ***not*** anticipated, their respective dependent claims are necessarily not anticipated, because they depend from the asserted independent claims and necessarily contain all of the elements of the respective independent claims from which they depend. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992); *In re Royka*, 490 F.2d 981, 983-985 (C.C.P.A. 1974); *see also In re Sernaker*, 702 F.2d 989, 991 (Fed. Cir. 1983). Based upon the foregoing, I find that Kaneka's Pre-2002

process does not anticipate dependent claims 2, 3, 4, 8, 9, 10, 12, 13, 14, 15, 20, 21, 23, 24, 25, 29, 30, 31, 32, 34, 35, 36, 37, 41, 42, 43, or 44 of the '340 patent.

2. U.S. Patent No. 3,066,080 ("Folkers")

Respondents' Position: Respondents assert that claims 1-3, 6-14, and 17-21 of the '340 patent are invalid as anticipated by U.S. Patent No. 3,066,080 ("Folkers"). (Citing RX-63.) Respondents say that Folkers discloses an industrial scale process for producing oxidized coenzyme Q10, culturing reduced coenzyme Q10 producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorus source, and a micronutrient to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10, disrupting the microbial cells to obtain reduced coenzyme Q10, oxidizing reduced coenzyme Q10 to oxidized coenzyme Q10 and extracting coenzyme Q10 by an organic solvent under an inert gas atmosphere. Respondents continue that Dr. Connors, Kaneka's expert, admitted that Folkers discloses all of the limitations of the independent claims of the '340 patent except for the 70% limitation. (Citing Tr. at 1185:22-1186:1.)

Respondents say that Folkers discloses culturing microorganisms in increasingly larger volumes from the initial seed cultures to commercial large scale production. (Citing RX-63 at 1:37-42.) Respondents continue that examples 10 and 11 of Folkers disclose culturing a 1000 liter broth and then extracting oxidized coenzyme Q10 from the microbial cells in that broth. (Citing *id.* at 8:1-9:11.) Respondents explain that Folkers classifies these examples as "commercial, large scale production." (Citing *id.* at 8:1-3, 8:70-74.)

Respondents disagree with Dr. Connors' argument that Folkers only discloses a pilot scale process. According to Respondents, Dr. Connors admitted that Folkers[7] enabled a person

[7] Based on context and the cited testimony by Dr. Connors, it appears that Respondents intended to refer to the '340 patent, not Folkers.

of ordinary skill in the art, as of December 27, 2001, to scale up the claimed process to an industrial scale production. (Citing Tr. at 1197:9-1200:25.) Respondents reason that if a person of ordinary skill was able to scale up to an industrial scale process based on the disclosure of the '340 patent of a 750 liter fermentation as Kaneka contends, Folkers would also be enabling because it was actually based on a larger fermentation. (Citing Tr. at 1195:20-1200:25.)

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Respondents disagree with Kaneka's argument that a production of 67.8 mg of oxidized CoQ10 is only a pilot scale. Respondent argue that "Kaneka attempts to undermine the significance of the 1,000-liter fermentation in the Merck patent, which is larger than the 750-liter fermentation disclosed in the '340 patent, by focusing on the fact that the subsequent purification was carried out on only 75 grams of dry cell weight and ultimately yielded 67.8 mgs of oxidized CoQ10." (RRB at 68.) Respondents respond to this argument, saying that the '340 patent filed more than 40 years after Folkers discloses an oxidized CoQ10 yield of 74 mg. (Citing JX-1 at 21:35-43.)

Respondents also disagree with Kaneka's argument that Folkers does not disclose industrial scale production because {

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Respondents argue that Folkers discloses the use of specific microorganisms to produce oxidized coenzyme Q10 in commercial significant amounts. (Citing RX-63 at 2:62-3:9.)

Respondents say that Dr. Connors admitted that Folkers discloses culturing these microorganisms in mediums that contain a carbon source, a nitrogen source, a phosphorus source, and a micronutrient. (Citing Tr. at 1157:6-1158:25; RX-63 at 1:47-2:14, 3:18-11:30.)

Respondents say that Folkers discloses using saponification to disrupt the microbial cells prior to extraction. (Citing RX-63 at 8:70-9:6; RX-392 at 33:8-34:25, 51:1-53:11, 76:11-77:5.) Respondents contend that Dr. Connors admitted that Folkers discloses a disruption step. (Citing Tr. at 1161:11-13.)

Respondents say that Kaneka has taken the position that oxidation must necessarily occur in a process that uses reduced coenzyme Q10 producing microorganisms to obtain a final product of oxidized coenzyme Q10 to meet the limitations of the asserted claims. (Citing JX-9 at ¶¶ 36-37.) Respondents continue, saying that Folkers discloses a process that uses reduced coenzyme Q10-producing microorganisms to make a final product of oxidized coenzyme Q10. Additionally, Respondents say that Dr. Connors admitted that the saponification step of Folkers is an oxidation step. (Tr. at 1161:14-1162:13.)

Respondents assert that Folkers discloses extracting coenzyme Q10 by organic solvents. (Citing RX-63 at 3:31-32, 3:62-66, 11:3-10.) Respondents contend that Folkers also discloses conducting the disruption and extraction process steps in "a protection atmosphere of non-reactive but oxygen excluding gas such as nitrogen, or maintenance of a reducing atmosphere such as hydrogen." (Citing *id.* at 3:53-61.) Respondents say that Dr. Connors admitted that Folkers discloses extracting coenzyme Q10 by an organic solvent under an inert gas atmosphere. (Citing Tr. at 1162:14-1163:21.)

Respondents disagree with Kaneka's assertion that Folkers does not disclose extracting under an inert gas atmosphere, saying that Folkers actually discloses conducting the extraction in

"a protection atmosphere of non-reactive but oxygen excluding gas such as nitrogen, or maintenance of a reducing atmosphere such as hydrogen." (Citing RX-63 at 3:53-61.) Respondents continue that Dr. Connors admitted that Folkers discloses extracting coenzyme Q10 under an inert gas atmosphere. (Citing Tr. at 1162:14-1163:21.)

Respondents say that Dr. Connors opined that the only claim element missing from Folkers was culturing reduced coenzyme Q10-producing microorganisms to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10. (Citing *id.* at 1185:22-1186:1.) Respondents disagree, asserting that the 70 mole % limitation is an inherent characteristic of the microbial culture and conditions specified in Folkers.

Respondents say that Folkers discloses producing coenzyme Q10 using microbial fermentation and culture conditions that are designated as suitable by the specification of the '340 patent. Respondents continue that the '340 patent acknowledges *pseudomonas denitrificans* is a reduced coenzyme Q10 producing microorganism because it produces microbial cells with 85 mole % reduced coenzyme Q10 when measured under the standard screening methods described by the '340 patent. (Citing JX-1 at 19:18-19, Table 2.)

Alternatively, Respondents assert that the 70 mole % limitation is nothing more than a characteristic of the culturing conditions. Respondents say that testimony establishes that different culturing conditions, including temperature, oxygen, and the passage of time, affect the ratio of reduced coenzyme Q10 among the entire coenzymes Q10 in the microbial cells. (Citing RX-623C, Qs. 202-253; RX-308C; RX-402C; RX-585C; RX-348C, Qs. 259-276, 416-417; RX-473C, Qs. 174-194; Tr. at 594:6-595:22, 607:11-610:8, 1011:7-1012:25, 1060:21-1061:12.) Respondents reason that a person of ordinary skill in the art, recognizing that the ratio of reduced

coenzyme Q10 within the microbial cells depends on the conditions of culture would know to put the cells in an oxygen deprived condition when looking to skew the ratio in favor of reduced coenzyme Q10. Respondents argue that Dr. Woodruff's testimony supports this conclusion.

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Respondents argue that even if the 70 mole % limitation provides an advantage or benefit when culturing to obtain a final product of oxidized coenzyme Q10, such a limitation is not a patentable feature because it is an inherent characteristic of the process and/or microorganism. (Citing *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F3d 1368, 1376 (Fed. Cir. 2001); *In re Cruciferous Sprout Litigation*, 301 F.3d 1343 (Fed. Cir. 2002

Respondents assert in the reply brief, Folkers and the '340 patent disclose culturing *Pseudomonas denitrificans* using a carbon source, nitrogen source, phosphorous source, and micronutrient at a temperature between 15 to 45°C. According to Respondents, the '340 patent demonstrates that *Pseudomonas denitrificans* produces reduced CoQ10 at a ratio of not less than 85 mole % among the entire coenzymes Q10 when measured under the standard culturing and measurement methods. (Citing JX-1 at 19:18-19.)

Respondents disagree with Kaneka's argument that the strains of *Pseudomonas denitrificans* in Folkers and '340 patent are different and that there is no evidence to suggest that the two different strains satisfy this limitation when cultured under the same conditions.

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Kaneka's Position: Kaneka asserts that Folkers fails to disclose the "industrial scale" limitation or the limitation requiring 70 mole % reduced coenzyme Q10. Kaneka says that Mr. Ebina testified that commercialization was an indicator of whether "industrial scale" was being achieved. (Citing Tr. at 652:9-653:8.) {

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Kaneka says that Mr. Ebina testified that none of the prior art references disclose a 70 mole % ratio of reduced coenzyme Q10 and Folkers does not contain any teaching or instruction on how to culture to obtain 70 mole % reduced coenzyme Q10. (Citing Tr. at 657:10-24, 664:22-665:8.) {

}

Kaneka asserts that there is no disclosure of extraction occurring under an inert gas atmosphere or in a sealed tank.

Kaneka says that although Folkers recognizes the existence of the reduced form of coenzyme Q10, it does not suggest that microorganisms produce predominantly reduced rather than oxidized coenzyme Q10, or reduced coenzyme Q10 at a ratio of at least 70 mole %. (Citing RX-63 at 3:71-72; CX-655C, Q. 3-126.) Kaneka continues that Dr. Woodruff's testimony supports this point. (Tr. at 485:20-487:3.) Kaneka says that Dr. Connors and Dr. Taylor agree that Folkers teaches away from the claimed inventions of the '340 patent by suggesting that microorganisms produce coenzyme Q10 predominantly in oxidized form. (Citing Tr. at 770:5-

772:12; CX-655C, Q. 3-126.) Kaneka says that the '340 patent describes the coenzyme Q10 obtained from its fermentation method as an orange residue, which is characteristic of the oxidized form of coenzyme Q10. Kaneka says that Folkers does not suggest that oxidation may be a desirable step in producing oxidized coenzyme Q10 through fermentation. (Citing CX-655C, Q. 3-126; RX-467C, Q. 338.) Kaneka continues that Dr. Taylor agrees that it was known to be undesirable and counterproductive to produce a high ratio of reduced coenzyme Q10 when attempting to produce oxidized coenzyme Q10 as a final product. (Citing Tr. at 770:3-15.)

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Kaneka disagrees with Dr. Trumpower's opinion that the *pseudomonas denitrificans* disclosed in Folkers would produce at least 70 mole % reduced coenzyme Q10. Kaneka says there is no evidence that the *pseudomonas denitrificans* disclosed in Folkers, which has a different accession number (NRRL B-1665) from the *pseudomonas denitrificans* strain disclosed in the '340 patent (IAM 12023), would necessarily produce reduced coenzyme Q10 at a ratio of not less than 70 mole % under the conditions specified by the '340 patent just because the strain disclosed in the '340 patent would do so.

Kaneka contends that the 70 mole % limitation is not inherently disclosed in Folkers. Kaneka says that Dr. Trumpower testified that he did not believe that 70% mole limitation was inherent at all. (Citing Tr. at 692:2-10.) Kaneka continues, arguing that the question of whether

or not this limitation is inherently disclosed in Folkers turns on whether the mere disclosure of *Pseudomonas denitrificans*, a microorganism capable of producing reduced-coenzyme Q10, "necessarily" means that it will culture reduced coenzyme Q10 at 70 mole percent given the culturing parameters disclosed in Folkers. Kaneka says that Folkers does not discuss the ratio of reduced coenzyme Q10 during culturing.

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} Kaneka concludes that even if one of ordinary skill in the art knew how to manipulate culturing conditions to affect the ratio of reduced Coenzyme Q10 in certain microorganism at the time of the invention of the '340 Patent, that has little, if anything, to do with whether the 70 mole % must necessarily result based on the disclosure of Folkers.

Kaneka argues that Dr. Taylor has offered contradictory positions regarding whether Folkers discloses an industrial scale production. Kaneka says that Dr. Taylor initially testified there is an industrial scale when there is demand for a product or the projected demand for a product at the time you are making it. (Citing Tr. at 778:2-4.) Kaneka continues that Dr. Taylor shifted his position and stated that industrial scale can be met by virtue of trying to create a market. (Citing Tr. at 778:25-779:9.) Kaneka concludes that the inconsistent testimony shows that Folkers did not disclose an industrial scale production.

Kaneka says that Folkers acknowledges that culturing conditions affect the amount of

coenzyme Q10 produced through fermentation. Kaneka continues that although Folkers provides an example of a 1000 liter fermentation, the purification was only carried out on 75 grams of dry cell weight, ultimately yielding 67.8 milligrams of oxidized coenzyme Q10. (Citing RX-63 at 9:1-10:40.) Kaneka asserts that in order for a process to operate at the commercial scale, it must be capable of producing coenzyme Q10 in sufficient quantities to satisfy the demands of the marketplace. (Citing CX-655C, Q. 3-126.) Kaneka asserts that the disclosure of a large fermentation tank does not alone anticipate an industrial scale process. (Citing CX-655C, Q. 3-126.)

In its reply brief, Kaneka says that Dr. Connors never agreed that a person of ordinary skill in the art would have been able to scale up a ten liter fermentation to industrial scale production as of December 27, 2001, as Respondents contend. (Citing Tr. at 1197:9-1200:25.) Rather, according to Kaneka, Dr. Connors merely stated that the disclosure in Folkers, though it discusses using a thousand-liter fermentation, did not yield a commercially significant amount at the time of patenting. (Citing Tr. at 1197:9-1200:12.)

Kaneka says that Dr. Connors never agreed that Folkers would enable industrial scale to one of ordinary skill in the art as of December 27, 2001. (Citing Tr. at 1197:9-1200:25.) Kaneka continues that Dr. Connor's testimony at the hearing is consistent with his initial analysis that Folkers "does not provide complete examples of industrial scale production of coenzyme Q10," especially considering "the low amount of coenzyme Q10 obtained from the microorganisms." (Citing CX-655C, Q. 1-47.)

Staff's Position: Staff says that Folkers issued on November 27, 1962, making it prior art to the '340 patent under 35 U.S.C. § 102(a). Staff continues that clear and convincing evidence does not show that Folkers discloses the "culturing reduced coenzyme Q10 producing

microorganisms," 70 mole %, and "oxidizing thus obtained/the extracted reduced Q10" limitations, as required by all asserted claims.

Staff says that example 10 of Folkers "illustrates commercial large scale production" and discloses fermentation in a 2000-3000 liter vat to produce 1000 liters of fermentation broth. (Citing RX-63 at 8:2-4, 8:44-60.) {

} (Citing Tr. at 778-79.) Staff reasons that in view of the marketplace, and as confirmed by Dr. Taylor, 2000-3000 liters was an industrial quantity. (Citing Tr. at 778:20-24.) Staff says this is far larger than the largest example in the '340 patent of 750 liters. Staff reasons that if Folkers is not found to disclose an industrial scale production then the '340 patent does not either.

Staff says that Folkers also discloses culturing reduced coenzyme Q10 producing microorganisms under Kaneka's proposed construction, as required by all claims. Staff reasons that because almost all Q10 producing microorganisms produce at least some Q10 in the reduced form, the evidence demonstrates that Folkers meets this limitation under Kaneka's proposed construction. According to Staff, additional limitations proposed in Staff's and Respondents' constructions are not disclosed by Folkers.

Staff says that Folkers discloses culturing in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient, as required by all claims. (Citing RX-63 at 1:55-2:13; RX-392C at 95-97; RX-437C, Q. 47.)

Staff says that Folkers does not disclose culturing to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10. According to Staff, the evidence at the hearing shows that the ratio of reduced coenzyme Q10 is

highly dependent upon the strain of bacteria used, the culturing conditions, and the testing conditions used to measure the ratio. Staff continues that the evidence demonstrates that different strains of the same organisms produce different proportions of reduced coenzyme Q10.

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} Staff continues that no party has provided actual testing data indicating that the strains disclosed in Folkers produced 70 mole % reduced coenzyme Q10.

Staff says that Folkers discloses disrupting the microbial cells to obtain the reduced coenzyme Q10. (Citing RX-63 at 3:49, 8:70-9:3.) Staff continues that Dr. Connors admitted that Folkers discloses disruption. (Citing Tr. at 1161:11-13.)

Staff says that Folkers discloses oxidizing reduced coenzyme Q10, by disclosing that the cells are heated in a mixture of ethanol, potassium hydroxide, and pyrogallol under reflux (i.e., the disruption step). Staff says that this does not meet the limitations of claims 1 and 22 because claims 1 and 22 require the oxidation to take place after the disruption step occurs, not during.

Staff says that Folkers discloses that all or substantially all of the coenzyme Q10 is oxidized prior to the extraction step. Staff reasons that because claims 11 and 33 require oxidation after the extraction step, Folkers does not meet this limitation.

Staff says that Folkers discloses extraction with organic solvents in an atmosphere of no-reactive gas. (Citing RX-63 at 3:53-61.) Staff continues that Dr. Connors admits that Folkers discloses extraction of coenzyme Q10 with an organic solvent in an inert gas atmosphere. (Citing Tr. at 1162:14-22, 1163:1-21.)

Discussion and Conclusions: Based on the evidence in the record, I find that Respondents have failed to offer clear and convincing evidence that Folkers anticipates claims 1-3, 6-14, and 17-21 of the '340 patent.

Although Folkers discloses the use of 1000 liter fermentation tanks, Respondents have failed to prove by clear and convincing evidence that Folkers discloses producing oxidized coenzyme Q10 on an industrial scale as required by the preambles of claims 1 and 11. Folkers explicitly states that "[t]he present invention makes possible the preparation of . . . Coenzyme Q-10 in substantial, commercially significant quantity by means of fermentations which may be conducted on a suitably large scale." (RX-63 at 1:37-42.) In example 10, Folkers explicitly states that "[t]his example illustrates commercial, large scale production . . . . Medium is prepared for one thousand liters as described above, but using larger quantities . . . . These ingredients are combined, in a two to three thousand liter fermentation vat . . . . They are combined and made up the volume with approximately one thousand liters of suitably pretreated purified water, either in the fermenter vessel, or a separate vat . . . ." (RX-63C at 8:2-50.)

This 1000 liter fermentation, alone, however, does not prove by clear and convincing evidence that Folkers itself discloses producing oxidized coenzyme Q10 on an industrial scale. Folkers says that only 760 mg of an orange residue containing coenzyme Q10 were produced when broth from the 1000 liter fermentation was processed. (RX-63C at 9:8-11.) Folkers continues that when 680 mg of this orange residue material was purified, only 67.8 mg of purified coenzyme Q10 was actually produced. (RX-63C at 9:43-45, 10:20-22.) Thus, Folkers discloses producing roughly 67.8 mg of purified coenzyme Q10.

Respondents' arguments that this production of 67.8 mg of purified coenzyme Q10 is on an "industrial scale" are not persuasive. First, Respondents correctly note that Example 6 of the

'340 patent says that 74 mg of high-purity oxidized coenzyme Q10 was obtained. This argument is disingenuous. Although this amount is similar to the 67.8 mg discussed in Folkers, example 6 of the '340 patent actually addressed a ten liter fermentation, not a 750 liter fermentation, as Respondents reply brief implies, or the 1000 liter fermentation actually discussed in Folkers. (JX-1 at 20:62-65, 21:19-25.) Thus, the '340 patent actually discloses producing more oxidized coenzyme Q10 in a 10L fermentation than Folkers disclosed producing following a fermentation one hundred times larger. This comparison, if anything, actually weighs against finding that producing 67.8 mg of purified coenzyme Q10 following the 1000 liter fermentation of Folkers is an "industrial scale" production.

Second, Respondents arguments regarding whether or not one of skill in the art *could* scale up the disclosure of Folkers to an industrial scale production, and testimony showing whether or not Folkers was actually manufacturing oxidized coenzyme Q10 are irrelevant for purposes of whether Folkers itself anticipates the claims of the '340 patent. Anticipation is a question of what is disclosed, explicitly or inherently, in a single prior art reference. *Schering Corp.* 339 F.3d at 1377. What one of ordinary skill in the art could potentially do (i.e., scaling up to an "industrial scale" production) after reading Folkers does not address what is actually disclosed in Folkers. Likewise, what Merck was actually doing, outside of the disclosure of Folkers, does not address what is actually disclosed in Folkers. Respondents have not argued that the ability to scale up, or Merck's activities relating to coenzyme Q10, was inherently disclosed in Folkers. As a result, these arguments are irrelevant for purposes of anticipation.

Because Folkers merely discloses producing roughly 67.8 mg of purified coenzyme Q10 following a 1000 liter fermentation, Respondents have failed to provide clear and convincing

evidence that Folkers discloses "a process for producing on an industrial scale the oxidized coenzyme Q10 . . . ."

Respondents have proven by clear and convincing evidence that Folkers discloses "culturing reduced coenzyme Q10 producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient," as required by the first element of the claims 1 and 11. Kaneka's expert admits that Folkers discloses culturing microorganisms in mediums that contain a carbon source, a nitrogen source, a phosphorus source, and a micronutrient. (Tr. at 1157:25-1158:25.) Kaneka does not contest whether this limitation is disclosed in Folkers. (See CIB at 102-105.) As a result, Respondents have proven by clear and convincing evidence that Folkers discloses "culturing reduced coenzyme Q10 producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient."

Respondents have failed, however, to prove by clear and convincing evidence that Folkers discloses "culturing . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by the first element of claims 1 and 11. Respondents have relied on an inherency argument to contend that this limitation is present in Folkers. I find, however, that the 70 mole % limitation is not inherent in Folkers because it is not necessarily disclosed in Folkers.

First, Respondents have not shown by clear and convincing evidence that the culturing conditions disclosed in Folkers would necessarily result in microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10. Respondents' brief admits that culturing conditions impact whether or not the 70 mole % limitation will be met. Indeed, Respondents say that: "the ratio of 70 mole % reduced CoQ10

claimed by Kaneka as the novel feature of the '340 patent is nothing more than a characteristic of the culturing conditions. The testimony in this case is clear: different culturing conditions—including temperature, oxygen and the mere passage of time—affect the ratio of reduced CoQ10 among the entire coenzymes Q10 in the microbial cells." (RIB at 103.)

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} This is not clear and convincing evidence that the culturing conditions disclosed in Folkers necessarily would result in reduced coenzyme Q10 at 70 mole percent being produced.

Testimony from one of Respondents' experts raises doubts that the culturing conditions disclosed in Folkers necessarily would result in reduced coenzyme Q10 at 70 mole percent being produced. When asked to identify where Folkers discloses the culturing conditions that would yield a ratio of 70 mole % reduced coenzyme Q10, Dr. Trumpower testified that "Dr. Folkers in

the Folkers patent describes culture conditions, including the usual carbon source, nitrogen, phosphorus and micronutrients, and I believe he actually talked about various carbon sources, for example, these people were experts, I believe they would know to vary that." (Tr. at 673:4-18.) Thus, Dr. Trumpower admitted that the disclosure of Folkers would have to be "var[ied]" in order to meet the ratio of 70 mole % reduced coenzyme Q10.

Second, the disclosure in the '340 patent that *Pseudomonas denitrificans* can produce 85 mole % reduced coenzyme Q10 does not mean that the mere disclosure of *Pseudomonas denitrificans* in Folkers necessarily discloses producing at least 70 mole % reduced coenzyme Q10. By Respondents own admission, "different culturing conditions—including temperature, oxygen and the mere passage of time—affect the ratio of reduced CoQ10 among the entire coenzymes Q10 in the microbial cells." (RIB at 103.) As explained above, Respondents have not provided clear and convincing evidence that the culturing conditions disclosed in Folkers necessarily would result in producing at least 70 mole % reduced coenzyme Q10. As a result, Folkers' disclosure of *Pseudomonas denitrificans* does not necessarily disclose producing at least 70 mole % reduced coenzyme Q10. As a result, Respondents have failed to provide clear and convincing evidence that Folkers discloses, explicitly or inherently, "culturing . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10."

Respondents have failed to prove by clear and convincing evidence that Folkers teaches "disrupting the microbial cells to obtain reduced coenzyme Q10," as required by the second element of claim 1. Although Folkers discloses using saponification to disrupt the microbial cells prior to extraction (RX-367C, Qs. 342-43; RX-63 at 8:70-9:6) and Kaneka's expert, Dr. Connors, admitted that Folkers discloses a disruption step (Tr. at 1161:11-13), Dr. Connors

testified that the alleged disruption step of Folkers also results in oxidation of the reduced coenzyme Q10. (Tr. at 1161:14-1162:13). Respondents actually rely on this testimony to assert the saponification step (the alleged disruption step) is an oxidation step. (RIB at 101.) Because the disruption step also causes oxidation, "reduced coenzyme Q10" is not obtained, as required by this element. As a result, I find that Respondents have failed to prove by clear and convincing evidence that Folkers teaches "disrupting the microbial cells to obtain reduced coenzyme Q10," as required by the second element of claim 1.

Respondents also have not proven by clear and convincing evidence that Folkers teaches "oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10 and then extracting the oxidized coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by the third element of claim 1. "Thus-obtained reduced coenzyme Q10" in the third element refers to the reduced coenzyme Q10 that was obtained by the "disrupting" step. In Folkers, however (as explained, *supra*), the coenzyme Q10 is oxidized during disruption, not after disruption. Because Folkers does not teach that oxidation occurs after disruption, Respondents have not proven by clear and convincing evidence that Folkers teaches "oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10 and then extracting the oxidized coenzyme Q10 by an organic solvent under an inert gas atmosphere."

Respondents also have not proven by clear and convincing evidence that Folkers teaches "extracting the reduced coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by the second element of claim 11. The saponification step of Folkers, which oxidizes the coenzyme Q10, occurs before extraction. (RX-63 at 3:29-35, 3:53-61; Tr. at 1161:14-1162:13.) As a result, the coenzyme Q10 that is extracted would already have undergone oxidization. (See *id.*) Respondents have not proven by clear and convincing evidence that any

reduced coenzyme Q10 remains after the saponification step. As a result, Respondents have failed to prove by clear and convincing evidence that Folkers teaches extracting reduced coenzyme Q10. I find that there is not clear and convincing evidence that Folkers teaches "extracting the reduced coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by the second element of claim 11of the '340 patent.

Respondents have not provided clear and convincing evidence that Folkers teaches oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10 as required by the third element of claim 11 because the coenzyme Q10 was already oxidized at the time it was extracted in Folkers. Based upon the foregoing, I find that the respondents have failed to prove by clear and convincing evidence that Folkers teaches the third element of asserted independent claim 11 of the '340 patent.

Based upon all of the foregoing, I find that the respondents have failed to prove by clear and convincing evidence that Folkers anticipates asserted claims 1 or 11 (or any other asserted claim) of the '340 patent.

A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined the asserted independent claims to be anticipated and invalid, I could still find that their respective dependent claims are valid. Since, however, I have found asserted independent claims 1 and 11 to be not anticipated, their respective dependent claims are necessarily not anticipated, because they depend from the asserted independent claims and necessarily contain all of the elements of the respective independent claims from which they depend. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992); *In re Royka*, 490 F.2d 981, 983-985 (C.C.P.A. 1974); *see also In re Sernaker*,

702 F.2d 989, 991 (Fed. Cir. 1983). Based upon the foregoing, I find that Folkers does not anticipate dependent claims 2-3, 6-10, 12-14, and 17-21 of the '340 patent.

C. Obviousness

Respondents' Position: Respondents contend that each of the independent Claims 1, 11, 2 and 33 of the '340 patent is obvious under either Kaneka's or Respondents' claim constructions from the Folkers Patent or Kaneka's Pre-2002 Process either by itself as it would be understood and applied by a PHOSITA.

Respondents argue that to the extent that the Folkers patent process or Kaneka's Pre-2002 Process is found to not anticipate or render the 70% limitation obvious, it would be obvious (or "obvious to try") for a PHOSITA to use microorganisms, culture media and culture conditions disclosed by U.S. Patent No. 3,769,170 ("Kondo")(RX-66) or Hajime Yoshida, et al., *Production of ubiquinone-10 using bacteria*, by, JOURNAL OF GENERAL APPLIED MICROBIOLOGY, (1998)("Yoshida")(RX-82). Respondents allege that Kaneka has "admitted those latter two references inherently satisfy the 70% limitation." Respondents add to the extent that any of the Folkers patent combined with the knowledge of PHOSITAs on the critical date might be deemed to not anticipate or render obvious any of the "industrial scale," "inert gas atmosphere" and "sealed tank" limitations, they are obvious from Kaneka's Pre-2002 Process.

Respondents argue that each of the asserted, dependent claims 2-10, 12-21, 23-32, 34-45 is obvious because it would have been obvious to a PHOSITA either from one of the principal references alone or "in combination with other references identified below."

Respondents aver that until Kaneka amended its claims to add limitations requiring "industrial scale" production and extracting either "under an inert gas atmosphere" or "in a sealed tank," the examiner consistently and repeatedly rejected all claims presented by Kaneka as

anticipated by or obvious from Kondo and Yoshida, "along with other references for some claims." Respondents elaborate that throughout the entire prosecution history, the examiner firmly rejected Kaneka's contention that patentability could be based on the claims' requirement that the cultured microorganism cells contain not less than 70 mole % reduced CoQ10. (Citing JX-2 at MGC00121708-718, MGC00121758-766, MGC00121775; JX-3 at MGC00122061-071; RX129C at Qs. 3-11) Respondents reason, therefore, the focal point of an obviousness determination should be those added limitations.

Respondents allow that the examiner "apparently conceded that these added limitations conferred patentability on the claims;" but assert that the examiner did not have the following evidence when he made his decision: (1) that industrial scale production of oxidized CoQ10 by fermentation of microorganisms and extraction with organic solvents had been conducted by PHOSITAs for more than 20 years before the critical date; (2) that the '340 patent did not disclose any advantages to "scaling-up" CoQ10 production from laboratory scale compared to the prior art; and (3) that extraction "under an inert gas atmosphere" and "in a sealed tank" were well known, at least by Kaneka's constructions of those terms. Respondents argue that, if the examiner had the evidence now before the Commission, she would have found the independent claims invalid in view of the knowledge of PHOSITAs.

Respondents contend that combining the references as suggested by Respondents would have been obvious to a PHOSITA at the critical date because all of the references either specifically relate to CoQ10 or—in the case of the citations to the McGraw Hill Encyclopedia of Science and Technology ("McGraw-Hill")(RX-44) and the *Fermentation & Biochemical Engineering Handbook* by Vogel & Todaro ("Vogel")(RX-76) are disclosures of relevant, generic processing procedures and equipment. Citing *In Re Johnston*, 435 F.3d 1381, 1384-85

(Fed. Cir. 2006) (motivation to combine teachings when both references deal with the same field of technology; *KSR* 550 U.S. at 416-421.) Respondents say that, Mr. Ebina, their expert, testified that the prior art, including that cited here, was a part of the "tool box" of persons of ordinary skill in the art. Respondents say he testified, "When such persons were faced with the problem of improving processes to manufacture Coenzyme Q10 by fermentation of microorganisms, it would have been obvious for such persons to combine the known techniques to perform the steps as claimed in the '340 patent or at least obvious to try those combinations." (Citing RX-129C at Qs. 5-16, 1-21, 1-29, 1-24, 5-6, 5-14; RX-367C, Q. 387) Respondents argue that any testimony to the contrary by Dr. Connors is not entitled to any weight. Respondents assert "because the obviousness combinations asserted by Respondents include prior art references and knowledge not before the examiner, the statutory presumption of validity is more easily overcome." Citing *i4i,* 131 S.Ct. at 2245 (2011.) *Cf. In re Portola Packaging, Inc.*, 110 F.3d 786, 791 (Fed. Cir. 1997) (no new issue of patentability when the same combinations were before the examiner.) "Prior art under the § 102(b) on-sale bar is also prior art for the purposes of obviousness under § 103." *Dippin' Dots,* 476 F.3d at 1344.

In their reply brief, Respondents say that Kaneka asks the Commission to believe, "based almost entirely on the uninformed testimony of Dr. Connors," that it would not have been obvious for a PHOSITA to combine the laboratory scale teachings regarding specific microorganisms suitable for producing CoQ10 with the general and specific CoQ10 knowledge of such persons "regarding industrial scale fermentation and extraction using organic solvents." Respondents contend that position is incorrect as a matter of fact and as a matter of law.

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} Respondents allege that Dr. Connors admitted that it would be obvious to try scaling up processes for producing CoQ10 to an industrial scale because "people in the industry knew how to scale up." Respondents argue that the '340 patent "relies on that obviousness to satisfy the enablement requirement." {

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Respondents argue that the prior art references cited in this case closely fit the pattern in *KSR Int'l Co. v. Teleflex, Inc.* 550 U.S. 398, 127 S. Ct. 1727 (2007). Respondents quote the opinion to say, *inter alia*:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.
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> * * * *
>
> Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.

Id. at 417-18. Respondents contend that in this investigation, all of the cited prior art is either from the same "field of endeavor," involving CoQ10 specifically, or the broader, pertinent field of culturing microorganisms and extracting desired products by extracting with organic solvents.

Respondents add that the *KSR* Court said:

> Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.
>
> * * * *
>
> Common sense teaches ... that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. .... A person of ordinary skill is also a person of ordinary creativity, not an automaton.

Id. at 420-21.

Respondents say that Mr. Ebina has testified without contradiction that the cited prior art was a part of the "tool box" of persons of ordinary skill in the art, continuing:

> When such persons were faced with the problem of improving processes to manufacture Coenzyme Q10 by fermentation of microorganisms, it would have been obvious for such persons to combine the known techniques to perform the steps as claimed in the '340 patent or at least obvious to try those combinations.

(Citing RX-129C, Q. 5-16)

Respondents reason that it would have been obvious for a PHOSITA on the critical date to combine prior art disclosing culturing specific microorganisms and extracting CoQ10 by use of organic solvents with the PHOSITA's knowledge of culturing other microorganisms and extracting CoQ10 by use of organic solvents on an industrial scale, and conducting extraction under an inert gas atmosphere or in a sealed tank. Respondents argue that knowledge could either be the PHOSITA's general knowledge or provided by one or more of the industrial scale references discussed by Respondents in this brief and their opening brief. Respondents say it would have been obvious, "or at least obvious to try", for a PHOSITA to combine any CoQ10-producing microorganism in an industrial scale, including those whose culturing inherently produced not less than 70 mole % in the reduced form, with known industrial scale processes for culturing and extracting CoQ10 and similar products.

Respondents argue even where the claimed ranges and prior art ranges do not overlap, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges are close enough that one skilled in the art would have expected them to have the same properties. (Citing *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003); *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985)). Respondents say mere changes in concentration or ratios are not patentable modifications in a production process unless the particular ranges are critical in producing new and unexpected results which are different in kind and not merely in degree from the results in the prior art. (Citing *In re Swain*, 156 F.2d 239, 241-42 (C.C.P.A. 1946); *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955); *In re Swenson*, 132 F.2d 1020, 1022-23 (C.C.P.A. 1942)) Respondents conclude that a PHOSITA need not engage in hindsight to see that there is no difference, in a process for making oxidized coenzyme Q10, between culturing microorganisms to obtain microbial cells containing at least 70 % reduced coenzyme Q10 and culturing microorganisms to obtain microbial cells containing at 60 % reduced coenzyme Q10. Respondents say the final product is oxidized, and the '340 patent "identifies no advantage to starting with 10% more reduced."

Respondents turn to the substance of their obviousness argument and note that the preamble of all four independent claims is the same and that obviousness of the "on an industrial scale" limitation is in dispute. Respondents state that claim 1 consists of the "industrial scale", "culturing", "70% reduced CoQ10", "disrupting", "oxidizing before extracting", "extracting oxidized CoQ10" and "extracting under an inert gas atmosphere" limitations.

Respondents argue that although the Patent examiner allowed the claims of the '340 patent over Kondo and Yoshida, based in part on the addition of the "industrial scale" limitation, she did not consider Folkers, Kaneka's Pre-2002 Process or the teachings of large scale

production methods that were known and taught in textbooks and encyclopedias long before the critical date, and was a part of the skill of a PHOSITA." Respondents aver that Folkers, McGraw-Hill and Vogel teach suitable, common industrial methods in existence before the critical date . (Citing RX-367C at Qs. 390 and 400; RX-63; RX-44; RX-9.)

Respondents argue that Folkers discloses examples for producing oxidized CoQ10 by growing microorganisms in fermentation vessels or tanks up to 3000L in size containing approximately 1000L of fermentation broth, which Folkers characterizes as "commercial, large scale production." (Citing RX-63 at 8:1 – 9:11, 1:37-42; RX-367C, Q. 341.)

Respondents argue that Kaneka's Pre-2002 Process was "undisputably on an industrial scale."

Respondents add that the record of this investigation does not reveal any obstacles that would prevent scaling up the prior art process of Folkers, Kondo or Yoshida. (Citing RX-367C, Q. 390; RX-66.) Respondents cite *SmithKline v. Apotex*, 2005 U.S. Dist. LEXIS 5999 (E.D. Pa. March 31, 2005 to hold that where the patent discloses no advantage to scaling up a process, an "industrial scale" limitation cannot distinguish the claimed process from the prior art.

Respondents aver that all four independent patent claims require the culturing limitation, and that it is undisputed that Folkers, Kaneka's Pre-2002 Process, Kondo, and Yoshida "each disclose such culturing and such a culture medium." Respondents allege that all CoQ10-producing microorganism cells produced by fermentation contain a mixture of oxidized and reduced CoQ10. The claimed culture medium is conventional for culturing microorganisms. (Citing RX-129C at Qs. 2-37, 5-23.)

Respondents argue that in its attempt to distinguish the prior art, Kaneka has placed great weight on the requirement in all four independent claims of "culturing … to obtain microbial

cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10." Respondents cite for example, during prosecution of the parent application to the '340 Patent, the applicants argued that their invention "is based on applicants' discovery that some microorganisms . . . actually contain reduced coenzyme Q10 at a high ratio, *i.e.*, a ratio of not less than 70 mole % among the entire coenzyme Q10." (Citing JX-2 at MGC00121744.)

Respondents add that to the extent that it might not have been obvious to satisfy the 70% requirement from Folkers or the Kaneka Pre-2002 process alone, it would have at least been obvious to try combining either of those references with the microorganism, culture media and culture conditions of Kondo or Yoshida in developing processes with increased yield.

Respondents note that, as pointed out by the examiner, one of the strains disclosed by Kondo, *Candida curvata* (ATCC 10567), is identical to one listed by Kaneka in Table 1 of the '340 patent as producing reduced CoQ10 at a ratio of 74 mole % among the entire CoQ10. (Citing JX-1 Table 1; JX-3 at MGC00122065-066; RX-66 at 1:53; RX-367C, Q. 392.)

Respondents state that the first three species and one strain of *Agrobacterium radiobacter*, ATCC 4718, disclosed by Yoshida are disclosed in Tables 1 and 2 of the '340 patent. (Citing RX-367C, Q. 373; JX-1; RX-367C, Q. 373; JX-1; RX-82 at 21.) Respondents aver that testing of that strain by Otte *et al.* proves that Yoshida meets the 70% limitation. (Citing RX-367C, Qs. 376, 377.) Respondents allege they performed culturing and fermentation of that strain in a manner that would be adequate to replicate the culturing, fermentation and extraction methods described by Yoshida. (Citing RX-367C, Q. 377; RX-306; RX-368.) Respondents add that Otte *et al.* repeated the extraction procedure using the extraction method described in Kaneka's European Patent No. 1446983, the European counterpart of the '340 patent with a nearly identical disclosure. Respondents conclude that both extracts were analyzed

via HPLC according to Kaneka Patent No. EP 1446983. Respondents assert that regardless of the extraction method used, more than 95% of CoQ10 in the cells was in the reduced form. (Citing RX-367C, Q. 377; RX-306, Q. 52.)

Respondents allege that Kaneka admitted in its June 8, 2007 Amendment and Response during the prosecution of the '249 Parent Application, that "Kondo et al. and Yoshida et al. disclose culturing the same microorganisms as those of the present invention, so that 'microorganisms' containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzyme Q10 are inherently disclosed." (Citing RX-367C, Q. 392; JX-2 at MGC00121775; RX-380 at 8) Respondents contend that neither the '340 patent nor the record in this investigation provides any credible evidence that there is any advantage to culturing microorganisms satisfying the 70% limitation, as compared with the prior art, when making oxidized CoQ10 as a final product. Respondents reason therefore, the 70% limitation has no utility, and cannot be used to distinguish the claims over the prior art. (Citing RX-367C, Qs. 431-433; Tr. at 156:13-157:12; RX-294C at 99:11-19; *Imperial Stone Cutters v. Schwartz*, 370 F.2d 425, 429 (8th Cir. 1966); *Amphenol Corp. v. General Time Corp.*, 397 F.2d 431, 438 (7th Cir. 1968))

Respondents assert that Folkers includes two disclosures that Dr. Connors admitted would cause disruption of the cells: a heat treatment called saponification and cell lysis. (Citing RIB Section III.C.2.) {

} Respondents add that Kondo meets this limitation as construed by Kaneka, because Kondo discloses the use of methanol, pyrogallol and 64 g sodium hydroxide and heated to reflux at 80°C for an hour. (Citing RX-66 at 2:57-61; RX-367C, Q. 394) Respondents continue that Yoshida discloses

disrupting concentrated cells with glass beads prior to extraction of CoQ10, and it teaches use of glass beads for physically disrupting the concentrated cells prior to extraction of CoQ10. Respondents say Yoshida also discloses blending in a Waring Blender, which would result in breaking the surface structure. (Citing RX-82 at 20; RX-367C, Q. 386) Finally, Respondents contend that Japanese Unexamined Patent Application, S57-70834 ("Kimizuka") also discloses a series of CoQ10 process steps including disrupting the microbial cells as claimed in the '340 patent. (Citing RX-25.)

Respondents note that claim 1 requires "oxidizing thus obtained reduced coenzyme Q10 to oxidized coenzyme Q10." Respondents say Mr. Ebina has testified that, because the product of culturing is a mixture of oxidized and reduced CoQ10, oxidation would be obvious in order to obtain a final product in the oxidized form. He also testified that it would be obvious to oxidize either before or after extracting. (Citing RX-129C, Qs. 2-8, 2-11, 5-54 and 5-55)

Respondents say as a practical matter in commercial production of CoQ10, one must oxidize CoQ10 to produce a final product that is oxidized CoQ10. Respondents reason that a PHOSITA would have understood that any commercial process for producing oxidized CoQ10 necessarily includes oxidizing obtained reduced CoQ10 to oxidized CoQ10. (Citing RX-129C, Qs. 2-10 – 2-13; RX-367C, Q. 360) (Citing the July 9, 2010 Office Action to say that although Kondo and Yoshida "do not explicitly distinguish between oxidized and reduced forms of coenzyme Q10 during the process of fermentation and extraction, the final products obtained are oxidized forms of coenzyme Q10." (JX-3 at MGC00122069))

Respondents contend that the CoQ10 molecule's natural tendency to become oxidized in ambient air outside of the cell was known before the critical date. (Citing RX-367C at ZMC108668, Q. 38.) Respondents argue if natural oxidation was not sufficient to convert all of

the reduced CoQ10 to the oxidized form, a PHOSITA would know, from the prior art, that an oxidizing agent could be used to oxidize the remainder. (Citing RX-367C, Qs. 380, 396.)

Respondents contend that Kaneka's "broad definition" suggests that the use of a "sealed tank" is necessarily present in any commercial process. Respondents reason that the construction of "sealed tank" advanced by Kaneka suggests that a PHOSITA at the critical date would consider use of such a tank for extracting at least an obvious choice, if not a necessary one, in a plant made in accordance with the prior art prior art processes, such those taught by Folkers, Kondo and Yoshida. (Citing RX-367C, Q. 399; RX-294C at 373:19 - 376:18; Tr. at 1201:1-17)

Respondents assert that the use of "sealed tanks" with organic solvents was a common safety precaution that was well-known to PHOSITAs before the critical date. Respondents cite the IPCS Safety Guide No. 105 (RX-328, *e.g.*, at § 4.5), the USDA Good Manufacturing Practice Guidelines (RX-62), and General Provisions for Safe and Healthy Design of Production Facilities, GB-5083 (RX-7) to teach common industrial safety practices, which references one would combine with the Folkers, Kondo and Yosida to use an "inert gas atmosphere" and/or a "sealed tank." (Citing RX-367C, Q. 384; RX-296 at 119, 187:11-14.)

Respondents argue to the extent that it might not have been obvious to satisfy the extracting in a sealed tank limitation from the Folkers patent or Kondo or Yoshida alone, it would have at least been obvious to try combining any one of the sealed tank references discussed above in designing a CoQ10 process on an industrial scale.

Respondents contend that each of the dependent claims is invalid for obviousness under 35 U.S.C. § 103(a), because the claimed subject matter and any differences between the claimed invention and the prior art would have been obvious to a PHOSITA from the prior art cited by Respondents and from the general knowledge of such persons. Respondents say that claims

including the patent's dependent claim limitations were rejected in Kaneka's applications, and the dependent claims were allowed only because of limitations in the independent claims from which they depend. Respondents allege that Kaneka did not argue that the dependent claim limitations—all common in the relevant prior art—separately contributed to patentability. (Citing RX-129C, Qs. 3-2, 3-30)

Respondents conclude that the limitations in the dependent claims would have been obvious "to the skilled artisan" based solely on one of Folkers, Kaneka's Pre-2002 Process, Kondo or Yoshida "in combination with common knowledge in the art."

In their reply brief, Respondents say that Kaneka seeks to distinguish each of the references cited by Respondents with one of three main arguments: (1) they do not disclose, teach, or suggest the 70% limitation, or (2) they do not disclose, teach, or suggest "industrial scale," or (3) they do not disclose, teach, or suggest the use of an "inert gas atmosphere" or a "sealed tank."

Respondents aver that in its opening brief, Kaneka asserts that "the protected innovation in the '340 Patent lies in the particular way that microorganisms are cultured, and the particular molar ratios required to be obtained by the '340 Process." (Citing CIB at 21.)

Respondents allege that Kaneka admits that practically all limitations in the '340 patent claims, other than the 70% limitation, were known or obvious. Respondents quote Kaneka's brief to state: "the concepts of culturing, fermenting, and extracting were known prior to the '340 Patent, as were the concepts of industrial scale and the use of sealed tanks and inert gas atmospheres." (*Id.*). Respondents continue that Kaneka admits that standard procedures for commercial production of CoQ10 include "disrupting the microorganisms when desired," extracting, and oxidizing reduced Coenzyme Q10, and that previous commercial production of

CoQ10 included safety measures for use of organic solvents and regulated tank systems for the containment of the process. (*Id.* at 4).

Respondents contend that Kaneka is relying now almost exclusively on the claim limitation requiring culturing to produce microorganisms that contain not less than 70 mole % reduced coenzyme Q10 (the "70% limitation") to distinguish the prior art, and has essentially abandoned its other, earlier arguments, including the patent prosecution and litigation arguments it has made regarding nonobviousness of industrial scale, inert gas atmosphere and sealed tank limitations.

Respondents say that Kaneka argues that Respondents' prior art references, including Kondo and Yoshida, do not satisfy the 70% limitation. Yet, the examiner found those three references did satisfy that limitation. (Citing JX-3 at MGC00122064-070; RX-66; RX-82; RX-27.) Respondents add that Kaneka's argument is made in spite of Kaneka's admissions concerning the inherent disclosure of this limitation by Kondo and Yoshida (Citing JX-2 at MGC00121775; CIB at 5, 95-100, 102 and 105-128; SIB at 121, 126, 133-134)

Respondents argue that valid prior art may be created by the admissions of the parties. (Citing *In re Fout*, 675 F.2d 297, 300 (CCPA 1982)), and an admission by an applicant during patent prosecution is binding upon him. (Citing *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569, 1570 (Fed. Cir. 1988)) Respondents argue, therefore, the Commission may properly hold that Kondo and Yoshida these references disclose the 70% limitation inherently on that basis alone. Respondents add that, setting aside estoppel issues, these references disclose both the microorganisms and the culturing conditions that Kaneka said would generate the 70% ratio. (Citing JX-1; JX-3 at MGC00122065-066; RX-66 at 1:53; RX-82 at 21; RX-367C, Qs. 373 and 392.) Respondents conclude that it is both fundamentally fair and scientifically justified

to hold that Folkers, Kondo, Yoshida, and the Pre-2002 Process inherently disclose the 70% limitation.

Respondents say that Kaneka argues that the cited prior art does not specifically disclose that any microorganisms produce not less than 70 mole % reduced coenzyme Q10. (Citing CIB at 101-102.) Respondents say that argument wrongly assumes that such a disclosure is necessary to anticipate or render obvious the 70% limitation, and wrongly assumes that there is any utility to culturing microorganisms to produce CoQ10 that is no less than 70% in the reduced form in making a final product that is to be entirely oxidized. Respondents reiterate that in spite of Kaneka's repeated assertions that its inventors discovered that CoQ10-producing microorganisms could be cultured to produce not less than 70% in the reduced form, that did not confer patentability on the '340 patent claims; because microorganisms and culturing conditions that inherently produced not less than 70% CoQ10 were already known.

Respondents say that Kaneka argues that each of the laboratory scale references does not disclose, teach, or suggest "industrial scale" production. (Citing CIB at 92-138.) Respondents counter that the fact that those references do not disclose any larger scale is a strong indication their authors' belief that PHOSITAs did not require industrial scale examples in order to enable practical use of their disclosures. Respondents "presume" that the many companies filing those patent applications were not doing that as an academic exercise and believed that their disclosures enabled industrial processes. (Citing admitted patents and applications in the range: RX-10 – RX-66.)

Respondents contend that the knowledge of PHOSITAs must be considered "in the context of the fact that { } MGC and others had been commercially producing oxidized CoQ10 by fermentation and extraction with organic solvents for 20 years before the December

27, 2001 critical date." (Citing RX-129C, Q. 5-17; RX-435C, Qs. 114-121.) {

} Respondents argue that scaling up was not difficult or nonobvious. (Citing Tr. at 781:2-9, 789:7-790:18, 1210:20-1211:9; SIB at 120, 126)

Respondents say that Kaneka argues that each of the laboratory scale references and Folkers do not disclose, teach, or suggest the use of an "inert gas atmosphere" and a "sealed tank." (Citing CIB at 110-126, 132.) Respondents contend that argument to be meritless, in view of "Kaneka's arguments that those limitations relate to "industrial scale" production, and the admissions by Kaneka and Dr. Connors." Respondents quite Kaneka's brief to say, "The '340 Process is carried out using much of the same equipment as previous commercial production of CoQ10, including safety measures for large scale use of organic solvents and regulated tank systems for the containment of the process and transfer of the working materials" (Citing CIB at 4), and that "the concepts of industrial scale and the use of sealed tanks and inert gas atmospheres" were known (Citing CIB at 21.) Respondents conclude that Dr. Connors testified that it would be obvious to use a sealed tank and an inert gas atmosphere when extracting with a solvent. (Citing Tr. at 1201:1 – 1203:9.)

Respondents turn to specific combinations of prior art in response to "nonobviousness allegations in Kaneka's and the Staff's opening briefs."

Respondents assert that the Pre-2002 process, at least in combination with the knowledge and experience of a PHOSITA, renders obvious claims 1-4, 8-15, 20-25, 29-37 and 41-44 of the '340 patent. Respondents argue that to the extent that the Commission finds that some claim limitation would not have been obvious from Kaneka's Pre-2002 Process alone, it should find

the claims would have been obvious from the knowledge and experience of a PHOSITA and/or the other prior art cited in Respondents opening brief.

Respondents assert that Folkers in combination with the knowledge and experience of a PHOSITA, renders obvious claims 1-4, 8-15, 20-25, 29-37 and 41-44 of the '340 patent. Respondents say that Kaneka argues that Folkers does not disclose producing coenzyme Q10 on an "industrial scale" and it fails to disclose 70 mole % reduced CoQ10. (Citing CIB at 102-103, 109-111.) Respondents reiterate the argument in their initial brief at 98-100 and 117.

Respondents say that Kaneka argues that "there is no disclosure of extraction occurring under an inert gas atmosphere or in a sealed tank" in Folkers. Respondents counter that nonobviousness arguments on these grounds are doomed by Dr. Connors' admissions that extracting under an inert gas atmosphere or in a sealed tank, under his constructions, were obvious. (Citing CIB at 104; RX-367C, Q. 383, Q. 398-399; Tr. at 1201:1-17, 1201:25-1203:9,).

Respondents add to the extent that the Merck Patent alone did not render the claims obvious with respect to either inert gas atmosphere, those claims are obvious at least in combination with Gullickson (RX-8), EPA (RX-2), and NFPA (RX-48 at 1.5.11, 1.5.18, 1.5.19, 2.5, and 5.8.3)[8]. (RIB at 124; RRB at 88.)

Respondents say that Kaneka continues to assert claims 4-5, 15-16, 25-26 and 37-38, which relate to the use of an oxidizing agent, yet their brief says nothing to rebut the obviousness of using an oxidizing agent in any process for producing CoQ10 by culturing and extracting.

Respondents state that Kaneka continues to assert claims 6, 7, 17, 18, 27, 28, 39 and 40, which relate to continuous or countercurrent extraction. Respondents aver that the only

[8] While Respondents make a similar argument regarding sealed tank disclosures, they first provide it in their reply brief (RRB at 88), and it is, therefore, improper new information in a rebuttal brief as I explained at the hearing when instructing the parties on the matter of initial and reply briefs.

reference to a disclosure of such extraction in the "Validity" section of Kaneka's Brief says that Folkers mentions the term in one sentence and provides no meaningful discussion or details as to how to achieve it. Respondents assert that the record shows that continuous and countercurrent extraction were generally known, as shown by Vogel (Citing RX-76 at SHENZITC790_166203-236) at SHENZITC790_166206, and McGraw-Hill (Citing RX-44 at ZMC104134-38) at ZMC104134, each of which includes a drawing "remarkably similar to Fig. 1 of the '340 patent."

Kaneka's Position: Kaneka opens that generally, as a fundamental concept, the art of culturing microorganisms on an industrial scale is not completely predictable and techniques that provide good results alone could result in reduced results when combined. Kaneka continues that it also does not appear that persons of ordinary skill in the art knew around the 2001 timeframe that Coenzyme Q10 could be produced by fermentation in predominantly the reduced form. Kaneka says they would have not appreciated that under certain culture conditions and for certain strains of microorganisms the ratio of reduced to oxidized Coenzyme Q10 would be as high as 70 mole %. Kaneka avers that MGC's expert, Mr. Ebina, noted that he has not seen in any prior art literature, including all of the public prior art references in this Investigation, that "would directly show [70 mole %], or what is exceeding that particular number." Kaneka concedes that Mr. Ebina is the only expert witness in this case in the specific field of "industrial research and development and production of coenzyme Q10." (Citing CX-655C, Qs. 1-155, 1-157; Tr. at 646:11-25.)

Kaneka says that the failure to observe the 70 mole % limitation also applies to Dr. Crane, the discoverer of Coenzyme Q10, who worked with the compound for several decades. Kaneka states that Dr. Crane learned of the invention claimed in the '340 Patent only recently at his deposition and stated that he never thought of the possibility of "chasing the reduced form" of Coenzyme Q10 at the time he worked on the molecule. (Citing CX-655C, Q. 1-158.)

Kaneka asserts that ultimately, the selection of the optimal conditions for culturing microorganisms to obtain the 70 mole % limitation requires testing of suitable microorganisms. Kaneka points to the testimony of its expert, Dr. Connors, who said during trial that it would be improper to engage in hypotheticals such as the importation of the teachings discussed in the '340 Patent into cited prior art such as Folkers and Kondo for invalidity purposes, because this exemplifies hindsight analysis. Kaneka concludes that the key references relied on by the Respondents (*i.e.* Folkers, Kondo, and Yoshida) never satisfy the "to obtain" coenzyme Q10 aspect of the culturing element from the '340 Patent. (Citing Tr. at 1173:21-1174-9 and 1225:1-5.)

Kaneka argues that there is no motivation to combine the various prior art cited by Respondents. (Citing CX-655C, Qs. 1-153 to 1-164.) Kaneka states that none of the prior art references, whether taken alone or in combination with each other or the general knowledge of the persons skilled in the art, renders the claimed inventions of the '340 Patent obvious. Kaneka disagrees that the claims of the '340 Patent are obvious in light of Folkers itself, or Folkers in combination with the general knowledge of a PHOSITA and one or more of the prior art references cited. Kaneka asserts that, although Dr. Trumpower believed that Kondo, in combination with Folkers, would allow one of ordinary skill in the art to achieve the 70 mole % limitation, he was unable to identify any point in the references where this can be achieved. (Citing Tr. at 674:2-24.) Kaneka says regarding whether it would be obvious to combine Folkers and Kondo to meet the 70 mole % limitation, Dr. Trumpower limits his analysis to references that have no relevance to the actual production of coenzyme Q10 – thus failing to demonstrate industrial scale. (Citing Tr. at 677:15-678:2.) Kaneka also disagrees that the claims of the '340 Patent are obvious in light of Kaneka's pre-2002 process in combination with the general knowledge of such a person and/or one or more of the prior art references cited.

Kaneka says that it is incorrect to cobble together from any combination of techniques disclosed in any prior art to show that such combinations would have been "obvious to try." Kaneka reasons that given the number of potential techniques and complexities in industrial fermentation, this assertion does not comport with the realities of this art. Kaneka continues that conditions such as temperature and the pH level, along with the time of culturing and the level of nutrients in the culturing broth can all affect the relative ratios of reduced to oxidized coenzyme Q10 with cells. (Citing Tr. at 707:1-709:15 and 761:8-25.) Kaneka argues that given so many variables, the 70 mole % of reduced coenzyme Q10 limitation would not be "obvious to try" for a PHOSITA.

Kaneka says its expert, Dr. Connors, does not find that there is a strong motivation to combine various techniques for producing Coenzyme Q10 within the framework of Folkers disclosure. Kaneka reiterates that Folkers does not disclose an industrial scale process, and adds that the art of culturing on an industrial scale is unpredictable and techniques that provide good results alone could result in reduced results when combined. Kaneka concludes that assumptions and understandings of oxidized and reduced forms of Coenzyme Q10 also lead to unpredictability, misinterpretation of experimental results and teachings away from the patented invention. (Citing CX-655C, Qs. 1-155 to 1-156.)

Pointing to Dr. Crane's testimony cited *supra*, Kaneka argues that persons of ordinary skill in the art were unaware as of the 2001 timeframe that Coenzyme Q10 could be produced by fermentation in predominantly the reduced form. Kaneka asserts they would have had no idea that under certain culture conditions and for certain strains of microorganisms the ratio of reduced to oxidized Coenzyme Q10 would be as high as 70 mole %. Kaneka adds that Dr. Trumpower also failed to recognize and appreciate culturing microorganisms to obtain Coenzyme Q10 primarily in the reduced form. Kaneka says that Dr. Taylor also recognized that Kondo and Folkers would not be

interested in the relative ratio of reduced to oxidized coenzyme Q10. (Citing Tr. at 678:3-13 and 770:3-771:4.)

Kaneka argues that, without knowing that microorganisms may produce reduced Coenzyme Q10 at a ratio at least as high as 70 mole % during fermentation, a PHOSITA would not have thought to require an oxidation step in the manufacturing process for oxidized Coenzyme Q10.

Kaneka contends that the fact that there was an alleged "intense activity" prior to the critical date of the '340 Patent to "find microorganism species, to develop mutant strains, and to develop particular culture media suitable for those species and strains, to produce a high yield of Coenzyme Q10 serves to further support the non-obviousness of the '340 Patent. Kaneka concludes that there is no motivation to combine the prior art upon which Respondents relied, especially with respect to Folkers. Kaneka adds that Dr. Trumpower's inability to explain the anticipatory effect of Folkers/Kondo/Crane on the numerous coenzyme Q10 references in the approximately 30 years between Folkers and the '340 Patent highlights the Respondents' myopic use of the hindsight bias in this case. (Citing Tr. at 683:5-686:5.)

Kaneka next focuses on the analysis of MGC's expert, Mr. Ebina, who expressed several opinions regarding the general knowledge of one of ordinary skill in the art. Kaneka cites its expert, Dr. Connors, to have testified that it would not have been obvious to a PHOSITA to use or try to use one of the microorganisms having the 70 mole % of reduced Coenzyme Q10 when looking for "high yielding microorganisms" because the fact that microorganisms may produce 70 mole % of the reduced form of Coenzyme Q10 or above during culturing was not known in the art until the invention of the '340 Patent.

Kaneka avers that Mr. Ebina's opinions on this issue are contrary to opinions expressed in other parts of his report. Kaneka adds that the opinion that it would have been obvious to a person of

ordinary skill in the art to use or try to use microorganisms producing 70 mole % of the reduced form of Coenzyme Q10 because "microorganism having that characteristic, according to the '340 Patent, were known," is another instance of the use of hindsight given the lack of knowledge on this issue prior to the invention of the '340 Patent. Kaneka points out that Mr. Ebina's opinion refers to no prior art references from his own personal observation that demonstrate the 70 mole % limitation. (Citing CX-655C, Qs. 1-132 to 1-133.)

Kaneka notes that Dr. Connors said that the prior art references cited by Mr. Ebina taught away from the idea that microorganisms produced Coenzyme Q10 predominantly in its reduced form. Kaneka reiterates that Dr. Connors reaffirmed during trial that there was no industrial fermentation process for the manufacture of oxidized CoQ10 starting with reduced CoQ10 before the invention of the '340 Patent. (Citing Tr. at 1127:9-16.) Kaneka says Dr. Connors believes that Mr. Ebina's opinions were formed with the benefit of hindsight. (Citing CX-655C, Q. 1-135.) Kaneka argues that Mr. Ebina's analysis employs a classic case of hindsight – taking components of the claims and opining that a person of skill in the art would assume them to be present, rather than taking prior art and determining whether it contains elements of the claimed invention. Kaneka adds that the level of oxygen that would trigger a dangerous condition depends on the organic solvent used. (Citing Tr. at 648:24-649:16.)

Kaneka says that Dr. Connors finds that the '340 Patent does advise PHOSITAs of the materials (inert gas atmosphere) and equipment (sealed tank) to be used for the safe operation of the industrial manufacturing process claimed. (Citing CX-655C, Q. 1-131; JX-1, 16:36-39 and Figure 1.)

Kaneka avers that Dr. Connors testified that a PHOSITA would not "have known that all microorganisms produced a high ratio of reduced Coenzyme Q10 until the inventions of the '340

Patent." Kaneka cites Dr. Connors to have said that a PHOSITA would not have known of a need to use an oxidizing agent since persons of skill in the art did not yet appreciate the amount of reduced Coenzyme Q10 produced by the microorganisms. Kaneka reiterates that prior to the '340 Patent it was not known that microbial cells may produce Coenzyme Q10 in predominantly the reduced form or that oxidation may thus be necessary to produce pure oxidized Coenzyme Q10. Finally, Kaneka says that Dr. Connors finds Mr. Ebina's opinions to be contrary when he first asserts that one of ordinary skill in the art would not necessarily have known of using closed extraction tanks because the "pollution risk varies," then subsequently asserting that it would have been "known and obvious" to one of ordinary skill to use a closed tank. (Citing CX-655C, Qs. 1-137, 1-134 and 1-138.)

Kaneka argues that the '340 Patent would not be rendered obvious by Kaneka's Pre-2002 process {

} Kaneka emphasizes that the initial burden rests with the Respondents to show why a reference renders a claim element obvious. {

} Kaneka counters that it only tends to confirm that Respondents do not have sufficient evidence to demonstrate that the '340 Patent was non-inventive.

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Kaneka avers that Dr. Connors disagrees with the opinion of MGC's expert Mr. Ebina that the independent claims of the '340 Patent would have been obvious to a PHOSITA based on what is publicly known about Kaneka's pre-2002 process. Kaneka asserts that the only public facts about Kaneka's pre-2002 Process upon which Mr. Ebina relies are (1) the fact that Kaneka was one of the largest manufacturers of Coenzyme Q10 from 1980-2001; (2) the fact that Kaneka's Coenzyme Q10 was produced by fermentation of yeast pre- 2002; (3) the fact that Kaneka's Coenzyme Q10 was advertised and sold as pure oxidized Coenzyme Q10. Kaneka says that those facts alone do not shed any insight on the true technical details regarding { } and cannot render the '340 Patent's claimed process obvious. (Citing CX-655C, Q. 1-129.)

Kaneka contends that Folkers lacks key limitations found in the claims of the '340 Patent, and says Folkers does not disclose the basic steps for production of Coenzyme Q10 by fermentation and extraction on an industrial or commercial scale. (Citing CX-655C, Qs. 1-45 to 1-54, 3-129 and 2-21.)

Kaneka contends that Folkers acknowledged that culturing conditions may affect the amount of Coenzyme Q10 produced through fermentation; but not the reduced/oxidized ratio. Kaneka says that in later references, the initial fermentation process as described in Folkers was said to be not suitable for industrial scale production because of the low amount of Coenzyme Q10 obtained from the microorganisms. Kaneka adds that many of the subsequent patents relating to manufacturing Coenzyme Q10 through fermentation fail to suggest any success in obtaining a high yield. Kaneka says subsequent to Folkers, development of the method of manufacturing Coenzyme Q10 through fermentation focused for the most part on selection of strains that produced a large amount of

Coenzyme Q10 in the microbial cells as well as adjustment of culturing conditions to increase total yield of Coenzyme Q10 (e.g., increasing the amount of Coenzyme Q10 produced in the microbial cells, increasing the productivity of the cells, or both).

Kaneka continues Folkers does not provide the scale extraction disclosures sufficient to inform persons of ordinary skill in the art before 2001. Saying, for instance, there is no disclosure in Folkers of reduced Coenzyme Q10 content, extraction occurring under an inert gas atmosphere, or extraction in a sealed tank. (Citing CX-655C, Qs. 1-51 to 1-52.)

Kaneka asserts that Dr. Connors notes that Mr. Ebina himself concedes that Folkers "indicated a path for future development of the fermentation process for making Coenzyme Q10." (Citing RX-129C, Q. 2-47) Kaneka argues this is an acknowledgement that the disclosure in Folkers is elementary and does not sufficiently describe the '340 Patent, especially given that this patent was issued approximately 50 years ago. Kaneka reasons, therefore, there is no support for the conclusion by Mr. Ebina that a PHOSITA would expect the ratio of the reduced form to total Coenzyme Q10 to be substantially the same for different strains of the same microorganism under the same culturing conditions and culturing medium.

Kaneka contends that Kondo lacks key limitations found in the claims of the '340 Patent. (Citing CX-655C, Qs. 1-55 to 1-59 and 3-130.) Kaneka continues that Kondo does not disclose a process for manufacturing Coenzyme Q10 on an industrial scale, as the maximum cultivation scale appears to be 5 liters. Kaneka adds that the Examiner considered Kondo during the prosecution of the patent application that led to the '340 Patent and found the claims patentable over Kondo. Kaneka says in the Amendment and Remarks immediately prior to the issuance of the Notice of Allowance, the applicant argued that Kondo is distinguishable because it did not focus on culturing to obtain 70 mole % of reduced Coenzyme Q10. Kaneka says culturing and measurement conditions

matter, and Kondo does not disclose or suggest the conditions that would yield the 70 mole % limitation. (Citing Tr. at 655:18-657:9, 674:2-10.) Kaneka adds that the applicant argued that Kondo does not suggest oxidizing and then extracting under inert gas atmosphere or in sealed tank (or extracting under inert gas atmosphere or sealed tank and then oxidizing), and does not teach disrupting to obtain reduced Coenzyme Q10 on an industrial scale.

Kaneka reiterates that Dr. Taylor imparts data displayed in the examples of the '340 Patent backward in time to Kondo, and argues that this attempt at "reverse extrapolation" is not scientifically sound. Kaneka concludes that without the benefit of hindsight provided by the '340 Patent, a PHOSITA would have reasonably determined that the microorganisms in question only produced oxidized Coenzyme Q10 as taught by Kondo.

Kaneka reiterates that various strains within a particular genus and species may have different properties with respect to their propensities to produce at least 70 mole % of reduced Coenzyme Q10. Kaneka says even if the strains were identical, the culturing conditions in Kondo and Example 1 of the '340 Patent are different, and therefore it does not necessarily follow that the strain cultured by Kondo produced at least 70 mole % of reduced Coenzyme Q10.

Kaneka reasons therefore, Dr. Taylor is incorrect in assuming that the strains and culturing conditions in Kondo would have necessarily produced at least 70 mole % of reduced Coenzyme Q10 among the entire coenzymes Q10. Kaneka argues it would not have been obvious to a PHOSITA to first oxidize the reduced Coenzyme Q10 and then later perform the extraction step. (Citing RX-367, Q. 396.) Kaneka says that Dr. Taylor did not address why one of ordinary skill would combine Kondo and Yoshida to arrive at a conclusion that first oxidizing and then extraction would be advantageous. Kaneka asserts that Kondo (and Yoshida) sought only to produce oxidized Coenzyme Q10 and did not know whether or how much reduced Coenzyme Q10 was being produced. Kaneka

reasons that, because of this, a PHOSITA considering Kondo may have treated reduced Coenzyme Q10 as an impurity worthy of being discarded.

Kaneka asserts that Kimizuka lacks key limitations found in the claims of the '340 Patent. (Citing CX-655C, Qs. 1-87 to 1-90.) Kaneka says that Kimizuka is directed to a specific way of oxidizing reduced coenzyme Qn to oxidized coenzyme Qn where n = 1-12, as Kimizuka suggests that certain methods of oxidization (e.g., oxygen in the presence of ferric chloride or caustic alkali) may not be suitable for "industrial purposes" due to secondary reactions and operational difficulties. Kaneka concludes that Kimizuka does not disclose production of oxidized Coenzyme Q10 by fermentation on an industrial scale. Kaneka adds that the examples in Kimizuka involve the production of less than 1 gram of oxidized Coenzyme Q10, and that Kimizuka also does not disclose extraction under an inert gas atmosphere or in a sealed tank.

Kaneka argues that Kimizuka does not suggest that microorganisms would produce reduced Coenzyme Q10 at a ratio of at least 70 mole %, and in fact, Kimizuka suggests the opposite. Kaneka quotes Kimizuka to say, "Even in manufacturing by fermentation, coenzyme Q could sometimes change into reduction-type coenzyme Q during manufacturing process or during incubation," which Kaneka says would suggest to a PHOSITA that microorganisms produce primarily oxidized Coenzyme Q10 during fermentation. Kaneka adds, even in the special conditions under which Kimizuka suggests microorganisms may produce reduced-type Coenzyme Q10 during a manufacturing process involving fermentation—e.g., from photosynthetic microorganisms when incubated under limited air flow—Kimizuka does not suggest that microorganisms would produce reduced Coenzyme Q10 at or in excess of a 70 mole %.

Kaneka argues that the '789 Application and Uragami/Koga are missing key limitations found in the claims of the '340 Patent. (Citing CX-655C, Qs. 1-103 to 1-107.) Kaneka says that the

'789 Application and Uragami/Koga are both directed toward the identification of specific microorganisms alleged to have high productivity of Coenzyme Q10. Kaneka notes the '789 Application identifies bacteria belonging to the genus *Hyphomonas*, and Uragami/Koga identifies the bacteria belonging to the genus *Oligomonas*.

Kaneka states that both the '789 Application and Uragami/Koga acknowledge that, as of the time of their respective applications, the productivity of Coenzyme Q10 producing microbes is still insufficient for "practical" use. (Citing RX-32.007 (SHENZITC790_115006)) Kaneka adds that neither the '789 Application nor Uragami/Koga provides examples of production of Coenzyme Q10 using the identified microorganisms on an industrial scale. Kaneka says the '789 Application only provides an example of culturing the microorganism of interest in a 200 ml flask, and the examples of culturing the microorganism in Uragami/Koga involve at most culturing in a 30 L tank. (Citing RX-32.012 (SHENZITC790_115011.) Kaneka concludes that neither reference suggests either that extraction of Coenzyme Q10 in a sealed tank or under an inert gas atmosphere, or that microorganisms produce reduced Coenzyme Q10 at a ratio of 70 mole % or greater.

Kaneka adds that both references acknowledge that there are a variety of recognized methods of identifying and quantifying Coenzyme Q10, including HPLC, elemental analysis, melting point measurement, infrared absorption, spectroscopy, ultra violet absorption spectroscopy, nuclear magnetic resonance spectroscopy and mass spectroscopy. (Citing RX-32.011 (SHENZITC790_115010)) Kaneka reasons there is no reason that "70 mole % reduced Coenzyme Q10" in the '340 Patent claims must be construed to include a particular exemplary method of quantification described in the specification of the patent.

Kaneka addresses Dr. Taylor's opinion that the '789 Application and Uragami/Koga render all claims of the '340 Patent obvious based on the knowledge and common sense of a PHOSITA.

Kaneka says that the '789 Application and Uragami/Koga describe processes for producing oxidized Coenzyme Q10 only on a laboratory scale, and neither of these references discloses, inherently or explicitly, culturing microorganisms to produce at least 70 mole % of reduced Coenzyme Q10 among the entire coenzymes Q10 on an industrial scale. Kaneka continues that neither teaches the use of an oxidizing step before extraction, and neither discloses the use of continuous extraction or countercurrent multistage extraction techniques. Kaneka reiterates that these references also do not disclose the use of an inert gas atmosphere, deoxygenized atmosphere and sealed tanks during extraction.

Kaneka contends that the Yoshida reference is missing key limitations found in the claims of the '340 Patent. (Citing CX-655C, Qs. 1-118 to 1-124 and 3-128) Kaneka describes Yoshida as a journal article that describes the effect of mutations and culture conditions (e.g., aeration) on specific desirable traits such as sedimentation characteristics (i.e., morphology) and production of ubiquinone-10 by one of the three bacterial strains: *Agrobacterium tumefaciens* KY-3085 (ATCC4452), *Paracoccus denitrificans* KY-3940 (ATCC19367) and *Rhodobacter sphaeroides* KY-4113 (FERM-P4675). Kaneka says the article concluded, among other things, that mutations and culturing conditions such as aeration have a significant impact on the amount of ubiquinone-10 produced.

Kaneka asserts that Yoshida does not discuss a process for manufacturing ubiquinone-10 on an industrial scale, and all of the examples provided were done on a laboratory scale. Kaneka adds that Yoshida does not suggest that any of the microorganisms discussed produces reduced Coenzyme Q10, much less that an oxidizing step is necessary or desirable in manufacturing ubiquinone-10 on an industrial scale through fermentation. Kaneka concludes that during prosecution of the '340

Patent, the patent examiner considered Yoshida during the prosecution of the patent application that led to the '340 Patent and found the claims patentable over Yoshida.

Kaneka says it has been alleged that during prosecution of the related abandoned '249 parent application, Kaneka admitted that "Yoshida [] disclose[s] culturing the same microorganisms as those of the present invention, so that 'microorganisms' containing reduced Coenzyme Q10 at a ratio of not less than 70 mole % among the entire Coenzyme Q10 are inherently disclosed." Kaneka counters that this statement "only served to mean that while certain microorganisms may be disclosed in Yoshida, it is not accurate that the microorganisms cited in Yoshida always and necessarily produce reduced coenzymes Q10 at a ratio of not less than 70 mole % among the entire Coenzyme Q10." Kaneka adds there is also no mention made of reduced Coenzyme Q10 production and no discussion of mole percentages.

Kaneka asserts that there is no basis for Respondents' position that the 70 mole % limitation is inherent based on Yoshida. Kaneka says although proper conditions may sometimes result in a particular result, this does not mean that the particular result is "inherent." Kaneka counters that the requirement of proper conditions for potential outcomes means that the result is not "inherent" to the organism or to the conditions. Kaneka charges that with the benefits of hindsight, Respondents again reverse extrapolate the data from the '340 Patent and attributed them to Yoshida.

Kaneka states that genus and species designations are necessary but not sufficient in determining the likeness of strains described in different publications. Kaneka reiterates that mutagenesis can alter the performance of a microbial strain in a given process without altering its genus and species designation. Kaneka adds conditions matter, and to this end, the differences in culturing conditions could affect the mole % ratio of reduced Coenzyme Q10 produced. Kaneka

concludes there is no basis for the opinion that Yoshida would have necessarily obtained the same or similar mole % results as those demonstrated by example 1 of the '340 Patent.

Kaneka says that Respondents assert that because Yoshida cultured strains of *Agrobacterium tumefaciens*, *Paracoccus denitrificans*, and *Pseudomonas denitrificans*, which are allegedly identical to those disclosed in Tables 1 and 2 of the '340 Patent, Yoshida would have necessarily obtained at least 70 mole % of reduced Coenzyme Q10. Kaneka responds that the strain numbers for the above mentioned strains disclosed in Yoshida are different than those disclosed in Tables 1 and 2 of the '340 Patent. Kaneka argues that a PHOSITA would understand that different strains within a particular genus and species may have unique, properties with respect to their ability to produce at least 70 mole % of reduced Coenzyme Q10. Kaneka concludes that Yoshida's use of the above mentioned strains does not establish that they would have necessarily produced at least 70 mole % of reduced Coenzyme Q10.

Kaneka then says Respondents imply that because the strain of *Agrobacterium radiobacter* (ATCC 4718) disclosed in Yoshida is identical to that disclosed in Table 1 of the '340 Patent, that strain would have necessarily produced at least 70 mole % of reduced Coenzyme Q10. Kaneka contends that even if the strains were identical, the culturing conditions in Yoshida and Example 1 of the '340 Patent are different, and therefore it does not necessarily follow that the strain cultured by Yoshida necessarily produced at least 70 mole % of reduced Coenzyme Q10.

Kaneka continues that the experiments in Yoshida were conducted on a laboratory scale, not an industrial scale. Kaneka argues that a PHOSITA would understand that, depending on a variety of factors, including differences in culturing conditions between a laboratory scale environment and an industrial scale environment, mole % ratios can vary. Kaneka reasons, therefore, Yoshida's disclosure of *A. tumefaciens* (ATCC 4718) is insufficient to show that Yoshida would have

necessarily obtained 70 mole % of reduced Coenzyme Q10 among the entire coenzymes Q10 on an industrial scale after culturing. Kaneka adds that the teachings of Yoshida contradict those found within the specification of the '340 Patent. Kaneka says Yoshida discusses conducting mutagenesis and screening for higher amounts of oxidized Coenzyme Q10, while the '340 Patent, conversely, discloses that mutagenesis and selection should be carried out to obtain higher productivity and mole % ratio of reduced Coenzyme Q10. (Citing JX-1 at 7:9-26 and 7:55-65)

Kaneka concludes that, because "Yoshida teaches away from the '340 Patent and conducted mutagenesis and selection for high oxidized Coenzyme Q10 produced after culturing, Dr. Connors concludes that Yoshida fails to demonstrate that the microorganism subject of its analysis necessarily obtained at least 70 mole % of reduced Coenzyme Q10."

Kaneka reiterates that a PHOSITA would not have found it obvious to oxidize before extraction in light of Kaneka's pre- 2002 process, and it would not have been obvious to perform the oxidation step after extraction in view of Yoshida and Kaneka's pre-2002 process. {

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Kaneka contends that in view of Yoshida, a PHOSITA would have understood that only oxidized Coenzyme Q10 was being produced, and there is no reason to combine Yoshida with an oxidizing step. Kaneka argues that contrary to Dr. Taylor's opinion, it would not have been obvious to one of ordinary skill in the art to combine the sealed tank or use of inert gas atmosphere from

Kaneka's Pre-2002 process with the disclosure in Yoshida, because Yoshida's experiments were strictly laboratory scale, and did not include teachings regarding the need to use an inert gas atmosphere or sealed tanks in the extraction process. Kaneka adds that Dr. Taylor's opinion that one of ordinary skill in the art would not have faced any barriers in scaling up the disclosure in Yoshida to industrial scale production is conclusory.

Kaneka asserts that Dr. Taylor did not explain how Yoshida, being unaware of the level of reduced Coenzyme Q10 being produced, would have been motivated to scale up the experiments to obtain at least 70 mole % of reduced Coenzyme Q10 among the entire coenzymes Q10 on an industrial scale after culturing. Kaneka says to the extent that Yoshida is demonstrative of the industrial scale, its points would be limited to productivity of oxidized Coenzyme Q10 through an alternative route—not the utilization of a high mole % ratio of reduced Coenzyme Q10.

In its reply brief, Kaneka argues that a finding of non-obviousness is supported when the prior art teaches away from the claimed combination and the combination yields more than predictable results. (Citing *Crocs, Inc. v. U.S. Int'l Trade Comm'n*, 598 F.3d 1294, 1309 (Fed. Cir. 2010) (use of foam as shoe straps is nonobvious, even though foams were known to be used in the art); *In re Omeprazole Patent Litigation*, 536 F.3d 1361, 1381 (Fed. Cir. 2008)) (where a general method that could have been applied to make the claimed product was known and within the level of skill of the ordinary skill, the claim may nevertheless be nonobvious if the problem which had suggested use of the method had been previously unknown.).

Kaneka refers to its initial brief and argues that it was admitted by all witness at the hearing that the 70 mole % limitation of reduced coenzyme Q10 was never explicitly disclosed in any prior art reference cited by the Respondents. Kaneka says the prior art was largely unconcerned about the ratio of reduced coenzyme Q10 within microorganisms during culturing

because the focus was on obtaining oxidized coenzyme Q10. Kaneka adds most of the prior art discussed were only limited to experiments on a laboratory scale. (Citing CIB at III.D.5.)

Kaneka argues that the claimed culturing of microorganisms to have a high ratio of reduced coenzyme Q10 would not be appreciated by one of ordinary skill to apply in the production of oxidized coenzyme Q10. Kaneka says instead, this technique was first appreciated by the inventors of the '340 Patent. (Citing Tr. at 156:13-21.) Kaneka says it was confirmed by Dr. Crane, Dr. Connors and Dr. Taylor, that culturing to get high levels of reduced coenzyme Q10 as an intermediate step teaches away from the goal of obtaining oxidized coenzyme Q10. (Citing Tr. at 770:3-771:18; RX-392 at 84:11-85:11; CX 655C, Q. 3-126) Kaneka contends the present situation mirrors *Crocs*, in which a finding of non-obviousness is supported when the prior art teaches away from the claimed combination.

Staff's Position: Staff submits that the evidence shows that, to the extent the Pre-2002 Process is not found to anticipate the asserted claims, when combined with what was known by a PHOSITA, it renders all of the asserted claims of the '340 patent obvious.

Staff asserts that the evidence does not show that Folkers discloses the "culturing reduced coenzyme Q10 producing microorganisms" limitation under Staff's proposed construction, or discloses the 70 mole % limitation or the "oxidizing. . .reduced coenzyme Q10" limitation under any proposed construction. Staff also believes the evidence shows that there are limitations of the '340 patent, such as continuous extraction, and extracting in a sealed tank, that are not disclosed by Folkers.

Staff contends that the evidence shows that a PHOSITA would have known how to conduct routine experiments regarding the best culture conditions for producing oxidized Q10; but Staff does not believe that the evidence shows that "the optimal conditions for culturing those

microorganisms to optimize production of oxidized Q10" would necessarily be the conditions that cause bacteria to satisfy the 70 mole % limitation. Staff explains that it does not believe the evidence shows that any of the Respondents satisfy the 70 mole % limitation, indicating that the ratio may be completely irrelevant to the efficiency of production processes. Staff says if this is the case, optimizing the conditions for culture would not necessarily result in microorganisms which satisfied the 70 mole % limitation. Therefore, Staff does not believe that the evidence shows that Folkers combined with the knowledge of a PHOSITA would render the asserted claims obvious.

Staff believes that the evidence shows that continuous extraction and countercurrent multistage extraction were well known to a PHOSITA at the time of the '340 patent, and that accordingly claims 1-4, 8-15, 20-25, 29-37, and 41-44 of the '340 patent were obvious in light of the Pre-2002 Process combined with the knowledge of a PHOSITA.

Staff agrees with Respondents that Kondo, alone or in combination with the knowledge of a PHOSITA, renders all of the claims of the '340 patent obvious. Staff says that Kondo, which issued in 1973, states in its introductory paragraphs that "coenzyme Q10 has been commercially produced by extracting animal tissues, however this is very expensive. . .it has now been found that coenzyme Q10 can be produced in large amounts in microbial cells. ." (Citing RX-66 at 1:20-30 (emphasis added by Staff).) Staff says that the evidence demonstrates that scaling up a process from the laboratory to industrial scale is well within the knowledge of a PHOSITA and that methods and procedures for doing so are well known. Staff says that both Dr. Taylor and Dr. Connors testified that such scale up was well within the capabilities of a person of ordinary skill in the art. (Citing Tr. at 781:2-9.) Staff avers that Dr. Taylor said that he had actually witnessed such scale-ups. (Citing Tr. at 789:7-790:18.) Staff states that Dr. Connors testified

that a person of ordinary skill in the art could scale up from a 10 liter scale to industrial scale. (Citing Tr. at 1210:20-1211:9.) Staff continues, though the '340 patent is directed to an industrial process, almost all of the specification is spent discussing laboratory scale experiments, and the largest volume mentioned is 750L. Staff reasons that, to the extent the '340 patent is enabled, the procedure in Kondo could be easily scaled up. Staff adds that the evidence shows that a PHOSITA would be motivated to use the Kondo method on an industrial scale. Staff argues that in an industrial scale process, the use of a culture medium of 750L was obvious to persons of skill in the art.

Staff says that Kondo was cited during the prosecution of the '249 application, and was the basis of a rejection, and in response, the applicants amended the claims. Staff asserts that in doing so the applicants admitted that Kondo "disclose[s] culturing the same microorganisms as those of the present invention, so that 'microorganisms' containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzyme Q10 are inherently disclosed." (Citing RX-380.) Thus, Kaneka has admitted that the microorganisms in *Kondo* inherently satisfy the 70 mole % limitation.

Staff notes that Kondo discloses the culture of *Candida curvata* (ATCC 10567). Staff says that Tables 1-3 of the '340 patent list the results obtained by the inventors when they cultured various microorganism strains in accordance with the methods in example 1 and tested them to determine the amount of reduced Q10. Staff avers that Table 1 includes *Candida curvata* ATCC 10567, the same strain disclosed in Kondo, and that Table 1 states that it produces 74 mole % reduced Q10 when cultured according to the patent.

Staff contends that Kondo specifically discloses that the culture medium should contain "an assimilable carbon source, an assimilable nitrogen source, inorganic salts and organic

nutrients." (Citing RX-66 at 2:3-6.) Staff says it also discloses a medium comprising ammonium phosphate (a source of nitrogen and phosphorus). (*Id.* at 2:5-17.) Staff notes that Dr. Crane testified that the use of a medium containing carbon, nitrogen, and phosphorous would have been obvious to a PHOSITA, because these elements are needed for the growth of any biological organism. Staff says Dr. Connors also admits that the Kondo reference discloses a medium containing these components. (Citing Tr. at 1164:13-1165:4)

Staff avers that, *Candida curvata* ATCC 10567, which is disclosed by Kondo, is listed in the '340 patent as meeting the 70% limitation. Staff argues that Kondo discloses adding methanol, pyrogallol and sodium hydroxide to the cell solution and refluxing it at 80°C for an hour. (*Id.* at 2:57-61.) Staff asserts that the evidence shows that this step disrupts the cells, and that it was commonly known in the art that disruption of cells eases extraction. Staff says Dr. Connors testified that to a PHOSITA it would have been obvious to use disruption when producing Q10 from a yeast. (Citing Tr. at 1211:14-1212:16.) Staff adds that Mr. Ebina stated that it was generally known to a PHOSITA that disruption was necessary. (Citing RX-129C, Q. 2-16.) Staff concludes that Dr. Taylor testified that use of a disrupting step had long been taught and implemented by the prior art. (Citing RX-367C, Q. 66.)

Staff says that Kondo discloses a procedure for producing Q10 from a bacteria that produces more than 70 mole % reduced Q10, and the evidence demonstrates that the inclusion of an oxidation step, or the use of an oxidizing agent, in such a process to produce oxidize Q10 would be obvious to a PHOSITA.

Staff argues that the evidence demonstrates that Kondo discloses the use of hexane, a hydrophobic organic solvent, to extract Q10. Staff continues that the evidence also shows that a PHOSITA the time would have believed that any extraction process using a solvent such as

hexane should be conducted either under an inert gas atmosphere or in a sealed tank for safety reasons. Staff notes that Dr. Taylor testified, sealed tanks "are very common in the prior art and very many introductory bioengineering textbooks." (Citing Tr. at 773:17-23.) Staff states that Q10 is a lipid, and Dr. Taylor testified that the use of inert gas atmospheres is "also a very standard practice throughout lipid chemistry. As far back as I can remember, we've used inert gases to protect lipids from degradation or oxidation." (Tr. at 786:17-20.) Staff says that Mr. Kayama testified that use of such conditions was commonplace in Japan, and indeed required by regulations. (RX-367C, Q. 74.) Staff adds that the evidence further shows that nitrogen gas is commonly used to provide an inert gas atmosphere.

Staff says that the evidence demonstrates that the use of a hydrophilic organic solvent, such as isopropyl alcohol, was well known at the time of the '340 patent.

Staff argues that the evidence shows that the use of a continuous extraction process and a countercurrent multistage extraction in an industrial process were obvious to persons of skill in the art.

Staff agrees with Respondents' assertion that Folkers combined with Kondo renders all of the asserted claims of the '340 patent obvious, because Kondo alone renders all of the asserted claims obvious, and that Folkers explicitly discloses extraction in an inert gas atmosphere, and industrial scale processes.

Staff supports Respondents' assertion that Folkers combined with Kondo and Kimizuka renders all of the asserted claims of the '340 patent obvious, because Kondo alone renders all of the asserted claims obvious, and Folkers explicitly discloses extraction in an inert gas atmosphere, and industrial scale processes.

Staff contends that Yoshida, either alone or in combination with the knowledge of a PHOSITA, renders all of the asserted claims of the '340 patent obvious.

Staff says Yoshida discloses a laboratory-scale process for manufacturing Q10, and Staff reiterates that scaling up a process from the laboratory to industrial scale is well within the knowledge of a PHOSITA and that methods and procedures for doing so are well known. Staff adds that the evidence shows that a PHOSITA would be motivated to use the Yoshida method on an industrial scale. Staff reiterates that the evidence shows that in an industrial scale process, the use of a culture medium of 750L was obvious to a PHOSITA.

Staff says that Yoshida was cited during the prosecution of the '249 application, and was the basis of a rejection, and in response, the applicants amended the claims. Staff says in doing so the applicants admitted that Yoshida "disclose[s] culturing the same microorganisms as those of the present invention, so that 'microorganisms' containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzyme Q10 are inherently disclosed." (Citing RX-380.) Staff concludes that Kaneka has admitted that the microorganisms in Yoshida inherently satisfy the 70 mole % limitation.

Staff adds that Yoshida discloses the culture of *Agrobacterium radiobacter* ATCC 4718. Staff says Tables 1-3 of the '340 patent list the results obtained by the inventors when they cultured various microorganism strains in accordance with the methods in example 1 and tested them to determine the amount of reduced Q10. Staff concludes that Table 1 includes *Agrobacterium radiobacter* ATCC 4718, the same strain disclosed in Yoshida, and states that it produces 78 mole % reduced Q10 when cultured according to the patent.

Staff contends that Yoshida discloses a medium comprising cane molasses and sucrose (carbon sources), ammonium sulfate (a source of nitrogen), potassium phosphate (a phosphorus

source) and corn steep liquor, a micronutrient. (Citing RX-82 at 20.) Staff alleges that Dr. Connors admits that Yoshida discloses a medium with these components. (Citing Tr. at 1167:2-20.) Staff says that the evidence also shows that the use of a medium containing carbon, nitrogen, and phosphorous would have been obvious to a PHOSITA, because these elements are needed for the growth of any biological organism.

Staff reiterates that *Agrobacterium radiobacter* ATCC 4718, which is disclosed by Yoshida, is listed in the '340 patent as meeting the 70% limitation. Staff adds that Dr. Ploeger and the Fraunhofer Institute designed and executed an experiment to recreate the Yoshida reference, and the procedures he used are described in his witness statement. (Citing RX-368C.) Staff contends that a comparison of the witness statement and the reference shows that they used the same strain, culture medium, culture method, and extraction method as described in the reference. (Citing RX-368C.) Staff avers that when the bacteria obtained was tested, the molar ratio of reduced Q10 was over 95 mole %. (Citing RX-368C, Q. 50.)

Staff argues that Yoshida discloses the physical disruption of cells with both glass beads and a Waring blender. (*Id* at 20.) Staff says the evidence shows that these steps disrupt the cells, and break their surface structures.

Staff asserts that Yoshida discloses a procedure for producing Q10 from bacteria that produces more than 70 mole % reduced Q10. Staff says the evidence demonstrates that the inclusion of an oxidation step, or the use of an oxidizing agent, in such a process to produce oxidize Q10 would be obvious to a PHOSITA.

Staff contends that the evidence demonstrates that Yoshida discloses the use of hexane and n-propanol, organic solvents, to extract Q10. Staff says the evidence also shows that a PHOSITA at the time would have believed that any extraction process using a solvent such as

hexane should be conducted either under an inert gas atmosphere or in a sealed tank for safety reasons. Staff states that the evidence shows that nitrogen gas is commonly used to provide an inert gas atmosphere.

Staff avers that Yoshida discloses the use of hexane, a hydrophobic organic solvent, and n-propanol, a hydrophilic organic solvent for extraction.

Staff reiterates that it believes the evidence shows that the use of a continuous extraction process and a countercurrent multistage extraction in an industrial process were obvious to PHOSITAs.

Staff agrees with Respondents' assertion that Folkers in combination with Yoshida renders all of the asserted claims obvious, because the evidence shows that Yoshida, either alone or in combination with the knowledge of a PHOSITA, renders all of the claims obvious, and Folkers explicitly discloses industrial scale production.

In its reply brief, Staff addresses Kaneka's arguments that the Kondo reference fails to render the claims of the '340 patent obvious because it allegedly does not disclose: 1) manufacturing Q10 on an industrial scale; 2) "the conditions that would yield the 70 mole % limitation;" 3) oxidizing the Q10 and extracting it under an inert gas atmosphere or sealed tank; and 4) disrupting to obtain reduced Q10. (Citing CIB at 111-12.)

Staff argues that the application for the '340 patent was initially rejected as obvious in light of the Kondo and Yoshida references, particularly with respect to the 70 mole % limitation, and in rejecting the claims the examiner stated that:

> The microorganisms the culturing conditions and the use of hydrophilic and/or hydrophobic extracting solvents in the cited US 3 769 170 (Kondo et a1.) and the reference by Yoshida et al. are identical to the limitations as claimed.

(Citing JX-3 at MGC00122069.) Staff asserts that the examiner acknowledged that the Kondo

reference discloses the same strain (*Candida curvata* ATCC 10567) and culture conditions as the '340 patent, and thus inherently discloses the 70 mole % limitation. Staff says, in response, Kaneka admitted that Kondo and Yoshida disclose the 70 mole % limitation, saying:

> Kondo et al and Yoshida et al disclose culturing the same microorganisms as those of the present invention, so that 'microorganisms' containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzyme Q10 are inherently disclosed.

(Citing JX-3 at MGC00121775.) Staff concludes that Kaneka has already admitted that the Kondo reference discloses the 70 mole % limitation, and conditions identical to those in the '340 patent.

Staff contends that Kondo discloses disruption by adding methanol, pyrogallol and sodium hydroxide to the cell solution and refluxing it at 80°C for an hour. (Citing RX-66, 2:57-61.) Staff says the evidence shows that the use of sodium hydroxide would disrupt the cells. Citing RX-367C, Q. 394.) Staff adds that the evidence also shows that it was commonly known in the art that disruption of cells eases the extraction of materials from within cells. (Citing RX-129C, Q. 2-42.) Staff states that Dr. Connors also testified that to a PHOSITA it would have been obvious to use disruption when producing Q10 from a yeast. (Citing Tr. at 1211:14-1212:16.) Staff asserts that Mr. Ebina stated that it was generally known to PHOSITAs that disruption was necessary. (Citing RX-129C, Q. 2-16.) Staff concludes that Dr. Taylor testified that use of a disrupting step had long been taught and implemented by the prior art. (Citing RX-367C, Q. 66)

Staff addresses the "industrial scale" limitation, conceding that the largest scale described in the Kondo reference is 5 liters; but Staff says the evidence demonstrates that scaling up a process from the laboratory to industrial scale is well within the knowledge of a PHOSITA and that methods and procedures for doing so are well known. Staff avers that both Dr. Taylor and

Dr. Connors testified that such scale up was well within the capabilities of a PHOSITA. (Citing Tr. at 781:2-9.) Staff continues that Dr. Connors testified that a PHOSITA could scale up from a 10 liter scale to industrial scale. (Citing Tr. at 1210:20-1211:9.) Staff states that Dr. Taylor said that he had actually witnessed such scale-ups. (Citing Tr. at 789:7-790:18.)

Staff turns to the requirements in the '340 patent for extraction under an inert gas atmosphere or in a sealed tank, and asserts that the evidence demonstrates that Kondo discloses the use of hexane, an organic solvent, to extract Q10. Staff says the evidence also shows that a PHOSITA at the time would have believed that any extraction process using a solvent such as hexane should be conducted either under an inert gas atmosphere or in a sealed tank for safety reasons. Staff quotes Dr. Taylor to have testified that sealed tanks "are very common in the prior art and very many introductory bioengineering textbooks." (Citing Tr. at 773:17-23.) Staff says Q10 is a lipid, and Dr. Taylor testified that the use of inert gas atmospheres is "also a very standard practice throughout lipid chemistry. As far back as I can remember, we've used inert gases to protect lipids from degradation or oxidation." (Citing Tr. at 786:17-20.) Staff concludes that Mr. Kayama testified that use of such conditions was commonplace in Japan, and indeed required by regulations. (Citing RX-367C, Q. 74.)

Staff says that Kaneka asserts that the Yoshida reference does not render the claims of the '340 patent obvious because it fails to disclose the 70 mole % limitation, manufacturing on an industrial scale, extraction under an inert gas atmosphere or extraction in a sealed tank. (Citing CIB at 122-123.) Staff argues that none of these assertions have merit. Staff reiterates that, during the prosecution of the '340 patent, Kaneka admitted that the Yoshida reference inherently discloses the 70 mole % limitation. Staff notes Kaneka's argument that the statement during prosecution "only served to mean that while certain microorganisms may be disclosed in

Yoshida, it is not accurate that the microorganisms cited in Yoshida always and necessarily produce reduced coenzymes Q10 at a ratio of not less than 70 mole % . . . there is also no mention made of reduced coenzyme Q10 production and no discussion of mole percentages. Indeed, there is no basis for Respondents' position that the 70 mole % limitation is inherent based on Yoshida." (Citing CIB at 123.) Staff counters that the text of Kaneka's statements to the examiner regarding the disclosure of the 70 mole % limitation by Yoshida is:

> Kondo et al and Yoshida et al disclose culturing the same microorganisms as those of the present invention, so that 'microorganisms' containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzyme Q10 are inherently disclosed.

(Citing JX-3 at MGC00121775.) Staff concludes that Kaneka's assertion that it did not concede that Yoshida discloses the 70 mole % ratio is entirely without merit.

Staff adds that Dr. Otte's work with the Fraunhofer Institute to recreate the Yoshida reference demonstrates that it meets the 70 mole % limitation. Staff says a comparison of Dr. Otte's witness statement and the Yoshida reference shows that he used the same strain, culture medium, culture method, and extraction method described in the reference. (Citing "RX-368C" generally.) Staff concludes that when the bacteria obtained was tested, the molar ratio of reduced Q10 was more than 95 mole %. (Citing RX-368C, Q. 50.)

Discussion and Conclusions: Based on the evidence in the record, I find that Respondents have failed to offer clear and convincing evidence that any of the asserted claims the '340 patent are obvious in view of the cited prior art.

In Section III.B.5, *supra*, I found that, in this case, the '340 patent is a process patent written in such a way that it clearly requires performance of specific steps in a specific sequence. In view of my findings about the disclosures of Folkers and Kaneka's Pre-2002 Process in Section IV.B, *supra*, the issues remaining to be resolved are Respondents' and Staff's allegations

that the following elements of the '340 patent are rendered obvious by the prior art identified in their respective initial briefs:

(1) the preamble and first element of independent asserted claims 1, 11, 22 and 33, which require, in relevant part:

A process for producing on an industrial scale the oxidized coenzyme Q10

* * * * *

which comprises culturing reduced coenzyme Q10 producing microorganisms ... to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10.

(2) the third element of claims 1 and 22 that requires oxidizing the coenzyme Q10 to be performed prior to extraction;

(3) that portion of the third element of claim 22 and the second element of claim 33 that requires extraction to be carried out in a "sealed tank;"

(4) the second element of claims 11 and 33 which teaches extraction of reduced coenzyme Q10; and

(5) the third element of claims 11 and 33 that requires oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10.

Although not clearly organized in the briefs, I am able to discern the following prior art combinations that require discussion: (a) Folkers in view of the knowledge of a PHOSITA; (b) Kaneka's Pre-2002 Process in view of the knowledge of a PHOSITA; (c) Either Folkers or Kaneka's Pre-2002 Process, in view of Kondo or Yoshida (or both Kondo and Yoshida).

In order to prevail on their claim that the'340 patent is invalid as obvious, Respondents must first demonstrate that the combination of prior art references discloses all of the limitations of independent asserted claims 1, 11, 22 and 33. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010) (upholding finding of non-obviousness based on the fact that there was substantial evidence that the asserted combination of references failed to disclose a claim limitation); *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003) (explaining that a

requirement for a finding of obviousness is that "all the elements of an invention are found in a combination of prior art references").

Equally important is the requirement that the Respondents establish by clear and convincing evidence that a person of ordinary skill in the art would have had reason to combine the various asserted prior art references to attempt to produce the invention and would have had a reasonable expectation of success in doing so. (See *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007))

I find that Respondents have failed to demonstrate by clear and convincing evidence that all of the limitations of independent asserted claims 1, 11, 22 or 33 are present in any of the asserted combinations of prior art references, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the asserted prior art references to create the process claimed in the invention of the '340 patent.

1. Folkers in view of the knowledge of a PHOSITA

In Section IV.B.2, *supra*, I found that Folkers does not anticipate any of asserted claims 1-3, 6-14, or 17-21 of the '340 patent, because it does not disclose each and every element of any of those asserted claims, including the sequence in which some of those elements must be performed in order to comply with the process taught in the '340 patent. While I will not, in the interest of brevity, repeat my rationale and findings in Section IV.B.2, *supra*, in summary I found that

Respondents had failed to prove by clear and convincing evidence that Folkers discloses:

(a) producing oxidized coenzyme Q10 on an industrial scale (claims 1 and 11);

(b) culturing . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10 (claims 1 and 11);

(c) disrupting the microbial cells to obtain reduced coenzyme Q10 (claim 1);

(d) oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10 and then extracting the oxidized coenzyme Q10 by an organic solvent under an inert gas atmosphere (claim 1); or

(e) extracting the reduced coenzyme Q10 by an organic solvent under an inert gas atmosphere (claim 11);

(f) oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10 (claim 11).

A thorough review of Folkers reveals it to be directed to a very basic level of preparation of coenzyme Q10, describing merely the cultivation (i.e. fermentation) of material in a broth preferably using aeration and agitation to encourage growth, and then simple extraction of coenzyme Q10 by ceasing aeration and agitation and filtering or centrifuging the cellular material. That cellular material is then processed by hydrolysis and extracted with a solvent, usually a fraction of petroleum similar to a hexane cut. Folkers does allow for other means, for example use of a protection atmosphere of non-reactive but oxygen-excluding gas such as nitrogen, or maintenance of a reducing atmosphere such as hydrogen. The invention also contemplates "direct extraction without prior hydrolysis," noting that "solvent treatments, agitation with chloroform, acetone, alcohol and the like, singly or mixed, have been found in the art to directly lyse cell walls and release cell constituents." (RX-63, 3:18-66)

Kaneka's expert, Dr. Connors, testified that there is no disclosure in Folkers of the configuration of extraction tanks or the details of the extraction process. (CX-655C, Qs. 1-51 to 1-53.) On cross-examination, however, Dr. Connors testified that at the time of the '340 patent's invention, using his definition of sealed tank, using a solvent for extraction was typically carried out

using a sealed tank, and that use of an inert gas atmosphere was also common. He testified that those methods would be obvious to a PHOSITA. (Tr. at 1201:1-1202:22.)

As discussed in detail in Section IV.B.2, *supra*, Folkers did not describe production of coenzyme Q10 on anything approaching an "industrial" scale. Mr. Ebina testified that "Folkers disclosed an example of commercial large scale production.'" (RX-129C, Q. 5-10 (Citing RX-63, 3:2-58).) He also testified, "Folkers described fermentation with 1000 liters of medium." (RX-129C, Q. 5-10 (Citing RX-63 3:33 and 3:68).) A review of RX-63 column 3 reveals no such described scale(s); the correct reference is found at RX-63C, 8:2-50. As I said in Section IV.B.2, *supra*, the 1000 liter fermentation disclosed producing approximately 67.8 mg of purified coenzyme Q10, which is far short of producing oxidized coenzyme Q10 on an industrial scale. (RX-63C at 9:8-11, 9:43-45, and 10:20-22.)

Mr. Ebina's testimony was that "[s]caling up generally was never a problem in the field of producing coenzyme Q10, from at least as early as ... 1978." (RX-129C, Q. 5-10.) During his deposition and again at the hearing, Dr. Connors admitted that it would be within the abilities of a PHOSITA at the time of the '340 patent's invention to scale up from a 10 liter scale to an industrial scale and that it would be obvious to try to do so. He indicated that, despite the '340 patent's silence on the method of scaling the fermentation process to an industrial level, a PHOSITA could have done it. (Tr. at 1199:16 – 1201:17; 1210:24-1211:9.) Both experts agree that scaling up generally was not a problem at the time of the '340 patent's invention. I find that combining Folkers with the general knowledge of a PHOSITA at the time of the invention of the '340 patent would render obvious the '340 patent's requirement to produce coenzyme Q10 on an industrial scale.

Despite the fact that methods to scale fermentation to an industrial level would be obvious to

a PHOSITA, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Folkers ***to follow the process in the '340 patent*** which specifically requires that oxidized coenzyme Q10 be produced on an industrial scale by a process which comprises "culturing reduced coenzyme Q10 producing organisms ... to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10." The process in Folkers creates oxidized coenzyme Q10 and nowhere mentions or hints at production of reduced coenzyme Q10 at any step of its process. (See RX-63, generally.) Because of Folkers' silence on the subject of reduced coenzyme Q10, disrupting cells to obtain that product, extracting that product or oxidizing it to produce oxidized coenzyme Q10 cannot be divined from anything found in Folkers. Also, I concur with Kaneka's point that, without knowing that microorganisms may produce reduced Coenzyme Q10 at a ratio at least as high as 70 mole % during fermentation, a PHOSITA would not have thought to require an oxidation step in the manufacturing process for oxidized Coenzyme Q10.

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Mr. Ebina, Respondents' expert, testified that the basic principles for producing coenzyme Q10 were well known and that oxidized coenzyme Q10 had been in commercial production for more than 20 years by 2001. He said that it would have been obvious for a PHOSITA to incorporate "any

of the ideas from the prior art of coenzyme Q10 that might be useful." (RX-129C, Q. 5-8.)

Regarding Folkers, Mr. Ebina said that a PHOSITA:

> Knowing that the coenzyme Q10 produced by fermentation was a mixture of the reduced and oxidized forms, it would have been obvious to oxidize the reduced form at some stage in the process to produce the desired pure, oxidized form. A strong motivation to combine various techniques for producing coenzyme Q10 within the framework of disclosure was provided by the economic advantages of increasing the yield of oxidized coenzyme Q10 in a safe production method on an industrial scale. Folkers also disclosed optional disruption of microbial cells to obtain coenzyme Q10 before extracting.

(RX-129C, Q. 5-9.) Mr. Ebina's opinion begins by assuming it was known that fermentation produced both reduced and oxidized forms of coenzyme Q10; but he makes no reference to evidence support a finding that a PHOSITA would be moved to follow the precise steps of the '340 patent. He refers vaguely to a strong motivation to "combine various techniques" provided by "the economic advantages of increasing the yield of oxidized coenzyme Q10." The only connection between Folkers and the knowledge of a PHOSITA in 2001, is the fact that Folkers discusses the production of oxidized coenzyme Q10. That discussion, however, is on a very basic level and does not point even vaguely to the process taught by the '340 patent. It remains a mystery, then, how a PHOSITA would be motivated by anything in Folkers to reproduce on an industrial scale or otherwise, the process claimed in the asserted claims of the '340 patent. In addition, Dr. Crane, who discovered Coenzyme Q10, and who worked with the compound for several decades until he retired in 1994, testified that he learned of the invention claimed in the '340 Patent only recently at his deposition, and he never thought of the possibility of "chasing the reduced form" of Coenzyme Q10 at the time he worked on the molecule. (RX-392C, 78:23-79:1; 84:11-85:9; CX-655C, Q. 1-158.)

Based upon all of the foregoing, I find that Respondents have failed to provide clear and convincing evidence that asserted independent claims 1 or 11 of the '340 patent are rendered obvious by Folkers in view of the knowledge of a PHOSITA at the time of the invention of the '340 patent.

2. Kaneka's Pre-2002 Process in view of the knowledge of a PHOSITA

In Section IV.B.1, *supra*, I found that the Respondents had failed to prove by clear and convincing evidence that the Kaneka Pre-2002 Process anticipated any of asserted claims 1, 11, 22 or 33, because they failed to demonstrate that it practiced each and every element of any of those asserted claims, including the sequence in which some of those elements must be performed in order to comply with the process taught in the '340 patent. More specifically, I found that Respondents had failed to prove by clear and convincing evidence that the Kaneka Pre-2002 Process discloses:

(a) A process for producing on an industrial scale the oxidized coenzyme Q10

* * * * *

> which comprises culturing reduced coenzyme Q10 producing microorganisms ... to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10. (claims 1, 11, 22 and 33)

(b) oxidizing the coenzyme Q10 to be performed prior to extraction (claims 1 and 22)

(c) extraction to be carried out in a "sealed tank" (claims 22 and 33)

(d) extraction of reduced coenzyme Q10 (claims 11 and 33); or

(e) requires oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10 (claims 11 and 33)

Kaneka's expert, Mr. Ebina, opines that Kaneka's Pre-2002 Process renders the independent asserted claims of the '340 patent obvious in view of the knowledge of a PHOSITA; but he admits that his opinion is based on "public information" and on his "knowledge and experience in the coenzyme Q10 manufacturing field." This is because he has not been informed

of the details of Kaneka's Pre-2002 process, since he is employed by MGC and is not authorized to have access to confidential business information in this investigation. (RX-129C, Qs. 5-36, 5-37.)

It appears from the evidence cited, *supra*, in the discussion of Folkers, that scaling fermentation from a laboratory level to an industrial level was obvious to a PHOSITA. I note, too, that on cross-examination Dr. Connors admitted that at the time of the '340 patent's invention using a solvent for extraction was typically carried out using a sealed tank. He testified that those methods would be obvious to a PHOSITA. (Tr. at 1201:1-1202:22.) {

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To provide clear and convincing evidence of obviousness, the Respondents must demonstrate that the combination of prior art references discloses ***all*** of the limitations of the claims alleged to be invalid. There is, however, no evidence that the Kaneka Pre-2002 Process would have led one ***to follow the process in the '340 patent*** which specifically requires that oxidized coenzyme Q10 be produced on an industrial scale by a process which comprises "culturing reduced coenzyme Q10 producing organisms … to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10." In addition, there is no evidence that the Kaneka Pre-2002 Process would have resulted in any particular approach to the timing of oxidizing reduced coenzyme Q10 as required by the asserted claims.[9] I refer to the findings and rationale in Section III.B.5, *supra*, regarding the specific steps and sequence of those steps required by the '340 patent's process.

[9] Claims 1 and 22 require that oxidizing occur prior to extraction, and claims 11 and 33 require that it occur after extraction.

I find that Respondents have failed to provide clear and convincing evidence that asserted independent claims 1, 11, 22 or 33 of the '340 patent are rendered obvious by the Kaneka Pre-2002 process in view of the knowledge of a PHOSITA at the time of the invention of the '340 patent.

3. Folkers or Kaneka's Pre-2002 Process in view of Kondo or Yoshida (or both Kondo and Yoshida)

Respondents assert that, if either Folkers or Kaneka's Pre-2002 Process is not found sufficient to establish obviousness of the asserted claims, then Folkers or Kaneka's Pre-2002 Process, in view of Kondo or Yoshida (or both Kondo and Yoshida), should be found to render the asserted claims of the '340 patent obvious.

Inasmuch as the Respondents must demonstrate that the combination of prior art references discloses ***all*** of the limitations of the claims alleged to be invalid, the addition of Kondo and Yoshida must disclose those elements that Folkers or Kaneka's Pre-2002 Process fails to render obvious. Kondo and Yoshida are two pieces of prior art that were considered by the examiner and appear on the face of the '340 patent. The "presumption of validity under 35 U.S.C. § 282 carries with it a presumption that the Examiner did his duty and knew what claims he was allowing." *Intervet Am., Inc. v. Kee-Vet Labs., Inc.,* 887 F.2d 1050, 1054, 12 USPQ2d 1474, 1477 (Fed.Cir.1989). Therefore, the challenger's "burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application." *Hewlett-Packard Co. v. Bausch & Lomb Inc.,* 909 F.2d 1464, 1467, 15 USPQ2d 1525, 1527 (Fed.Cir.1990).

Kondo is directed to a method of producing coenzyme Q10 by culturing microorganisms. It describes, among other things, methods of culturing, including pH levels, temperatures and culture duration. Kondo describes "[a]s the microbial cells contain a large amount of coenzyme Q10, the cells can be used as nutrients and medicines." (RX-66, 2:18-27.) Kondo says that coenzyme Q10 may also be isolated from the cells by conventional methods, and it describes a

process for extracting coenzyme Q10 from the cells by a solvent such as n-hexane. (RX-66, 2:27-34.) Kondo gives 9 examples of methods to culture and extract coenzyme Q10, none of which include oxidizing reduced coenzyme Q10. In fact, reduced coenzyme Q10 is mentioned nowhere in Kondo. There is no hint of the specific steps or sequence of steps involved in the process of the '340 patent for producing oxidized coenzyme Q10 on an industrial scale.[10] (*See* RX-66.)

Respondents allege that Kaneka admitted in its June 8, 2007 Amendment and Response during the prosecution of the '249 Parent Application, that "Kondo et al. and Yoshida et al. disclose culturing the same microorganisms as those of the present invention, so that 'microorganisms' containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzyme Q10 are inherently disclosed." (Citing RX-367C, Q. 392; JX-2 at MGC00121775; RX-380 at 8.)

Respondents have omitted much of the paragraph which continues:

> However, it cannot be emphasized too strenuously that the subject matter of the present invention is not a microorganism itself but "a process for producing reduced coenzyme Q10 from microorganisms as maintaining high ratio of reduced type in the microorganisms." As the Examiner admits Yoshida et al. and Kondo et al. do not show that the disruption and extraction are carried out under the condition that the reduced coenzyme Q10 is protected from an oxidation reaction. The Examiner argues that it would be obvious to carry out the disruption and extraction under the condition that the reduced coenzyme Q10 is protected from an oxidation reaction according to Venturoli et al. and Wakabayashi et al. However, applicants submit that is an incorrect conclusion.

(JX-2, MGC00121775.) Thus, in their concession to the examiner the applicants drew a clear distinction between disclosure of the same ***microorganisms*** as those of the present invention, which they agreed resulted in the inherent disclosure of microorganisms that contain "reduced

[10] Despite mention that Q10 "can be produced in large amounts in microbial cells," Kondo itself describes only laboratory level testing, and does not treat production on an industrial scale. (RX-66, 1:27-34, and Examples 1-9)

coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzyme Q10" and the ***process for producing coenzyme Q10 using those microorganisms***, which they clearly indicated to be the subject of the present invention. The applicants clearly did not concede that the latter was inherent in either Kondo or Yoshida.

Yoshida describes production in a laboratory setting of coenzyme Q10[11] using three strains of bacteria known to contain Q10. The strains tested were *Agrobacterium tumefaciens* KY-3085 (ATCC4452); *Paracoccus denitrificans* KY-3940 (ATCC19367); and *Rhodobacter sphaeroides* KY-4113 (FERM-P4675). The point of the experiments described in Yoshida was to locate coenzyme Q10 producing bacteria and to improve productivity. Yoshida describes the materials and methods used to produce coenzyme Q10 in its experiments, including cultivation methods, specific ingredients, times, temperatures and pH levels. (RX-82, SHENZITC790_002513-_002514.) Yoshida describes extraction using a Waring Blender for one phase of extraction and a solvent (n-hexane) for a second phase of extraction. In one instance, Yoshida describes use of "limited supply of air" as something that would increase productivity – noting that aeration had a tendency to reduce Q10 production. (RX-82, SHENZITC790_002517-_002518.) At one point, Yoshida states "[t]he effect of aeration on ubiquinone-10 production was so remarkable that this might almost cover the important traits to increase production, even if such properties were acquired by mutation." (*Id.*) Despite the detail provided in Yoshida, it does not disclose or suggest the specific process and sequence of steps required by the '340 patent that are lacking in the combination of Folkers and the Kaneka Pre-2002 Process. Yoshida also does not distinguish between reduced and oxidized coenzyme Q10. It merely describes the yield of Q10 generally. Yoshida does not describe any sequence of steps

[11] The authors use the term "ubiquinone-10." To avoid confusion, the term "coenzyme Q10" is used herein.

that includes oxidation and extraction, such as specifically described in asserted claims 1, 11, 22 and 33 of the '340 patent.

Respondents' expert Dr. Richard Taylor, testified that both Kondo and Yoshida render asserted claims 1, 11, 22 and 33 obvious. (RX-367C, Qs. 369, 389.) Regarding Kondo, Dr. Taylor testified that Kondo discloses cultivation to achieve at least 70 mole % of reduced coenzyme Q10, disruption and extraction by an organic solvent. (*Id.* at Qs. 390-394.) He does not refer to any specific part of Kondo as disclosing "disrupting the microbial cells to obtain reduced coenzyme Q10." He merely describes the disruption and extraction without any reference to the specific object to "obtain" reduced coenzyme Q10. (*Id.* at Q. 394.)

Dr. Taylor refers to testing performed by *"Otte, et al."* to confirm that Yoshida discloses the limitation requiring that fermentation "obtain" reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzyme Q10. Dr. Taylor opines that the testing "would be adequate to replicate the culturing, fermentation and extraction methods described by Yoshida, and that the extraction procedure was that described in Kaneka's European Patent No. 1446983, which is the European counterpart of the '340 patent. (RX-367C, Qs. 376-379.)

The testing performed by *Otte, et al.*, is described in the Project Report: Analysis of oxidized and reduced forms of Coenzyme Q10 produced by *Agrobacterium radiobacter* fermentation. (RX-306) ("Fraunhofer"). The testing was performed on a strain identified in Table 1 of the '340 patent. The results are reported to show greater than 95% reduced coenzyme Q10 present in the fermentation. (RX-306, ZMC006721.)

The sequence of oxidation following extraction or prior to extraction is clearly stated in the asserted independent claims of the '340 patent. I have already found that Kaneka's Pre-2002 Process, { } does not practice the related

elements of the asserted claims 1, 11, 22 or 33, {

} While Dr. Taylor discusses oxidation as something a PHOSITA would know to perform when encountering reduced coenzyme Q10, he does not offer any insight into how a PHOSITA would be caused by Kondo or other knowledge to apply the sequences required by the asserted claims of the '340 patent. (RX-367C, Qs. 396, 397.) He is similarly opaque in his discussion of oxidation in connection with the Yoshida reference. (*Id.* Qs. 380, 381.)

I find that neither Kondo nor Yoshida have been shown by clear and convincing evidence to disclose the elements of the '340 patent that have been found to be absent in Folkers and the Kaneka Pre-2002 Process, when considered singly or in combination with one another and with the knowledge of a PHOSITA at the time of the invention of the '340 patent.

The foregoing discussion demonstrates that Kondo, Yoshida, Folkers and the Pre-2002 Kaneka process all share a common interest in the production of coenzyme Q10; but they also share an absolute lack of any hint or suggestion that would move a PHOSITA to employ their teachings to create the process of the '340 patent. None of those prior art references move beyond the creation of coenzyme Q10 to consider a breakdown of reduced CoQ10 and oxidized CoQ10 on an industrial scale by following the steps taught in the '340 patent to result in a greater production of oxidized coenzyme CoQ10.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that asserted independent claims 1, 11, 22 or 33 of the '340 patent, are rendered obvious to a PHOSITA by Folkers, Kaneka's Pre-2002 Process, Kondo or Yoshida, either alone or in any combination of those references.

A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined the asserted

independent claims to be rendered obvious and invalid, I could still find that their respective dependent claims are valid. Since, however, I have found asserted independent claims 1, 11, 22 and 33 to be ***not*** rendered obvious, it follows that their respective dependent claims are not obvious, because they depend from the asserted independent claims and necessarily contain all of the elements of the respective independent claims from which they depend. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992); *In re Royka*, 490 F.2d 981, 983-985 (C.C.P.A. 1974); *see also In re Sernaker*, 702 F.2d 989, 991 (Fed. Cir. 1983). Based upon the foregoing, I find that dependent claims 2, 3, 4, 8, 9, 10, 12, 13, 14, 15, 20, 21, 23, 24, 25, 29, 30, 31, 32, 34, 35, 36, 37, 41, 42, 43, and 44 of the '340 patent are not rendered obvious by the foregoing prior art.

4. Secondary Considerations of Non-obviousness

Kaneka's Position: Kaneka avers that its expert, Dr. Connors, concludes that there is a nexus between the claimed invention and secondary considerations, and that the secondary considerations favor a finding of nonobviousness with respect to the '340 Patent. (Citing CX-655C at Q1-134 to 142.) Kaneka says Dr. Trumpower concurred with Dr. Taylor's analysis with respect to this issue and did not provide any independent analysis. Kaneka concludes that Dr. Connors also finds his discussion to be sufficient to address Mr. Ebina's "generally vague and unsupported comments" regarding secondary considerations.

Kaneka asserts that Dr. Connors' finding of a nexus is bolstered by the witness statement of

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Kaneka contends that commercial success can be measured by the sales of the product made by the claimed invention. Kaneka says Dr. Taylor assumes that commercial success cannot be demonstrated merely because a product made by methods other than the claimed invention at issue has been previously sold. Kaneka argues that the commercial success of the infringing product can be evidence of commercial success of the claimed invention. Kaneka reasons that Dr. Taylor's statement that "more recent increases in sales volumes have been influenced by factors such as . . . a ready supply of safe, pure and less expensive Coenzyme Q10 from, for example, the Respondents in this case" can be interpreted to support the contention that the '340 Patent has achieved commercial success. Kaneka concludes that Dr. Taylor has offered no specific proof for his statement that "Coenzyme Q10 was a commercially successful product for decades prior to Kaneka's alleged invention." (Citing RX-367C, Q. 415.)

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Regarding long felt but unresolved need/unpredictable results, Kaneka charges that Respondents' experts understate the difficulties of industrially manufacturing Coenzyme Q10. Kaneka argues that the fact that oxidized Coenzyme Q10 may have been commercially available since the 1980's should not discount Kaneka's patented innovations and improvements in the field of Coenzyme Q10 manufacturing. {

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Kaneka says that Dr. Connors notes that Dr. Taylor declined to acknowledge that the innovation of culturing cells containing reduced Coenzyme Q10 at a ratio of not less than 70 mole % among the entire Coenzyme Q10 must be accomplished on an industrial scale, while maintaining standards of safety and efficiency. Kaneka adds that Dr. Taylor avoids mention of an important expression of long felt need directly out of Respondents' exhibit, a reference dated in 1988.

Kaneka says that Coenzyme Q10 has been produced in the prior art by extracting from animal or plant tissue and purifying, and methods of extracting Coenzyme Q10 from microbial cells obtained by culturing microorganism have come to be known in recent years. Kaneka contends that

Coenzyme Q10 productivity of microorganisms is still inadequate, and the discovery of microorganisms with greater Coenzyme Q10 productivity is desired. Kaneka states that the object pursued by the present inventors was to obtain a microorganism with greater Coenzyme Q10 productivity. Kaneka says as a result of research efforts intended to discover Japanese Unexamined Patent Application Publication S63–36789 a microorganism strain that produces large quantities of Coenzyme Q10, the present inventors discovered that microorganism strains belonging to the genus *Hyphomonas* produce large quantities of Coenzyme Q10, thereby arriving at the present invention. (Citing RX-33.005 (SHENZITC790_114997).)

Kaneka says that based on this information, Dr. Connors notes that prior to the invention of the '340 Patent, there was a long felt but unresolved need for a safe and efficient method of manufacturing Coenzyme Q10 on an industrial scale with microorganisms that can produce high yields. Kaneka states that Dr. Connors disagrees with Respondents experts' opinion that "taking steps to recover a relatively high amount of reduced Coenzyme Q10 as a preliminary step for producing oxidized Coenzyme Q10 has no utility and resolves no unmet need." Kaneka counters that taking steps to recover a high amount of reduced Coenzyme Q10 does have utility and resolved a previously long felt need otherwise Kaneka would not have implemented this approach.

Kaneka asserts that Dr. Connors opines that one of ordinary skill in the art would be required to perform undue experimentation to achieve to 70% mole of reduced Coenzyme Q10 claim element without the foregoing data. Kaneka says the identification of specific microorganisms disclosed in the not have been able to appreciate prior the critical date of the '340 Patent. {

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In its reply brief Kaneka asserts that it has established a nexus between evidence of secondary considerations and the merits of the claimed invention sufficient for secondary considerations to be given substantial weight. (Citing CIB at 136-139; *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010).) Kaneka argues that Respondents' reliance on the unreported District Court decision in *SmithKline Beecham Corp. v. Apotex Corp.*, 2005 WL 941671, at *14 (E. D. Pa. March, 31, 2005) is misguided and does not support the Respondents' case. Kaneka states that in *SmithKline*, the Court found that the primary reason for finding no nexus was that the Defendants had "submitted unrebutted evidence that Plaintiffs do not use the processes set forth in the [asserted patent] to produce [the accused product]." *Id.* Kaneka says in this Investigation, the Respondents have presented no such evidence. {

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Respondents' Position: Respondents argue that any assertions by Kaneka of alleged secondary considerations of nonobviousness do not overcome the evidence supporting a holding of obviousness. Respondents contend that in order to rely on secondary considerations of

nonobviousness, the patentee bears the burden of establishing a nexus between the evidence of commercial success and the patented invention. (Citing *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996 (holding that the proponent must offer proof "that the sales were a direct result of the unique characteristics of the claimed invention"); *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995 ("For objective [evidence of secondary considerations] to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention.").)

Respondents argue that secondary considerations of nonobviousness cannot overcome a strong *prima facie* case of obviousness. (Citing *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008); *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1344 (Fed. Cir. 2008); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (holding that the objective considerations of nonobviousness presented, including substantial evidence of commercial success, praise, and long-felt need, were inadequate to overcome a strong showing of primary considerations that rendered the claims at issue invalid); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1371 (Fed. Cir. 2006) ("The presence of certain secondary considerations of nonobviousness are insufficient as a matter of law to overcome our conclusion that the evidence only supports a legal conclusion that Claim 1 would have been obvious.").)

Respondents recite "[W]here the inventions represent[] no more than 'the predictable use of prior art elements according to their established functions,'. . . secondary considerations are inadequate to establish nonobviousness as a matter of law." (Citing *Wyers v. Master Lock Co.*, Case No. 2009-1412, 2010 U.S. App. LEXIS 15271, *34-35 (Fed. Cir. July 22, 2010).) Respondents refer to issues of commercial success, long felt need, prior failure or near

simultaneous invention, and unexpected results and say that Mr. Ebina testified that any evidence regarding these factors was not due to the inventions claimed in the '340 Patent. (Citing RX-129C, Qs. 1-21, 1-29, 1-24, and 5-71to 5-74.) Respondents state that Dr. Taylor provided similar testimony. (Citing RX-367C at Qs. 414-420.)

Respondents contend that there is a presumption that a patented invention is commercially successful when a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent. (Citing *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997).) Respondents continue, in order to find that a patent is commercially successful, the asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art. *Id.*

Respondents say in *SmithKline*, the court stated that a patentee must establish some "nexus" between the merits of the claimed invention and the commercial success of the product in order to establish commercial success. Respondents continue in *SmithKline*, plaintiffs were unable to establish a "nexus" between the '233 patent and the commercial success of the product manufactured by that process. *Id.* Respondents assert that, while the product was one of the most commercially successful drugs on the market, it was widely produced, marketed, and sold beginning almost a decade prior to the '233 patent's approval. *Id.* at *55.

Respondents argue that the facts in this case are similar to *SmithKline*, because Kaneka has failed to establish that the oxidized coenzyme Q10 produced by its current process is more commercially successful than the oxidized coenzyme Q10 produced by Kaneka's prior production process or any other prior art process used to manufacture oxidized coenzyme Q10 prior to December 27, 2001. {

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Respondents add that Kaneka has failed to present any evidence to support a claim that the '340 patent discloses a safer and more efficient process for producing oxidized coenzyme Q10. Nor is there any evidence to support a claim that the '340 patent produces an oxidized coenzyme Q10 product with better purity, volume metrics, and/or product value. (Citing RX-367C at Qs. 432-433.)

Respondents next address the issue of whether or not the invention solved a long-felt, but unsolved need in the field. (Citing "*Graham*, 383 U.S. at 18".) Respondents assert that the nature of the problem which persisted in the art, and the inventor's solution, are factors to be considered in determining whether the invention would have been obvious to a person of ordinary skill in that art. (Citing *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 935 (Fed. Cir. 1990).) Respondents say recognition of a long-felt need, and difficulties encountered by those skilled in the art in attempting to solve that need, are classical indicia of nonobviousness. (Citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).)

Respondents argue that Kaneka has failed to establish that the processes in the '340 patent solved a long-felt need for the industrial-scale production of oxidized coenzyme Q10, because {

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Respondents add that Folkers publically disclosed an industrial-scale process for the efficient and economical production of oxidized coenzyme Q10 more than 40 years before the

priority date of the '340 patent. (Citing RX-63.) Respondents say that the evidence presented by Respondents establishes that there were a number of Japanese companies with industrial scale fermentation processes for producing oxidized coenzyme Q10 going back to the 1970s. (Citing RX-429; RX-430.)

Respondents turn to a third indicia of nonobviousness - whether other inventors failed to solve the problems addressed by the patented claims or, conversely, whether inventors operating independently developed the same process around the same time (*i.e.*, near simultaneous invention). (Citing "*Graham*, 383 U.S. at 18".) Respondents contend that failure of others to provide a feasible solution to a long standing problem is probative of nonobviousness; however, near simultaneous invention by two or more equally talented inventors working independently may be an indication of obviousness. (Citing *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 835 (Fed. Cir. 1991).)

Respondents argue that Kaneka has failed to provide substantive evidence identifying prior failures encountered by other persons of ordinary skill in the art, and Kaneka not identified the problems solved by the '340 patent inventors in light of those prior failures. Respondents contend, to the contrary, the prior art shows that oxidized coenzyme Q10 has been widely produced, marketed, and sold for more than two decades before the priority date of the '340 patent. Respondents conclude that Kaneka has failed to offer evidence to support any assertion that the '340 patent discloses an industrial scale production process that is superior to other processes for producing oxidized coenzyme Q10.

Finally, Respondents address the issue of whether or not the process claimed by the patent had unexpected results, noting that a finding of unexpected results may provide strong support for a conclusion of nonobviousness. (Citing *In re Glaug*, 283 F.3d 1335, 1341 (Fed. Cir.

2002) (quoting *In re Soni*, 54 F.3d 746, 750 (Fed. Cir.1995).) Respondents contend that unexpected results exist when the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected. *Id.* Respondents say the principle of unexpected results applies most often to the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results. (Citing *In re Mayne*, 104 F.3d 1339, 1343 (Fed. Cir. 1997))

Respondents argue that Kaneka has no evidence to support a claim of unexpected results because the '340 patent describes well known processes for producing oxidized coenzyme Q10. Respondents allege that the processes for producing oxidized coenzyme Q10 claimed by the '340 patent were the expected result of practicing the prior art. (Citing *In re Outtrup*, 531 F.2d 1055, 1058-59 (C.C.P.A. 1976) (court affirmed USPTO decision that two prior art references combined (one suggesting that the protein could be found in and produced by the respective bacteria, and the other suggesting the means for recovering that protein from a mixed solution) rendered the claims of the patent application obvious).) Respondents argue that this supports a holding that the process in the '340 patent is the expected result of applying well-known principles to culture microorganisms that produce microbial cells containing coenzyme Q10 and then extracting that coenzyme Q10 under an inert gas atmosphere or sealed tank using organic solvents like hexane.

Respondents say to the extent Kaneka claims that the limitation of "culturing reduced coenzyme Q10-producing microorganisms . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzyme Q10" is the novel feature of the '340 patent claims, there is a lack of evidence offered by Kaneka. Respondents allege that Kaneka has failed to offer substantive evidence showing the alleged improvements offered by the processes claimed by the '340 patent over the prior art processes

for producing oxidized coenzyme Q10. (Citing *In re Aller, et al.*, 220 F.2d 454, 456 (1955) (finding that the record did not show any significant improvement in the efficiency of the process resulting from a difference in temperature or concentration, and it held that the application was properly denied on the grounds that changes in temperature and acid concentration would have been obvious to one skilled in the art over a prior art reference specifically acknowledged in the patent application).)

Staff's Position: Staff does not believe that the evidence supports Kaneka's position. First, Staff does not believe that the evidence shows that KNL practices the process of any of the asserted claims. Staff adds that the evidence demonstrates that since the Respondents have begun producing Q10 and marketing it in the United States, {

} Staff does not believe that Kaneka has provided sufficient evidence of secondary considerations of non-obviousness to rebut the showing of obviousness.

Discussion and Conclusions: I found in Section IV.C, *supra*, that Respondents have failed to prove by clear and convincing evidence that any of the asserted claims of the '340 patent are rendered obvious by the prior art. It is, therefore, unnecessary for me to consider Kaneka's contentions regarding secondary considerations. Nevertheless, assuming *arguendo* that the Commission finds that one or more claims of the '340 patent are rendered obvious by the prior art asserted by Respondents, I would find that Kaneka has adduced no evidence of secondary considerations that would overcome a clear and convincing showing of obviousness.

Secondary considerations may include evidence of copying, long felt but unsolved need, failure of others, commercial success, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the

invention, and skepticism of skilled artisans before the invention. *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998). Reviewing the evidence of secondary considerations is an important step in the obviousness analysis. As explained by the Federal Circuit:

> It is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case, patent cases included. Thus evidence rising out of the so-called "secondary considerations" must always when present be considered en route to a determination of obviousness. Indeed, evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.

Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538-39 (Fed. Cir. 1983) (citations omitted).

Even when evidence of secondary considerations is present, it cannot overcome a strong *prima facie* showing of obviousness. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

In explaining the relevance of licensing as a secondary consideration, the Federal Circuit has cautioned that:

> Such [licensing] programs are not infallible guides to patentability. They sometimes succeed because they are mutually beneficial to the licensed group or because of business judgments that it is cheaper to take licenses than to defend infringement suits, or for other reasons unrelated to the unobviousness of the licensed subject matter. Such a "secondary consideration" must be carefully appraised as to its evidentiary value and we have tried to do that here.

EWP Corp. v. Reliance Universal Inc., 755 F.2d 898, 907-908 (Fed. Cir. 1985). The Federal Circuit also explained that "[l]icenses taken under the patent in suit may constitute evidence of nonobviousness; however, only little weight can be attributed to such evidence if the patentee does not demonstrate 'a nexus between the merits of the invention and the licenses of record.'" *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995) (citation omitted).

In *Ormco Corp. v. Align Technology, Inc.*, the Federal Circuit rejected Align's attempt to show commercial success as a secondary consideration to overcome obviousness, concluding "that the evidence does not show that the commercial success ***was the result of claimed and novel features.***" 463 F.3d 1299, 1312-13 (Fed. Cir. 2006) (emphasis added). In that case, the Court explained that evidence of commercial success, or other secondary considerations,[12] is only significant if there is a nexus between the claimed invention and the commercial success. *Id. at 1312* (citing *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563 (Fed.Cir.1997)). The Court also pointed out that the presumption that commercial success is due to the patented invention applies "if the marketed product embodies the claimed features, and is coextensive with them." *Id.* at 1312 (Citing *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed.Cir.2000).) The court noted that where the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant. *Id.* at 1312 (Citing *Brown & Williamson*, 229 F.3d at 1130; *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1377 (Fed.Cir.2000); *J.T. Eaton*, 106 F.3d at 1571). So too, if the feature that creates the commercial success was known in the prior art, the success is not pertinent. *Id.* at 1312 (Citing *J.T. Eaton*, 106 F.3d at 1571; *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed.Cir.1983).)

In this case I have found in Section VI.C, *infra*, that Kaneka has failed to prove by a preponderance of evidence that KNA practices at least one valid claim of the invention of the '340 patent in producing coenzyme Q10. Because Kaneka's assertions of secondary considerations are all based upon Kaneka's current process which has not been shown to practice

[12] The Federal Circuit included in its reasoning that the assertion of meeting "a long-felt but unresolved need" and the "failure of others" must also arise from "claimed and novel features." (*Ormco* at 1313)

the invention of the '340 patent, they are not relevant and Kaneka's secondary considerations arguments must fail.

D. Other Defenses:

1. Invalidity Under 35 U.S.C. § 101

Respondents' Position: Respondents argue that under 35 U.S.C. § 101, "Laws of nature, natural phenomena, and abstract ideas" are not patentable. (Citing *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1293 (2012) (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)); *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010).) Respondents say in *Prometheus*, the Court found that certain process claims were not patentable because "the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field." (Citing *Id.* at 1294.) Respondents continue the natural law at issue was the level of 6-TG in blood: "The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes." (Citing *Prometheus*, 132 S. Ct. at 1296-1297.) Respondents state that in holding that the claim at issue was not patentable subject matter, *Prometheus* reconfirmed the principle that has been reiterated by a long line of cases decided by the Supreme Court and Federal Circuit: an inventor may not avoid the bar against claiming natural phenomena simply by adding "conventional" or "obvious" steps to the method claim. (Citing *Parker v. Flook*, 437 U.S. 584, 594 (1978).)

Respondents argue that the purported discovery that "reduced coenzyme Q10-producing microorganisms" produce at least 70 mole % reduced coenzyme Q10 is, at best, a discovery of a law of nature. Respondents assert that the ratio of reduced coenzyme Q10 in the "microorganism" is a function of the metabolic process of the "microorganism," namely the rate

at which the coenzyme Q10 within the "microorganisms" accepts electrons and hydrogen cations from sources of assimilable carbon and the rate at which the coenzyme Q10 within the "microorganisms" donates electrons and hydrogen cations in the presence of molecular oxygen. (Citing RX-651; RX-623C at Qs. 39, 53, 55, 210-211; RDX-60C.) Respondents argue this is just like the *Prometheus* discovery concerning the level of 6-TG in blood, which the Supreme Court held to be "a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes." (Citing *Prometheus*, 132 S. Ct. at 1296-1297.)

Respondents reason that under *Prometheus*, the issue is not whether the law of nature is newly discovered, but whether the rest of the claim limitations "consist of well-understood, routine, conventional activity already engaged in by the scientific community." (Citing *Prometheus*, 132 S. Ct. at 1298.) Respondents say if they do, then the claims fail the *Prometheus* test. Respondents assert here, there can be no question that the remaining claim limitations drawn to "culturing," "disrupting," "extracting" and "oxidizing", and the use of certain solvents, extraction systems and oxygen-free gas atmospheres were "conventional" and "obvious" steps long before the filing date of the '340 Patent. (Citing *Bilski*, 130 S. Ct. at 3230 ("[T]he prohibition against patenting abstract ideas 'cannot be circumvented by' . . . adding 'insignificant post-solution activity.'") (quoting *Diehr*, 450 U.S. at 191-192).) Respondents assert that all experts, including Dr. Connors , have opined that the steps of "culturing," "disrupting," "extracting" and "oxidizing" are "well-understood, routine, conventional activity previously engaged in by researchers in the field"; these arguments need not be repeated here. (Citing Tr. at 1142:8-1143:2, 1157:15-1158:25, 1161:11-1162:2, 1162:14-1163:21, 1201:1-1203:9.)

Kaneka's Position: In its reply brief, Kaneka argues that the '340 Patent claims are not invalid under 35 U.S.C. § 101. Kaneka says Respondents claim that the 70 mole % ratio element

is at once, "obvious" "inherent" and a "law of nature" when it comes to validity; yet, this same property is elusive, undetectable and impossible to measure when discussing infringement. Kaneka asserts that Respondents attempt to show that none of their products meet this limitation by casting accusations and theories of testing error at the data which demonstrates infringement.

Kaneka contends that Respondent's § 101 argument fails, because the claims of the '340 Patent do not cover laws of nature. Kaneka notes Respondents rely on the *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1297 (2012), in which the Supreme Court found that "a process reciting a law of nature" is unpatentable. Kaneka argues that Respondents' analysis of Supreme Court's *Prometheus* decision misses an important holding: that "an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." (Citing *id.* at 1294 (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981).) Kaneka alleges that Respondents further color the holding of *Prometheus* in their explanation of whether claim limitations are well-understood and routine. Kaneka says it is only *after* a patent claim is found to be claiming a "law of nature" that the court engages in the additional analysis of determining whether of the remainder of the claim elements are "simply appending conventional steps." (Citing *Prometheus*, 132 S. Ct. at 1300.)

Kaneka argues that Respondents cannot meet this threshold inquiry because the '340 Patent does not claim a law of nature or a process reciting a law of nature. Kaneka notes that microorganisms produced CoQ10 is a law of nature, and although it is true that the ratio between reduced and oxidized forms of coenzyme Q10 can naturally fluctuate in certain coenzyme Q10-producing microorganisms, the '340 Patent does not purport to cover either phenomenon. Kaneka says instead, the '340 Patent requires the step of purposefully culturing microorganisms to achieve a very specific mole percentage ratio of reduced coenzyme Q10 as an intermediate

step of producing oxidized coenzyme Q10 on an industrial scale. Kaneka argues this is reflected in the independent claims themselves, as the claims require "culturing… to obtain" coenzyme Q10. (Citing JX-1 at claims 1, 11, 22 and 33.)

Kaneka continues that the Respondents offer no explanation of how specific culturing conditions can be merely a "law of nature." Kaneka asserts that both Mr. Ebina and Dr. Connors agreed during trial that culturing conditions during the manufacturing process of coenzyme Q10 have a profound effect on the mole % of reduced coenzyme Q10 during culturing. (Citing Tr. at 987:18-988:14, 1170:17-1171:15.) Kaneka adds that the extensive testing and research that lead to the conception of the '340 Patent demonstrate this point. (Citing RX-294 at 335:1-336:2.)

Kaneka contends that given that the Respondents have not demonstrated that the '340 Patent claims a mere law of nature, it is unnecessary to engage in the discussion of whether the remaining claim limitations were "conventional" or "obvious." Kaneka says, nevertheless, it has repeatedly demonstrated that its claim limitations are novel and nonobvious. (Citing CIB at III.D.)

Discussion and Conclusions: The question here is whether the process of the '340 patent is merely the restatement of natural phenomena coupled with well-understood, routine, conventional activity previously engaged in by researchers in the field; or the application of the law of nature to a new and useful end. The latter is patentable; but the former is not. *Prometheus*, 132 S. Ct. at 1294.

It is true that the '340 patent treats a phenomenon occurring in nature, which is the production of coenzyme Q10 by microorganisms. It is also true that the ratio between reduced and oxidized forms of coenzyme Q10 can naturally fluctuate in certain coenzyme Q10-producing microorganisms. Respondents focus in the portion of asserted claims 1, 11, 22 and 33 of the

'340 patent that describes the production of microbial cells containing "reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10" and argue that this is the "discovery" of the '340 patent, and that the remaining steps in the process described in the independent asserted claims "were "conventional" and "obvious" steps long before the filing date of the '340 patent.

While Respondents cite *Prometheus* in support of their argument, I find that the facts of this case run counter to the result in *Prometheus*. In *Prometheus* the Court considered a process that described a known natural phenomenon, which was a toxic reaction in humans to a high level of thiopurine in the blood, which the Court describe as "a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes." The patented process taught "administering" the drug, set forth the relevant natural laws and then taught "determining" the level in the blood of the thiopurine. The methods for determining the levels were well-known in the art. The Court in *Prometheus* concluded that the patent claims at issue effectively claimed the underlying laws of nature themselves and found the claims to be invalid. *Prometheus*, 132 S. Ct. at 1297-98, 1305.

The facts of this case are much closer to *Diamond v. Diehr*, which is cited in *Prometheus* to illustrate an instance in which a discovery that embodied the equivalent of natural laws (*i.e.* a mathematical equation) was found patent eligible, because of the way the additional steps of the process integrated the equation into the process as a whole. Those steps included "installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time." 450 U.S. 175, 187 (1981).

Here, the '340 patent describes a process that requires control of timing, temperature and

environment to produce reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzyme Q10, and then applying certain steps in specific sequences that will accomplish disruption, oxidation and extraction of coenzyme Q10 to ultimately produce oxidized coenzyme Q10 on an industrial scale. The steps to be applied were the subject of Respondents' unsuccessful attempt to prove by clear and convincing evidence that the invention of the '340 patent was obvious. (*See* Section IV.C, *supra.*) Clearly, the process described in the '340 patent is more than the recitation of a natural phenomenon coupled with "well-understood, routine, conventional activity previously engaged in by researchers in the field."

I find that the Respondents have failed to prove by clear and convincing evidence that the processes taught by independent asserted claims 1, 11, 22 and 33, are invalid as unpatentable.

2. Lack of a Written Description and the New Matter Bar (Claims 22-45)

Respondents' Position: Respondents argue that claims 22-45 are invalid under 35 U.S.C. § 112, ¶ 1 for lack of a written description of a process for producing oxidized coenzyme Q10 on an industrial scale in which extracting takes place in a "sealed tank" and for impermissible addition of "sealed tank" as new matter, in violation of 35 U.S.C. § 132(a). Respondents aver that there is no written description in the '340 patent of the claimed "sealed tank" requirements under any construction of "sealed tank." Respondents say that the '340 patent specification does not disclose the structure or use of a sealed extraction tank, and does not describe any advantage for using a sealed extraction tank in an industrial process for producing oxidized CoQ10. Respondents analogize to *Ariad Pharm., Inc. v. Eli Lilly & Co.*, saying the '340 patent disclosure as originally filed fails to "convey[s] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." (Citing 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*).)

Respondents argue that the concept of producing oxidized coenzyme Q10 on an "industrial scale" including a step of "extracting ... in a sealed tank" was not introduced into the application for the '340 patent until the amendment dated August 27, 2010. (Citing JX-3 at MGC00122089 *et seq.*) Respondents say the Remarks section of that amendment explained that the purpose of these limitations was to distinguish the prior art, including Kondo, Yoshida and Suzuki that had been the Examiner's basis for rejection of similar claims lacking these limitations. (Citing JX-3 at MGC00122100-108.) Respondents conclude the Remarks did not point to any disclosure of the "sealed tank" concept in the original application as filed. (Citing *id.*; RX-129C, Q. 4-5; RX-367C, Q. 140; Tr. at 297:24-299:22.)

Respondents contend that the only disclosure in the '340 patent of extracting any form of coenzyme Q10 on a larger scale is in Example 8. (Citing JX-1 at 23:23-45.) Respondents say that describes a process using a 750L fermentation tank for extracting reduced coenzyme Q10, and in that example, the extraction was conducted in "a countercurrent 3-step continuous extraction apparatus shown in Fig. 1" (Citing *id.*) Respondents say as described and schematically depicted, that apparatus comprises six separate tanks, each with various pipes going in and out of each tank, and arrows indicating liquid flow. (Citing Tr. at 297:24-298:23.) Respondents assert that neither the tanks in Example 8 and Fig. 1 nor the depicted system as a whole are described as "sealed". Respondent continue neither those tanks nor the system as a whole could perform their described functions if any of the tanks were arranged to prevent liquids from going in and out of each tank during extraction. Respondents add that example 8 says nothing at all about gases in the tanks and there is no indication at all regarding gases in Fig. 1. (Citing RX-287C at 95:8-98:16.) Respondents argue that this system of interconnected tanks

is not the same as "a … tank." (Citing *Agilent Tech., Inc. v. Affymatrix, Inc.*, 567 F.3d 1366, 1377 (Fed. Cir. 2009) (distinguishing "an enclosure" from a "system of enclosures").)

Respondents argue that, because the "sealed tank" limitations that were added by amendment are "new matter" and are not supported by the original written description, Claims 22-45 are invalid under 35 U.S.C. § 112, ¶ 1 and § 132(a).

Kaneka's Position: Kaneka states that 35 U.S.C. § 112, ¶ 1 provides, in relevant part, that:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same…

Kaneka says "[t]he test is whether the disclosure 'conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.'" (Citing *Streck, Inc. v. Research & Diagnostic Systems. Inc.*, 665 F.3d 1269, 1285 (Fed. Cir., Jan. 10, 2012) (citing *Ariad Pharm*, 598 F.3d at 1351).) Kaneka continues "[t]his test requires an 'objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.'" and "[a] patentee may also rely on information that is 'well-known in the art' to satisfy written description." (Citing *id.*)

Kaneka asserts that the claim term "sealed" finds support in the specification in connection with process vessels at the time the application was filed. Kaneka says the term "sealed" appears in connection with several of the process examples set forth in the specification as initially filed. Kaneka says for instance, the term "sealed" appears in Example 7 of the specification as originally filed as follows:

> The obtained cells were disrupted for 2 times at 80mPa of disruption pressure by a pressure homogenizer (manufactured by Lanni Co.) ***sealed*** with nitrogen gas to obtain a cell-disrupted solution. The ratio of reduced Coenzyme Q10 in the cell-disrupted solution was 97% relative to the entire coenzymes Q10 including oxidized

> Coenzyme Q10. 200 mL of the cell-disrupted solution was mixed with isopropanol and n-hexane at the ratios shown in the first extraction section in the following Table 4 so as to adjust the total solvent amount to be 500 mL and the mixtures were stirred at 400C for 30 minutes to carry out the first extraction. After completion of the extraction, the resultants were kept standing for 10 minutes and the separated upper layers were collected.

(Citing JX-2.044 (MGC00120943) lines 11-25 (emphasis added by Kaneka).)

Kaneka says while the word "sealed" appears in connection with the described disruption, there is no disclosure here of any transfer to a different vessel for extraction. Kaneka continues additional original disclosure shows that disruption and extraction may be conducted together, quoting "It is needless to say that the cell disruption and extraction can be carried out at the same time." (Citing JX-2.020, lines 23-24.) Kaneka adds that the words of original claim nine bear this out, quoting "The process according to any one of Claims 1 to 8, wherein the microbial cells are disrupted in the extraction." (Citing JX-2.049, lines 17-19.) Kaneka concludes that the original disclosure shows that extraction may be carried out in the same vessel as the disruption, one that may be sealed under pressure and with nitrogen gas.

Kaneka says in another instance, the term "sealed" appears in Example 8 of the specification as originally filed as follows:

> The obtained cells were disrupted for 2 times at 140 mPa of disruption pressure by a pressure homogenizer (manufactured by Lanni Co.) ***sealed*** with nitrogen gas to obtain a cell-disrupted solution. The cell-disrupted solution was subjected to continuous extraction by a countercurrent 3-step continuous extraction apparatus shown in Fig. 1.

(Citing JX-2.046, lines 27-33 (Emphasis added by Kaneka).)

Kaneka avers that Figure 1 as originally filed discloses extraction tanks that are sealed and it shows valves that allow material to controllably pass. Kaneka adds that Figure 1 supports Kaneka's construction of "sealed tank" – a tank that substantially prevents direct exposure of its contents to the atmosphere.

Kaneka says that according to Dr. Connors, the claim term does not result in the lack of a written description of the invention, quoting in relevant part:

> The "sealed tank" limitations of the claims do not lack a written description. Contrary to Dr. Taylor's opinion, Figure 1 of the '340 Patent, which was included as part of the initial patent application, clearly depicts an embodiment of the sealed tank extraction process as claimed in claims 22-45. One of ordinary skill in the art would know that the "sealed tank" extraction process described in the claims would also include the extraction process depicted in Figure 1. The claim limitation was not improperly used to distinguish the prior art because the limitation did not focus simply on the use of the "sealed tank" but the unique combination of elements claimed by the '340 Patent.

(Citing CX-655C, Q. 3-142.)

In its reply brief, Kaneka argues the purpose of the written description requirement (35 U.S.C. § 112) and the corollary new matter prohibition (35 U.S.C. § 132) is to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date. Kaneka contends that the primary inquiry is whether the material added by amendment is contained in the original specification. (Citing *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1352 (Fed. Cir. 2000).) Kaneka adds that the inquiry is whether the disclosure "***reasonably*** conveys to the artisan that the inventor had possession… of the later claimed subject matter" at the time of the original application. (Citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (emphasis added by Kaneka).)

Kaneka contends that under the aforementioned framework, the addition of "sealed tank" during prosecution in the claims neither constitutes new matter nor lacks written description. Kaneka says at the outset, patents are presumed to be valid, and the Examiner considered the inclusion of "sealed tank" and found it to be patentable. (Citing JX-3 at MGC00122115, MGC00122089-MGC00122108.) Kaneka adds one of ordinary skill in the art would know the ordinary meaning of sealed tank as used in the context of commercial production of CoQ10. (Citing SIB at 136.)

Kaneka says Respondents' argument is premised on the unreasonable and overly literal construction that "sealed tanks" must be absolutely sealed to prevent the escape of any gases during extraction. Kaneka contrasts the testimony of Dr. Taylor, Dr. Connors, and Mr. Ebina, saying they all agree that, as would be understood by one of ordinary skill in the art, a "sealed tank" used during the extraction process of manufacturing coenzyme Q10 would necessarily include piping and ventilation. (Citing Tr. at 1140:10-14, 776:9-16, 773:21-774:13, 658:13-659:2.) Kaneka continues with the understanding that extraction tanks must reasonably contain *some* ventilation piping, there are at least two instances discussed explicitly by the Respondents (Example 8 and Fig. 1) where such extraction tanks are taught. Kaneka concludes that Respondents provide no discussion as to why extraction tanks having a ventilation system could not be ***reasonably*** construed by one of ordinary skill in the art as a "sealed tank".

Kaneka says on one hand, Respondents argue that "sealed tank" would be obvious to one of ordinary skill in the art prior to the patent and at the same time arguing that a "sealed tank" as claimed would not convey meaning to one of ordinary skill based on the disclosure of the '340 Patent.

Kaneka asserts that the Federal Circuit has said:

> Section 132 of the Patent Act provides: '[N]o amendment shall introduce new matter into the disclosure of the invention.' 35 U.S.C. § 132. The fundamental inquiry is whether the material added by amendment was inherently contained in the original application. To make this judgment, this court has explained that the new matter prohibition is closely related to the adequate disclosure requirements of 35 U.S.C. § 112. Section 112, in turn, requires: "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable* any person skilled in the art ... to make and use the same." 35 U.S.C. § 112 (1994) (emphasis in original). Thus, to avoid the new matter prohibition, an applicant must show that its original application supports the amended matter.

(Citing *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1352 (Fed. Cir. 2000) (citations omitted).)

Kaneka avers that the claim term "sealed tank" was added by amendment during prosecution on August 27, 2010, as part of new claims 131 and 142. (Citing JX-3.001-.004.) Kaneka asserts that the Examiner obviously and correctly understood that there was no new matter being added by this new term. Kaneka says in the next correspondence with Applicant, on January 11, 2011, the Examiner issued a Notice of Allowance for new claims 110-144 (which became claims 1-45). (Citing JX003.322-.325.)

Kaneka says that in his witness statement, MGC's expert, Mr. Ebina, asserts that the word "sealed" is not found anywhere in the Japanese and U.S. patent applications as originally filed to which the '340 Patent claims priority. (Citing RX-129C, Q. 6-11.) Kaneka continues that the '249 application, which ripened into the '340 Patent, points to a different conclusion. (Citing JX-2 ("generally").) Kaneka states that the word "sealed" appears multiple times in the original U.S. application that entered the national stage as translated into English from the originally filed Japanese application. (Citing JX-2.003 (MGC00120902).) Kaneka asserts that the term "sealed" appears in connection with several of the process examples set forth in the specification as initially filed, and the term "sealed" appears in Example 7 of the specification as originally filed as follows:

> The obtained cells were disrupted for 2 times at 80mPa of disruption pressure by a pressure homogenizer (manufactured by Lanni Co.) ***sealed*** with nitrogen gas to obtain a cell-disrupted solution. The ratio of reduced Coenzyme Q10 in the cell-disrupted solution was 97% relative to the entire coenzymes Q10 including oxidized Coenzyme Q10. 200 mL of the cell-disrupted solution was mixed with isopropanol and n-hexane at the ratios shown in the first extraction section in the following Table 4 so as to adjust the total solvent amount to be 500 mL and the mixtures were stirred at 40°C for 30 minutes to carry out the first extraction. After completion of the extraction, the resultants were kept standing for 10 minutes and the separated upper layers were collected.

(Citing JX-2.044, lines 11-25 (Emphasis added by Kaneka).)

Kaneka contends that while the word "sealed" appears in connection with the described disruption, there is no disclosure here of any transfer to a different vessel for extraction. Kaneka

contends that additional original disclosure shows that disruption and extraction may be conducted together, quoting "It is needless to say that the cell disruption and extraction can be carried out at the same time." (Citing JX-2.020 lines 23-24.) Kaneka points to original claim no. 9 to bolster this disclosure: "The process according to any one of Claims 1 to 8, wherein the microbial cells are disrupted in the extraction." (Citing JX-2.049 lines 17-19.) Kaneka concludes that the disclosure shows that extraction may be carried out in the same vessel as the disruption, one that may be sealed with nitrogen gas and under pressure, and the term "sealed tank" in connection with extraction is thus inherently disclosed in the application as filed.

Kaneka notes that its expert, Dr. Connors, testified that the term "sealed tank" is supported in the specification as originally filed:

> It is my opinion that a person of ordinary skill in the art would not view the term "sealed tank" in isolation, but would properly read it in conjunction with the Figure 1 of the specification which shows that where there is both continuous extraction and countercurrent multistage extraction, then liquids and gases must necessarily enter and exit the sealed tank in a controlled manner. Figure 1 was in the original Japanese and U.S. applications, and has always provided support for the "sealed tank" limitation. Therefore, adding the term "sealed tank" by amendment in 2010 did not add new matter. Rather, the "sealed tank" limitation has always been supported by what was taught and depicted by Figure 1.

(Citing CX-655C, Q. 1-152.)

Kaneka contends there was no new matter added by the claim term "sealed tank" during prosecution. (Citing *Yingbin-Nature (Guangdong) Wood Indus. Co., Ltd. v. Int'l Trade Comm'n*, 535 F.3d 1322, 1328-29 (Fed. Cir. 2008) (Commission reversal of ALJ's holding of lack of written description upheld - merely adding the generic word "clearance" to describe spaces shown in figures and specification did not constitute new matter).) Kaneka says in reversing the ALJ, the Commission properly "relied on *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347 (Fed.Cir.2000) for the proposition that the use of a new term by the patentee to describe what was already disclosed does not constitute

new matter, *id.* at 1352." (Citing *Yingbin-Nature*, 535 F.3d at 1329.) Kaneka concludes that the addition of the term sealed tank to the claims had already been expressly or at least inherently disclosed in the specification and Figure 1 of the application as filed, and Respondents lack clear and convincing evidence to show otherwise.

Staff's Position: Staff notes that Section 112, paragraph 1 contains a "written description" requirement and quotes the Federal Circuit to have explained in *Ariad*:

> [T]he [written] description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." [*Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555,] at 1563 (citing *In re Gosteli,* 872 F.2d 1008, 1012 (Fed. Cir.1989)). In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. *Id.* (quoting *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir.1985)); *see also In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir.1983).

(Citing *Ariad Pharmaceuticals v. Eli Lilly*, 589 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*).)

Referring to the discussion regarding obviousness, Staff says the evidence shows that persons of skill in the art at the time (and indeed, presently) believed that for purposes of safety, preventing explosions, and environmental reasons, industrial scale extraction with organic solvents should be done either under an inert gas atmosphere or in a sealed tank. Staff believes that the evidence shows that a person of ordinary skill in the art would have known that use of a sealed tank was desirable in any industrial extraction process utilizing organic solvents. Staff does not believe that Respondents have carried their burden and provided clear and convincing evidence of invalidity due to lack of written description and the addition of new matter.

Discussion and Conclusions: Respondents' argument centers on the term "sealed tank," which Respondents claim to be both inadequately described in the specification and "new matter." This contrasts with Respondents' argument in Section IV.C, *supra*, that the term

"sealed tank" would have been obvious to a PHOSITA at the time of the invention of the '340 patent.

Based upon Respondents' argument and the supporting evidence, I found that performing extraction in a "sealed tank" (as construed herein) when using solvents was obvious to a PHOSITA at the time of the invention of the '340 patent.

In its reply brief, Kaneka notes correctly that a purpose of the written description requirement (35 U.S.C. § 112) and the corollary new matter prohibition (35 U.S.C. § 132) is to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date. The primary inquiry is whether the material added by amendment is contained in the original specification. *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1352 (Fed. Cir. 2000). The inquiry is whether the disclosure "***reasonably*** conveys to the artisan that the inventor had possession... of the later claimed subject matter" at the time of the original application. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)(emphasis added).

As Staff points out, the Federal Circuit explained in *Ariad Pharmaceuticals v. Eli Lilly*, 589 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*) that the test on written description is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. First, example 7, as originally proposed, describes a process that requires disruption in a pressure homogenizer sealed with nitrogen gas. The disrupted solution was then subjected to extraction using organic solvents. There is no mention of removing the disrupted cells from the sealed homogenizer. (JX-2.044, lines 11-23.) Moreover, one embodiment of the invention of the '340 patent discloses optionally conducting disruption and extraction "at the same time." (JX-1 at 9:17-21.) In view of this disclosure, I find that the '340 patent can be read to disclose using a "sealed tank" for extraction.

Second, even if the '340 patent did not explicitly disclose using a sealed tank for extraction, extraction in a sealed tank was reasonably conveyed to those of ordinary skill in the art. Dr. Connors testified that using a sealed tank for performing extraction with organic solvents was "typically how microbial natural products were extracted" at the time of the invention of the '340 patent. (Tr. at 1201:6-17.) Dr. Taylor testified that "common sense would guide one of skill in the art to use inert gases and sealed tanks when handling organic solvents." (RX-367C, Q. 366.) As a result, I find that by disclosing extraction by the use of organic solvents, extraction in a sealed tank was reasonably conveyed to those of ordinary skill in the art.

Based upon the foregoing, I find that the use of "sealed tank" in the '340 patent does not violate either the written description requirement of Section 112 or the new matter proscription of Section 132.

3. Improper Inventorship

Respondents' Position: Respondents argue that inventorship is a question of law that should be decided based on underlying findings of fact. (Citing *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998).) Respondents say that Title 35, Section 102(f) of the Patent Act "mandates that a patent accurately list the correct inventors of a claimed invention." (Citing 35 U.S.C. § 102(f); *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348-49 (Fed. Cir. 1998) (citations omitted).) Respondents quote "Accordingly, if nonjoinder of an actual inventor is proved by clear and convincing evidence, a patent is rendered invalid." (Citing *id.*) Respondents recite that conception is the touchstone to determining inventorship. (Citing *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997).) Respondents quote "[T]he critical question for joint conception is who conceived, as that term is used in the patent law, the subject matter of the claims at issue." (Citing *Ethicon*, 135 F.3d at 1460.)

Respondents say the issue of joint inventorship is governed by Section 116 of the Patent Act, which requires a joint inventor to "(1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art." (Citing *Pannu*, 155 F.3d at 1351.) Respondents contend that for persons to be joint inventors, "there must be some element of joint behavior, such as collaboration or working under common direction, one inventor seeing a relevant report and building upon it or hearing another's suggestion at a meeting." (Citing *Kimberly-Clark Corp. v. Proctor & Gamble Distrib. Co.*, 973 F.2d 911, 917 (Fed. Cir. 1992).)

{

}

Respondents say in *Ethicon*, the Federal Circuit affirmed a district court's holding that an intervenor, Choi, was a joint inventor of a surgical instrument comprising, *inter alia*, a blade surface and a blunt probe located in a shaft that allowed the blunt probe to pass through an aperture in the blade surface. (Citing 135 F.3d at 1461-62.) Respondents state that although the named inventor, Yoon, had conceived of using a blunt probe, Choi had conceived of "'locating the blunt probe in the shaft and allowing it to pass through an aperture in the blade surface.'" Respondents conclude since Choi had contributed a limitation to the claimed combination, he was properly a joint inventor of that combination. (Citing *Id.* at 1462.)

Respondents assert that the evidence shows that, as in *Ethicon*, {

} conceived and contributed the 70 mole % limitation. Respondents allege that {

}

Kaneka's Position: In its reply brief, Kaneka argues that Respondents have failed to adduce clear and convincing evidence showing improper inventorship. Kaneka contends that the claim of improper inventorship must fail because {

}

Kaneka states that a party challenging a patent's validity for failure to name a co-inventor must prove contribution to the invention by clear and convincing evidence. (Citing *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1461 (Fed. Cir. 1998).) Kaneka adds that a purported joint inventor must be shown to have contributed to the conception or the reduction to practice in a "significant" manner. (Citing *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998).) Kaneka concludes that corroborating evidence is required to support such a challenge. (Citing *Ethicon*, 135 F.3d at 1461.)

Kaneka contends that the Federal Circuit has taught that evaluating corroborating evidence requires application of a "rule of reason" analysis. (Citing *Price v. Symsek*, 988 F.2d 1187, 1195 (Fed. Cir. 1993).) Kaneka says under the rule of reason, all pertinent evidence must be evaluated to determine the credibility of an inventorship challenge. (Citing *id.*) Kaneka

states that factors pertinent to the rule of reason analysis include: "(1) the relationship between the corroborating witness and the alleged prior user, (2) the time period between the event and trial, (3) the interest of the corroborating witness in the subject matter in suit, (4) contradiction or impeachment of the witness' testimony, (5) the extent and details of the corroborating testimony, [and] (6) the witness' familiarity with the subject matter of the patented invention and the prior use...." (Citing *Woodland Trust v. Flowertree Nursery, Inc.,* 148 F.3d 1368, 1371 (Fed.Cir.1998).)

Kaneka reasons that under this standard, the Respondents' claim of improper inventorship is not credible, and there is no corroborating witness to support Respondents' claim.

{

}

Kaneka adds that there is a logical disconnect in Respondents' argument, to wit: the { } reduced coenzyme Q10 is different from the conception and reduction to practice of the 70 mole % of reduced coenzyme Q10 as claimed as "a culturing requirement to obtain" in the '340 Patent. Kaneka explains that { } what the inventors ultimately conceived through their research and screening is obtaining the 70 mole % of reduced coenzyme Q10 under particular culturing conditions and the use of that culturing step in a process. (Citing RX-294 at 102:2-19.) Kaneka states that Respondents offer no credible support linking the 70 mole % disclosure reflected in the testing results of the specification { }

Staff's Position: Staff notes that misjoinder or nonjoinder of inventors must be proven by clear and convincing evidence. (Citing *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998) ("An assertion of incorrect inventorship must be based on facts proved by clear and convincing, corroborated evidence.").)

Staff is of the view that the evidence demonstrates that the named inventors were not indeed the first individuals inside of Kaneka to notice that the microorganisms used to manufacture Q10 produced a high ratio of reduced Q10. Staff contends, however, that the purported invention of the '340 patent is not limited to the observation that some microbes produce reduced Q10 in a ratio of greater than 70 %. Staff says rather, the patent discloses a list of microorganisms that meet the 70% limitation and describe the use of such microbes in an industrial scale process for the production of Q10. Staff contends that the evidence demonstrates

{

} it was the inventors who performed the testing to determine what other organisms met this limitation, standardized the conditions for culture and testing, and described the steps of an industrial Q10 production process.

{

}

Discussion and Conclusions: Respondents assert that the '340 patent is invalid, because it was not Mr. Yajima or Mr. Kato who "first conceived the 70 mole % limitation"; but an

{

} There is no allegation of any involvement in the invention of the process of the '340 patent by this unnamed individual.

There is no evidence in the record that a Kaneka employee has come forward to dispute the inventorship of the '340 Patent, and there is no evidence that any of the inventors of the '340 Patent has stated that the 70-mole % limitation was conceived by someone other than the properly identified inventors. (*See* RX-287C at 120:7-13; RX-294C at 31:20-32:11.)

{

}

In my view Kaneka is correct {

} is different from the conception and reduction to practice of the 70 mole % of reduced coenzyme Q10 as claimed as "a culturing requirement to obtain" in the '340 Patent.

I find that Respondents have failed to provide clear and convincing evidence to support their claim that the proper inventors are not set forth on the '340 patent as issued.

V. INFRINGEMENT

A. Applicable Law

A complainant must prove either literal infringement or infringement under the doctrine of equivalents. Infringement must be proven by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). A preponderance of the evidence standard "requires proving that infringement was more likely than not to have occurred." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n. 15 (Fed. Cir. 2005).

Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008). Literal infringement requires the patentee to prove that the accused device contains each and every limitation of the asserted claim(s). *Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004).

As for the doctrine of equivalents:

> Infringement under the doctrine of equivalents may be found when the accused device contains an "insubstantial" change from the claimed invention. Whether equivalency exists may be determined based on the "insubstantial differences" test or based on the "triple identity" test, namely, whether the element of the accused device "performs substantially the same function in substantially the same way to obtain the same result." The essential inquiry is whether "the accused product or process contain elements identical or equivalent to each claimed element of the patented invention[.]"

TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc., 529 F.3d 1364, 1376-77 (Fed. Cir. 2008) (citations omitted).

Thus, if an element is missing or not satisfied, infringement cannot be found under the doctrine of equivalents as a matter of law. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538-39 (Fed. Cir. 1991). Determining infringement under the doctrine of equivalents "requires an intensely factual inquiry." *Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1381 (Fed. Cir. 2000).

B. Maypro

Discussion and Conclusions: During the prehearing conference, Kaneka and Maypro explained that no evidence against Maypro would be presented at the hearing. (Tr. at 11:5-15.) Because no evidence was presented by any party regarding Maypro, there has been no showing that Maypro infringes any claim of the '340 patent. (Tr. at 11:22-12:12.)

C. Shenzhou

Kaneka's Position: Kaneka contends that Shenzhou's process for manufacturing coenzyme Q10 infringes at least claims 1, 3-4, 6, 8-11, 13-15, 17, 19-22, 24-25, 27, 29-33, 35-37, 39, and 41-45 of the '340 patent.

Kaneka asserts that Shenzhou's process is "a process for producing on an industrial scale the oxidized coenzyme Q10 . . ." as required by the preambles of all of the asserted independent

claims. {

}

Kaneka contends that Shenzhou's process includes "culturing reduced coenzyme Q10 producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient," as required by the first element of all of the asserted independent claims. {

}

Kaneka says a percentage of this coenzyme Q10 will be in its reduced form. (Citing CX-653C, Q. 144.) {

}

In its reply brief, Kaneka disagrees with Shenzhou's arguments that Kaneka's testing is unreliable. {

} Kaneka also points to testing of its expert, Dr. Kittendorf, to rebut Shenzhou's arguments. {

} Kaneka argues that this evidence is uncontroverted. Kaneka says that Dr. Kittendorf also testified that once frozen, metabolism stops and subsequent viability of cells is compromised, if not lost altogether. (Citing Tr. at 209:13-210:2.) Kaneka continues, saying that Dr. Spormann likewise testified that freezing is the best way to stop metabolism. (Citing Tr. at 596:19-20.) Kaneka argues that all of this testing was done in accordance with the '340 patent. (Citing Tr. at 965:5-23.)

Kaneka says that the elapsed time between sampling to completion of testing of any given sample was about 60 hours (2 ½ days), {

}

Kaneka contends that Shenzhou's process includes a step of "disrupting the microbial cells to obtain reduced coenzyme Q10" as required by the second element of claims 1 and 22 and "disrupting the microbial cells" as required by claims 14 and 36. {

}

Kaneka contends that Shenzhou's process includes a step of "oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10," as required by the third element of claims 1

{

}

In its reply brief, Kaneka disagrees with Shenzhou's argument that the oxidation claim element cannot be met unless oxidation is the main purpose of the step. Kaneka says that the claims have no such requirement. {

}

says that absent these steps, oxidizing the reduced coenzyme Q10 would take much longer to accomplish.

Kaneka contends that Shenzhou's process includes a step of "extracting the oxidized coenzyme Q10 by an organic solvent," as required by the third element of claims 1 and 22.

{

}

Kaneka asserts that this extraction takes place "under an inert gas atmosphere," as required by the third element of claim 1. (Citing CX-653C, Q. 154; CX-180C at 96:18-97:22; 121:17-122:9.) {

}

Kaneka asserts that Shenzhou's extraction takes place "in a sealed tank," as required by the third element of claim 22. (Citing CX-653C, Q. 155.) {

}

Kaneka contends that Shenzhou's process includes a step of "extracting the reduced coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by the second element of claim 11 and "extracting the reduced coenzyme Q10 by an organic solvent in a sealed tank" as required by the second element of claim 33. {

}

Kaneka contends that Shenzhou's process includes "oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10," as required by the third element of claims 11 and 33. {

}

Kaneka asserts that in Shenzhou's process "the extraction . . . is carried out by using a hydrophobic organic solvent," as required by claims 3, 13, 24, and 35. {

}

Kaneka asserts that Shenzhou's process includes a step of "disrupting the microbial cells," as required by claims 14 and 36. (Citing CX-653C, Q. 160; CX-179C at 38:13-43:21.)

Kaneka asserts that Shenzhou's process oxidizes reduced coenzyme Q10 "with an oxidizing agent," as required by claims 4, 15, 25, and 37. {

}

Kaneka asserts that in Shenzhou's process, "the inert gas atmosphere comprises nitrogen gas," as required by claims 9, 20, and 30. {

}

Kaneka asserts that in Shenzhou's process, "the sealed tank is sealed under an inert gas atmosphere" and "under a deoxygenized atmosphere," as required by claims 29 and 41. {

}

Kaneka asserts that in Shenzhou's process, "the deoxygenized atmosphere comprises an inert gas" and "nitrogen gas" as required by claims 42 and 43, respectively. {

}

Kaneka asserts that in Shenzhou's process "the culture medium is at least 750 L," as required by claims 10, 21, 31, and 44. {

}

Shenzhou's Position: Shenzhou asserts that Kaneka has failed to prove that Shenzhou's process utilizes "reduced coenzyme Q10 producing microorganisms," as required by each asserted independent claim. Shenzhou says that Kaneka never tested Shenzhou's microorganisms under the standard screening method explicitly set forth in the '340 patent at col. 4, line 51 to col. 5, line 43. (Citing RX-473C, Q. 163; RX-348C, Qs. 243-248.) {

} Shenzhou additionally asserts that Kaneka waived this doctrine of equivalents argument. (Citing Tr. at 22:12-23:24.)

Shenzhou says that Kaneka's collection and sample handling procedures of samples it relies on to show the 70 mole % limitation is met were flawed and created an oxygen deficiency. (Citing RX-623C, Qs. 206-221; RDX-59C; RDX-60C; RX-348C, Qs. 262-276, and 416-417; RX-473C, Qs. 174-194; RX-625C, Qs. 66-70; RX-626C, Qs. 162-177; Tr. at 184:13-187:10, 190:16-192:15, 193:14-194:7, 247:5-253:22, 254:17-256:20, 594:6-595:22, 607:11-610:8, 1011:7-1012:25, 1060:21-1061:12.) {

}

Shenzhou concludes that the environment in which the biologically active samples existed thus no longer resembled the *in vivo* conditions of the culturing tank, but the artificial, *in vitro* conditions of the oxygen-purged sample vials. (Citing RX-623C, Qs. 206-221; RDX-59C;

RDX-60C; RX-348C, Qs. 262-276, and 416-417; RX-473C, Qs. 174-194; Tr. at 247:5-253:22, 254:17-256:20, 594:6-595:22, 607:11-610:8, 1011:7-1012:25, 1060:21-1061:12.)

Shenzhou says this environmental difference was exacerbated by Kaneka's decision to refrigerate, rather than freeze, the samples. (Citing RX-623C, Qs. 206-221; RX-348C, Q. 115, 162, 262-276, and 416-417; RX-473C, Qs. 174-194; Tr. at 184:13-187:10, 190:16-192:15, 193:14-198:25, 247:5-253:22, 254:17-256:20, 594:6-595:22, 607:11-610:8.) Shenzhou says that whereas frozen samples stop metabolizing immediately upon freezing, refrigerated samples continue to metabolize. (Citing RX-623C, Qs. 206-235; RDX-59C; RDX-60C; RDX-61C; RDX-62C; RDX-63C; RX-348C, Qs. 273-274, and 416-417; RX-473C, Qs. 186-188; Tr. at 184:13-187:10, 190:16-192:15, 193:14-198:25, 250:11-253:22, 254:17-254:19, 594:6-595:22, 607:11-610:8.) Shenzhou asserts that the result of Kaneka's handling of the samples was to shift the *in vivo* ratio of reduced-to-oxidized coenzyme Q10 within the cells in favor of the reduced form, which happened very rapidly. (Citing *id.* RX-623C, Qs. 212-221; Tr. at 594:6-595:22.)

Shenzhou says that an analysis of the samples collected from the various manufacturers, including Kaneka, confirms that Kaneka's sample collecting and handling protocol led to results that were skewed in favor of reduced coenzyme Q10. {

}

Shenzhou says that Dr. Connors had no explanation for these discrepancies. (Citing Tr. at 252:16-253:22, 254:17-254:19.) Shenzhou says that in contrast, Respondents' experts explained that allowing biologically active samples to metabolize in an oxygen deficit artificially shifts the coenzyme Q10 pool towards the reduced form. (Citing RX-623C, Qs. 202-253; RX-308C; RX-402C; RX-585C; RDX-59C; RDX-60C; RDX-61C; RDX-62C; RDX-63C; RDX-64C; RDX-65C; RDX-66C; RDX-67C; RX-348C, Qs. 259-276, and 416-417; RX-473C, Qs. 174-194; Tr. at 594:6-595:22, 607:11-610:8, 1011:7-1012:25, 1060:21-1061:12.) Shenzhou concludes that Kaneka's HPLC analyses of refrigerated samples do not accurately reflect the ratio of reduced coenzyme Q10 in Respondents' manufacturing processes. Shenzhou notes that, in Dr. Taylor's expert opinion, the HPLC analysis of the frozen samples is also unreliable

because of an insufficient sample population and the lack of reproducible results. (Citing RX-348C, Qs. 262-275.)

{

}

these results, combined with problems with Kaneka's handling and sampling procedure, demonstrate that Shenzhou does not infringe any claims of the '340 patent.

{

}

responds to Kaneka's allegations that Shenzhou tested two culturing samples but never revealed the results of one of the samples by saying there is no evidence in the record to support these

allegations, the allegations were not raised in Kaneka's pre-hearing brief and no knowledgeable witness was questioned on the issue.

Shenzhou asserts in Respondents' reply brief that Kaneka does not deny that the ratio of reduced coenzyme Q10 increases over time when stored unfrozen in oxygen-deprived conditions. Shenzhou says that Dr. Kittendorf's testing confirms this point. (Citing RX-623C at QW. 239-244; RX-308C; RX-348C, Qs. 186-195, 262, 266; RX-473C, Qs. 186-188; Tr. at 195:21-195:25.) {

}

Shenzhou responds to Kaneka's criticism of limiting the infringement analysis to a specific testing method by saying that if Kaneka's approach were adopted, the 70% limitation, which Kaneka claims is the "heart of the invention," would be completely meaningless since "conditions matter". (Citing Tr. at 310:14-16, 675:10-676:22.) Shenzhou says that its experts utilized the '340 patent and the testing protocol provided by Kaneka to attempt to replicate the protocol that Kaneka had developed. (Citing RX-365C, Qs. 11-17.) Shenzhou asserts that its experts' use of this protocol does not prevent it from criticizing the protocol, as Kaneka suggests.

Shenzhou asserts that its process also does not include the step of "extracting . . . under an inert gas atmosphere," as required by asserted claims 1 and 11 of the '340 patent. {

}

Shenzhou says that Dr. Connors admitted to speculating on the composition of the atmosphere inside Shenzhou's tank during extraction. (Citing Tr. at 328:9-13.) {

}

amount of the reduced coenzyme Q10 present. Shenzhou concludes that because Kaneka failed to introduce any evidence regarding the atmospheric composition within Shenzhou's extraction tanks, Kaneka has not shown infringement under any party's claim construction.

Shenzhou asserts that its process does not include a step of "extracting . . . in a sealed tank," as required by asserted independent claims 22 and 33. {

} Shenzhou says that Dr. Connors admitted as much. (Citing Tr. at 320:6-322:13.) {

}

Shenzhou says that its process does not include a step of disrupting the microbial cells to obtain reduced coenzyme Q10, as required by claims 1 and 22 of the '340 patent, because it cultures its microorganisms to obtain microbial cells containing oxidized CoQ10. {

} Shenzhou contends that these results demonstrate that it does not conduct the disruption of microbial cells under the condition that the reduced coenzyme Q10 is protected from an oxidation reaction throughout disruption.

{

} Shenzhou concludes that there is no support for Dr. Connors' contention that Shenzhou's process disrupts the microbial cells to obtain reduced coenzyme Q10.

{

}

Shenzhou says that its process does not include a step of oxidizing reduced coenzyme Q10 as required by asserted independent claims 1, 11, 22, and 33. Shenzhou contends that its process does not include a separate step of active oxidation and Dr. Connors never opines that Shenzhou's process includes a step of active conversion.

{

}

steps, the main purpose of the step was something other than oxidation of the reduced coenzyme Q10. {

} (Citing RX-447C, at ¶187.) {

} Shenzhou reasons that reading the claims to encompass passive oxidation as an oxidation step makes the oxidation step unavoidable because at some point, the reduced fraction of the total coenzyme Q10 will be exposed to air.

Shenzhou says that Kaneka may argue that there is an oxidizing agent in Shenzhou's

process. {

}

Shenzhou says that the alleged oxidizing steps do not occur in the order required by {

}

Shenzhou says that even if the "oxidizing" step only requires increasing the rate of oxidation, Kaneka has introduced no evidence at all respecting the relative rates of oxidation at different points in the Shenzhou process and therefore failed to meet its burden of proof.

Shenzhou asserts that Kaneka has failed to establish that Shenzhou's process uses an oxidizing agent as required by claims 4, 15, and 25. Shenzhou says that Dr. Connors admitted that he was unable to identify the alleged oxidizing agent used in Shenzhou's manufacturing process. (Citing RX-447C, at ¶222.) {

}

Q10 is readily oxidized when exposed to air. {

} Accordingly, Kaneka has failed to meet its burden of proof that Shenzhou infringes claims 4, 15, and 25 because there is no evidence in the record of an oxidizing agent in Shenzhou's process.

Shenzhou asserts that Kaneka did not present any evidence that Shenzhou's manufacturing process meets the 70 mole % limitation after disruption or extraction when measured as required by claims 8, 19, 32, and 45. {

}

Respondents' reply brief, Shenzhou says that Kaneka seeks to interpret the term "upon" to mean "prior to," but offers no support. Respondents contend that the ordinary meaning of "upon disrupting" is once disruption has begun and "upon extracting" is once extraction has begun.

{

} Shenzhou continues that Dr. Connors has failed to provide any evidence or testing on the composition of the atmosphere in Shenzhou's tank during extraction. (Citing Tr. at 328:6-329:2.) Shenzhou concludes that Kaneka has failed to meet its burden of proof that Shenzhou infringes claims 41-43 of the '340 patent.

Staff's Position: Staff says that Kaneka has accused the process Shenzhou uses to manufacture oxidized Q10 of infringing claims 1, 3-4, 8-11, 13-15, 17, 19-22, 24-25, 27, 29-33, and 41-45 of the '340 patent. (Citing CX-653C, Q. 140; Kaneka Stipulation re Asserted Claims.)

Staff asserts that there is no real dispute that the Shenzhou process is a process for producing on an industrial scale the oxidized coenzyme Q10.

{

} (Citing CX-653C, Q. 122.) {

}

Staff says that Kaneka has not submitted any information regarding the mole % ratio of reduced coenzyme Q10 in the Shenzhou bacteria when cultured and assayed as required by Staff's and Respondents' construction. (Citing RX-473C, Qs. 161-164; Tr. at 343:1-9.) {

} Staff concludes that, as a result, the evidence does not show that the Shenzhou process meets this limitation under the constructions offered by Staff and Respondents.

Staff says that Kaneka's construction requires only that the Shenzhou process culture microorganisms that produce any amount of reduced coenzyme Q10. Staff reasons that because

the evidence shows that the bacteria used by Shenzhou produces some reduced coenzyme Q10, this limitation is met under Kaneka's construction.

{

} Staff

notes that Shenzhou does not appear to dispute that its process satisfies this limitation.

Staff argues that the only way to determine if a process satisfies the 70 mole % limitation is to test a sample taken at the end of the fermentation step using the procedure described in the '340 patent at column 5 lines 8-42 and in Example 1. Staff continues that Kaneka has not provided the results of any testing performed according to the procedures of the '340 patent. Staff says that if the construction of Staff and Respondents for this limitation is adopted, the evidence does not show that the Shenzhou process meets this limitation.

Staff says that Kaneka relies on testing performed by Dr. Kittendorf on samples taken from Respondents' plants. (Citing CX-653C, Q. 149; CX-72.) {

} Staff

argues that the evidence clearly demonstrates that the method used to collect and store these samples from Respondents' plants and Dr. Kittendorf's testing are substantially flawed and would have acted to skew the ratio of Q10 produced by increasing the percentage of reduced Q10.

Staff says that Drs. Lee, Spormann, Taylor, and Trumpower all believe that Kaneka's procedures to collect and store samples, and Dr. Kittendorf's testing, are so flawed as to be unreliable. (Citing Tr. at 594:15-23, 1011:12-17; RX- 365C, Q.55; RX-473C, Q. 174.) {

}

Staff says that Dr. Kittendorf admitted that the bacteria in the refrigerated samples was still alive and metabolizing. (Citing Tr. at 192:7-10.) Staff contends that this creates a problem, because, as Dr. Trumpower explained, "if you limit oxygen delivery to an oxygen, to an aerobic growing microorganism that the coenzyme Q10 content, the reduced coenzyme Q content is going to go up, way up." (Citing Tr. at 675:22-25, 722:2-7; RX-473C at Q183, 186, 188; RX-289C at 96:14-99:1.) Staff says that Dr. Spormann agreed and testified that "when you take a sample of fermentation broth out of the tank and put it in an oxygen deficient environment, such as a test tube blanketed with nitrogen or argon gas and capped, the coenzyme Q10 pool within the cells rapidly shifts towards the reduced form." (RX-623C at p.56.)

Staff says that multiple prior art references indicate that in an anaerobic environment the ratio of coenzyme Q10 and similar coenzymes shifts towards reduced. (Citing RX-623C, Qs. 212-221; RX-646; RX-645; RX-25; RX-644.) Staff continues that the prior art also shows that this shift occurs as quickly as 1-2 minutes after the oxygen supply via aeration has stopped.

(Citing RX-623C, Q. 217.) Staff concludes that both the prior art and expert testimony demonstrate that allowing microorganisms to metabolize in an anaerobic environment inevitably, artificially, and substantially increases the ratio of reduced Q10.

Staff argues that Dr. Kittendorf's testing confirms this increase in the reduced form of coenzyme Q10. {

} Staff says that even Dr. Kittendorf admits that these tests demonstrate that the amount of oxygen available affects the ratio of coenzyme Q10. (Citing Tr. at 198:4-8; RX-289C at 105-110, 115-117.)

Staff argues that there are a number of additional flaws with Dr. Kittendorf's analysis. Staff says that Dr. Lee criticized Dr. Kittendorf's testing of some samples in triplicate and others once, a questionable method of measuring standards, and an unusual method of washing the HPLC line. (Citing RX-375C, Qs. 59-76.) Staff continues that Dr. Taylor identified other problems with Dr. Kittendorf's methodology, including the use of single data points and the failure to determine Fx/Fh factor. (Citing RX-367C, Q. 166.)

Staff concludes that because of these flaws, Kaneka has not provided sufficient reliable evidence to carry its burden to demonstrate that the Shenzhou process meets this limitation, even if Kaneka's own claim construction is adopted.

{

}

Staff says that Shenzhou's process includes a step of oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10 under Kaneka's construction, but not under Staff's and Respondents' construction. {

} Staff reasons that, as a result, if the constructions of Staff or Respondents are adopted, the evidence does not show that the Shenzhou process meets this limitation.

Staff asserts that Shenzhou's process includes a step of oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10, as required by independent claims 11 and 33. {

} Staff reasons, therefore, that the evidence indicates that this limitation is satisfied under Kaneka's proposed construction. {

}

Staff asserts that Shenzhou's process does not include a step of extracting the oxidized coenzyme Q10 by an organic solvent under an inert gas atmosphere, as required by asserted independent claims 1 and 22. {

} As a result, Staff concludes that the evidence does not show that this limitation is met under Kaneka's proposed construction.

Staff says that no data has been submitted regarding the content of the atmosphere in the extraction tank, {

} Staff contends that this indicates the presence of substantial amounts of oxygen. As a result, Staff concludes that the evidence does not show that this limitation is met under Staff's or Respondents' constructions.

Staff asserts that Shenzhou's extraction tank is sealed under Kaneka's construction but is not sealed under Staff's and Respondents' construction. {

} Staff therefore concludes that this limitation is met under Kaneka's construction.

{

}

Staff asserts that Shenzhou extracts oxidized coenzyme Q10 using a hydrophobic organic solvent, as required by claims 3, 13, 24, and 35. {

}

Staff asserts that in Shenzhou's process the reduced coenzyme Q10 is oxidized with an oxidizing agent, as required by claims 4, 15, 25, and 37. Staff says that in claims 4 and 25, this limitation refers to oxidizing reduced Q10 {

}

Staff asserts that Kaneka has failed to establish that in Shenzhou's process, the reduced coenzyme Q10 upon disrupting has a ratio of not less than 70 mole % among the entire coenzyme Q10 when measured under the condition that the reduced coenzyme Q10 is protected from an oxidation reaction. Staff says that Kaneka asserts this limitation is met by Dr. Kittendorf's testing of the late-fermentation samples from Shenzhou. {

}

Staff argues that in Shenzhou's process, the extraction atmosphere is not an inert gas atmosphere that comprises nitrogen gas, as required by claims 9, 20, 30, and 43. {

}

limitation and Kaneka has submitted no testing data to demonstrate the composition of the atmosphere in Shenzhou's extraction tanks. As a result, Staff concludes that Kaneka has not carried its burden to show that this limitation is met.

Staff says that there is no real dispute that the Shenzhou process meets the claims 10, 21, 31, and 44 limitation that requires the culture medium is at least 750L.

Staff says that Kaneka has not shown that in Shenzhou's process there is a sealed tank sealed under a deoxygenized atmosphere, as required by claims 41-43. Staff says that Kaneka has not provided any testing data regarding the composition of the atmosphere of the extraction tank in the Shenzhou process. Staff concludes, as a result, that the evidence does not show this limitation is met.

Discussion and Conclusions: Kaneka has failed to prove by a preponderance of the evidence that Shenzhou's process of producing coenzyme Q10 infringes any asserted claim of the '340 patent. Although there are other minor disputes between the parties, the key disputes between Kaneka and Shenzhou are whether or not Shenzhou's process meets the 70 mole % limitation (as required by all asserted independent claims), whether or not Shenzhou's process meets the limitations requiring extraction of coenzyme Q10 under an inert gas atmosphere (as required by asserted independent claims 1 and 11), and whether or not Shenzhou's process meets

the limitations requiring extraction of coenzyme Q10 in a sealed tank (as required by asserted independent claims 22 and 33). I find that Kaneka has failed to carry its burden of proof on all of these issues.

First, Kaneka has failed to show by a preponderance of the evidence that Shenzhou's process of producing coenzyme Q10 includes a step of "culturing reduced coenzyme Q10-producing microorganisms . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by each asserted independent claim (claims 1, 11, 22, and 33). {

}

at 19-20.) XKGC's expert, Dr. Spormann, explained that such storage (refrigeration in an oxygen deprived environment) would cause the mole % of the reduced form of coenzyme Q10 to increase over time. (RX-623C, Qs. 206-235.) Drs. Taylor and Trumpower provided similar testimony. (RX-348C, Qs. 263-66; RX-473C, Qs. 181-88.)

Moreover, Kaneka's expert, Dr. Kittendorf, admitted that the amount of oxygen available affects the ratio of reduced coenzyme Q10 (Tr. at 198:4-8), and Kaneka's testing data confirms that, under Kaneka's storage and testing protocol, the amount of reduced coenzyme Q10 in

samples increased over time when refrigerated. Dr. Kittendorf performed time elapsed testing on certain refrigerated samples from Kaneka's (not respondents') process. (Tr. at 194:8-20.) {

}

Kaneka's speculation regarding how much the percentage of reduced coenzyme Q10 changes in a refrigerated sample in two and one-half days between sampling and testing is rebutted by Kaneka's own test data. Dr. Kittendorf actually tested duplicative samples to compare the effects of freezing to refrigeration. (Tr. at 197:4-198:1.) In contrast with refrigeration, which Dr. Kittendorf admitted permits microorganisms to continue to metabolize oxygen (Tr. at 198:9-13), Dr. Kittendorf testified freezing causes microorganisms' metabolisms to slow greatly, or even go into a resting state. (Tr. at 209:13-209:17; 252:13-15.)

{

}

In addition to the questions regarding the accuracy of Kaneka's testing, Shenzhou actually conducted duplicative testing on refrigerated samples that found less than 70 mole % reduced coenzyme Q10. {

}

Kaneka responds to Shenzhou's testing by arguing that this measurement is equivalent to 70 mole % reduced coenzyme Q10 and was a single mid-culture sample and should be discounted. (CRB at 20.) These arguments are not persuasive. {

}

Second, Kaneka's argument that Shenzhou's testing was based on a single mid-culture sample and should be discounted would apply equally to Kaneka's own testing. {

}

Thus, by its own argument, Kaneka's test data cannot be relied upon to show infringement because it is a "mid culture" sample.

Based on Shenzhou's testing data and the questions regarding the accuracy of Kaneka's testing data discussed above, I find that Kaneka has failed to prove by a preponderance of the evidence that Shenzhou's process of producing coenzyme Q10 includes a step of "culturing reduced coenzyme Q10-producing microorganisms . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by all asserted independent claims.

Second, Kaneka has also failed to prove by a preponderance of the evidence that Shenzhou's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by asserted independent claims 1 and 11. As addressed in Section III.B.7, *supra*, an "inert gas atmosphere" is "an atmosphere of inert gas (such as nitrogen, carbon dioxide, helium, argon, or hydrogen) that is free or substantially free of oxygen." As addressed in Section III.B.5, *supra*, "extracting" means "recovering coenzyme Q10 from the microbial cells." Kaneka's brief raises two arguments that Shenzhou's process utilizes an inert gas atmosphere during extraction. Neither is persuasive.

{

}

microbial cells into the extraction tank. (CX-581C at 100:22-101:4; 108:5-8; 109:2-5; 111:11-20.)

{

} Dr. Connors admits, however, that this is pure speculation:

Q. Do you have any testing of the atmosphere inside that extraction tank, sir?
A. No.
{

} *Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1319-1320 (Fed. Cir. 2006) (finding conclusory testimony of an expert insufficient to demonstrate infringement). Moreover, Dr. Connors' speculation actually conflicts with testimony provided by a Shenzhou employee,

{

} In view of this conflicting evidence, Dr. Connors' speculation is insufficient to meet the preponderance of evidence standard.

{

} Dr. Connors admits that he has no data regarding the atmosphere of the extraction tank at any point. Rather, he speculates based on Shenzhou's procedure documents:

> Q. And you have no data on any of the -- you have no data respecting the atmosphere inside the extraction tank at any point, do you, sir?
> A. I don't have the data, just based on what I'm reading in the procedure.
> Q. And in your report, you don't report any data, correct?
> A. No, there's no data.

(Tr. at 328:19-328:2.) {

} Based on the foregoing, I find that Kaneka has failed to prove by a preponderance of evidence that Shenzhou's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by asserted independent claims 1 and 11.

Third, Kaneka has also failed to prove by a preponderance of evidence that Shenzhou's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent in a sealed tank," as required by asserted independent claims 22 and 33. As addressed in Section III.B.9, *supra*, a "sealed tank" is "a tank that is closed to prevent the entry or exit of materials."

{

} To the extent Kaneka is attempting to argue that a sealed system is equivalent to a sealed tank, I note that Kaneka waived any arguments of infringement under the doctrine of equivalents. (Tr. at 23:23-24.)

{

}

Based on the foregoing, Kaneka has failed to prove by a preponderance of the evidence that Shenzhou's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent in a sealed tank," as required by claims 22 and 33.

Kaneka has likewise failed to demonstrate by a preponderance of the evidence that Shenzhou's process of producing coenzyme Q10 infringes asserted claims 3-4, 6, 8-10, 13-15, 17, 19-21, 24-25, 27, 29-32, 35-37, 39, and 41-45 of the '340 patent because those claims depend variously from claims 1, 11, 22, and 33. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.").

D. XKGC/PRI

Kaneka's Position: Kaneka contends that XKGC's process for manufacturing coenzyme Q10 infringes at least claims 1, 4-6, 9, 11, 15-17, 20, 22, 25, 27, 29, 30, 33, 37-39, 41, 43, and 45 of the '340 patent.

Kaneka says that XKGC's process proceeds on an industrial scale. (Citing CX-653C, Q. 120; CX-206C at ¶ 166.) Kaneka continues that XKGC currently produces coenzyme Q10 in { } (Citing CX-626C at Q 20-21; CX-199C; RX-640C; RX-641C.)

Kaneka contends that XKGC's process includes "culturing reduced coenzyme Q10 producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient," as required by the first element of all of the asserted independent claims. (Citing CX-653C, Qs. 121-123; CX-206C at ¶ 159; CX-200C at 138:10-139:3; RX-626C, Q. 24.) Kaneka says that XKGC uses { }to produce coenzyme Q10, which will produce at least some reduced coenzyme Q10. Kaneka continued that the culture media used to cultivate XKGC's {

} contain sources of carbon (e.g. {

} nitrogen (e.g. {

} phosphorus {

} and micronutrients {

} (Citing CX-197C.098-.099; RX-641C.108; RX-626C, Qs. 36, 41, 46; Tr. at 847:17-849:15.)

Kaneka says that { } is a "microorganism," even if the term is construed only to include "nonphotosynthetic bacteria or yeast," because XKGC's {

} (Citing CX-653C, Qs. 121-123; CX-206C at ¶ 169.) Kaneka argues that as utilized in the XKGC commercial process, {

}

Kaneka asserts that XKGC cultures { }"to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by the first element of all of the asserted independent claims. Kaneka says that during the March 17, 2012 inspection of XKGC's manufacturing facility, various samples were taken from various points in XKGC's process and the mole % of reduced Coenzyme Q10 were measured. Kaneka continues that these measurements found {

} (Citing CX-206C at ¶ 166.)

Kaneka argues that XKGC's criticism of Dr. Kittendorf's testing is merely speculative. Kaneka says that the first time XKGC tested its frozen samples in February 2012 it found { } (Citing RX-585.015 at Table III.) Kaneka says that XKGC tested a second set of frozen samples in March 2012, and found { } (Citing RX-585.028 at Table IV.) Kaneka continues that XKGC then modified its collection, handling, and testing procedures and tested new samples in April 2012, which found { } (Citing Tr. at 960:25-967:20.) Kaneka argues that these new procedures were merely a pretext to find some way to obtain favorable results. Kaneka says that XKGC never confirmed that its new theory had any basis in fact once it obtained the favorable results. (Citing Tr. at 967:15-20.) As a result, Kaneka argues that XKGC's testing data is not credible.

In its reply brief, Kaneka asserts that XKGC has introduced no evidence to establish that Kaneka's refrigeration of XKGC's microbial cells a mere 2-3 days changed the ratio from { }. Kaneka says that the evidence shows that the mole % ratio of reduced coenzyme Q10 increases only 0.75% per day under these conditions. (Citing Tr. at 207:13-208:17.)

Kaneka contends that XKGC's process includes a step of "disrupting the microbial cells to obtain reduced coenzyme Q10" as required by the second element of claims 1 and 22 and "disrupting the microbial cells" as required by claims 14 and 36. Kaneka argues that XKGC's steps of { } have the well-known effect of disrupting the microbial cells to obtain Coenzyme Q10. (Citing CX-653C, Q. 126; CX-206C at ¶ 170; CX-111C.010 at (f); CX-117C at 43:2-21; Tr. at 851:20-852:2, 854:6-855:25.) Kaneka says that { } (Citing CX-206C at ¶ 160; CX-197C; CX-199C; RX-626C, Qs. 50-57; RX-641C at XKGCITC0418855; RX-640C at XKGCITC0418885.) Kaneka continues, saying that by { } XKGC is breaking the surface structure of the microbial cells to obtain reduced coenzyme Q10. (Citing Tr. at 855:16-25.) According to Kaneka, XKGC's corporate representative testified that the { } steps caused disruption of the microbial cells. (Citing CX-202C at 320:21-321:19; CX-199C.042 at 2.2; Tr. at 857:11-858:18.)

In its reply brief, Kanaka argues that the 70 mole % limitation is entirely separate from the disrupting limitation and XKG's arguments to the contrary are wrong.

Kaneka contends that XKGC's process includes a step of "oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10," as required by the third element of claims 1 and 22 and "oxidizing the extracted reduced Coenzyme Q10 to oxidizing Coenzyme Q10" as required by the third element of claims 11 and 33. Kaneka says that the data obtained by NSF Shanghai and the XKGC tests clearly demonstrate that oxidation is occurring before and after extraction in XKGC's process. (Citing CX-653C, Q. 127; CX-206C at ¶¶ 172-174; RX-585C.028.) Kaneka continues that the obtained samples demonstrated a range { } which { } reduced coenzyme Q10 after { } (Citing CX-206C at ¶161; CX-199C.044-.048, .076; RX-626C, Qs. 60-66; CX-653C, Q. 127; CX-206C at ¶ 172.) Kaneka says that the {

} (Citing CX-653C, Q. 127; CX-206C at ¶ 173.) Kaneka says this is greater than the rate at which reduced Coenzyme Q10 in a hexane extract of human plasma oxidizes (156 micrograms/hour).

Kaneka asserts in its reply brief that XKGC's process clearly oxidizes any reduced coenzyme Q10 that exists after disruption, before extraction and after extraction. (Citing CX-206C at ¶166.)

Kaneka contends that XKGC's process includes a step of "extracting the oxidized coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by the third element of claim 1 and "extracting the reduced coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by the second element of claim 11. (Citing CX-653C, Q. 127; CX-206C at ¶ 173.) Kaneka says that XKGC uses {

} (Citing CX-653C, Q. 135; CX-206C at ¶ 162; CX-199C.049 at 2.1-3, .050 at 4.2-4.5; RX-626C, Qs. 72-75, 78-79, 84, 92-108; Tr. at 862:24-863:6.)

Kaneka says that a {

} (Citing CX-199C.050 at 4.2 - 4.5; RX-626C, Q. 94.) Kaneka continues, saying that the {

} (Citing RDX-58C at 0.47.) Kaneka argues that extraction is not complete until {

} (Citing CX-626C, Q. 93.) Kaneka concludes that it is clear that the extraction takes place under and inert gas atmosphere since XKGC {

}

Kaneka asserts in its reply brief that one of ordinary skill in the art would understand that XKGC's { } constitutes an inert gas atmosphere. Kaneka says that {

} Kaneka continues that {

} (Citing CX-199C.049 at 4.2-4.5; RX-626C, Q. 94.) Kaneka argues that the mere fact that { } does

not allow XKGC's process to escape the broad scope of the claims. (Citing Tr. at 236:12-240:6.)

Kaneka asserts that XKGC's process includes a step of "extracting the oxidized coenzyme Q10 by an organic solvent in a sealed tank," as required by the third element of claim 22 and "extracting the reduced coenzyme Q10 by an organic solvent in a sealed tank," as required by the second element of claim 33. (Citing CX-653C, Qs. 131-132, 135, 136; CX-206C at ¶¶ 182-189.) Kaneka says that XKGC's{ } Kaneka continues that the {

} (Citing CX-199C.050 at 4.5.)

Kaneka says that the {

}

(Citing CX-199C.050 at 4.2; RX-626C, Q. 94; CX-203C at 453:4-16.) Kaneka continues that the {

} (Citing CX-199C.050 at 4.2.) Kaneka argues that this cannot be considered {

} Kaneka contends that the mere fact that {

} does not change the {

}

In its reply brief, Kaneka asserts that {

} (Citing CX-199C.049; RX-62C, Q. 94; CX-203C at 453:4-16.) Kaneka says that later, the {

} (Citing CX-199C.049 at 4.2.)

Kaneka argues that {

} Kaneka says {

} (Citing CX-199C.049.)

Kaneka says that {

} as required by claims 3, 13, 24, and 35. (Citing CX-653C, Qs. 131-132; CX-206C at ¶ 177.)

Kaneka asserts that XKGC's process oxidizes reduced coenzyme Q10 "with an oxidizing agent," as required by claims 4, 15, 25, and 37. (Citing CX-653C, Q. 128; CX-206C at ¶ 175.) Kaneka says that the parties have agreed that "oxidizing agent" may be interpreted as "[a] reagent other than ambient air that is used to oxidize the reduced Coenzyme Q10." Kaneka continues that the XKGC process obtains levels of reduced Coenzyme Q10 { } and then no later than { }

Kaneka argues that it is difficult to identify a single electron acceptor responsible for the oxidation of reduced Coenzyme Q10 to oxidized Coenzyme Q10, {

} (Citing CX 653C, Qs. 124-125; CX-206C at ¶¶ 166-169.)

Kaneka asserts that in XKGC's process, "the sealed tank is sealed under an inert gas atmosphere" and "under a deoxygenized atmosphere," as required by claims 29 and 41. Kaneka says that in XKGC's process, extraction occurs under an inert gas atmosphere and in a sealed tank. (Citing CX-653C, Qs. 131-137; CX-206C at ¶¶ 176-189.) Kaneka says that during the

extraction, when {

}

Kaneka asserts that in XKGC's process, "the inert gas atmosphere comprises nitrogen gas," as required by claims 9, 20 and 30. Kaneka says that XKGC's process meets the additional limitation of dependent claims 9, 20, and 30 {

} (Citing CX-653C, Qs. 131-137; CX-206C at ¶¶ 176-189.)

Kaneka asserts that in XKGC's process, "the deoxygenized atmosphere comprises an inert gas" and "nitrogen gas" as required by claims 42 and 43, respectively. Kaneka says that XKGC's process meets the additional limitation of dependent claim 42 and 43 because the deoxygenized atmosphere comprises { } (Citing CX-653C, Qs. 131-137; CX-206C at ¶¶ 176-189.)

Kaneka asserts that in XKGC's process "the culture medium is at least 750 L," as required by claims 10, 21, 31, and 44. Kaneka says that XKGC currently produces Coenzyme Q10 in a { } (Citing CX-653C, Q. 120; CX-206C at ¶ 158.)

Kaneka asserts that XKGC's process includes a "continuous extraction," as required by claims 6, 17, 27, and 39. (Citing CX-653C, Q. 138; CX-206C at ¶¶ 190-191.) Kaneka says that even though XKGC asserts that it {

}

(Citing CX-199C.)

Kaneka asserts in its reply brief that although {

} as

XKGC contends.

XKGC's Position: XKGC says that Kaneka never tested its microorganisms under the standard screening method explicitly set forth in the '340 patent at col. 4, line 51 to col. 5, line 43. (Citing RX-473C, Q. 163; RX-348C, Qs. 243-248.) XKGC says that Shenzhou's testing of its own strain of { } showed it does not produce greater than 70 mole % reduced coenzyme Q10. (Citing RX-473C, Qs. 166, 171; RX-450C at Table 6; RX-478C.)

XKGC says the { } microorganisms used in its process are { } (Citing RX-473C, Qs. 151-153; Tr. at 316:4-317:4.) XKGC argues that the mere fact the { } (RX-473C, Qs. 50, 150-153; RX-348C, Qs. 215-253.) XKGC says this argument was rejected by Kaneka's own expert. (Citing Tr. at 16:14-317:4.) XKGC additionally asserts that Kaneka waived this doctrine of equivalents argument. (Citing Tr. at 22:12-23:24.)

XKGC criticizes Kaneka's collection and sample handling procedures used for samples to prove the 70 mole % limitation is met for the same reasons as Shenzhou. XKGC also criticizes Kaneka's failure to present evidence concerning how it collected or analyzed samples from XKGC, what the results were, or why those results should be credited. (Citing Tr. at 240:13-243:22, 244:1-245:3.) XKGC says that Dr. Connors did not cite or explain any evidence in support of his opinions other than an unexplained block citation to exhibits. (Citing CX-653C, Q. 117; Tr. at 241:5-245:3.) XKGC continues that Dr. Connors relied upon only one end-of-culturing fermentation tank sample from XKGC, and ignored the plethora of data presented by XKGC. (Citing Tr. at 246:18-25, 248:5-20, 253:5-257:4.) XKGC concludes that Kaneka failed to present sufficient evidence to prove that XKGC's process meets the 70 mole % limitation specifically.

XKGC additionally says samples it took from its manufacturing process and had tested by Alliance Technologies repeatedly tested below the 70 mole % threshold. (Citing RX-625C, Qs. 60, 84, 107; RX-585C; RX-623C, Qs. 165-66.) XKGC continues that the test data shows reduced coenzyme Q10 measurements { } depending on the batch that was sampled, the collection protocol, the amount of time that passed between collecting and freezing, and the thawing protocol. (Citing *id.*) XKGC asserts that no end-of-culturing fermentation tank samples analyzed by Alliance Technologies contained at least 70 mole % reduced coenzyme Q10. XKGC contrasts this testing with { } after the cells were permitted to metabolize nearly 60 hours in an oxygen deficient environment.

XKGC says that end-of-culturing samples are the appropriate samples to use for the molar ratio of reduced coenzyme Q10. (Citing RX-623C, Q. 82; RX-348C, Qs. 210-212; RX-360C, Q. 3-17; Tr. at 246:2-17, 362:20-364:8, 797:19-798:5.) XKGC continues that culturing in XKGC's process indisputably ends when { } (Citing RX-623C, Q. 132; RX-626C, Qs. 50-52; Tr. at 613:8-614:14, 855:4-11.) Alternatively, XKGC argues that even if it were appropriate to use samples taken from XKGC's { } to satisfy the 70 mole % limitation, Alliance Technologies' results for frozen samples were less than that threshold. (Citing RX-623C, Qs. 225-230; RX-585C; RDX-62C; RDX-63C.)

In its reply brief, XKGC says that every end of fermentation sample that Alliance Technologies analyzed—regardless of sample collection and handling protocol—tested below 70 mole %. (Citing RX-625C, Qs. 60, 84, 107; RX-585C at 10, 15, 19, 28, 31, 35; RX-623C, Qs. 165-166, 202; RDX-61C.) XKGC disagrees with Kaneka's argument that XKGC collected and

analyzed samples on three different occasions because it was "[u]nsatisfied with its two previous results." XKGC says that its data demonstrate Kaneka's argument to be incorrect. (Citing Tr. at 603:1-9, 605:25-610:8.) XKGC says that its February 2012 data showed an average of { } reduced coenzyme Q10 { } (Citing RX-585C at 10, 15; RX-625C, Qs. 25-30; RX-623C, Qs. 170, 175, 202, 222-224; RDX-61C.) XKGC says that the results to which Kaneka presumably points are not culturing samples at all; rather, they are results of analyses of a sample taken { } a process that { } (Citing RX-585C at 10, 15; RX-625C, Qs. 27, 31; RX-623C, Qs. 176-178; RX-626C, Qs. 48-52, 55, 126, 132-138; RX-640C; RX-641C; Tr. at 612:24-614:21, 854:6-855:11.)

XKGC says it did not collect the March 2012 samples; rather, Kaneka did, and provided half of the samples to XKGC for analysis. (Citing RX-585C at 18; RX-625C, Qs. 66-67, 71-72; RX-626C at 167; RX-623C, Qs. 179-180; Tr. at 603:17-21, 604:9-16, 605:4-21.) XKGC says that the relevant end-of-fermentation samples { } averaged { } reduced coenzyme Q10, respectively – not at least "70 mole %" reduced. (Citing RX-585C at 18, 28, 30, 35; RX-625C, Q. 74; RX-623C, Qs. 183, 192-193, 201; RDX-61C.) XKGC says that { } pertains to certain earlier fermentation tank samples, initially placed on ice (*i.e.*, not flash frozen), which Dr. Spormann and Dr. Connors agreed were not relevant to determining whether the 70 mole % limitation was met. (Citing RX-623C, Qs. 237-238; Tr. at 246:2-17.) XKGC says that the results of Alliance Technologies' March and April analysis of: {

} (Citing RX-585C at 19, 28, 31, 35; RX-625C, Qs. 71-72, 76, 90, 101-112; RX-623C, Qs. 225-230; RDX-62C; RDX-63C.)

XKGC says it did not collect and analyze a third set of samples in April 2012 because it was "[u]nsatisfied with its two previous results" as Kaneka contends. Rather, XKGC says that Dr. Spormann requested analysis of third set of samples to test his hypothesis that sample collection (refrigeration versus freezing, as well as the amount of time to freeze the samples) and thawing affected the results. (Citing RX-623C, Qs. 222-236; RDX-61C; RDX-62C; RDX-63C; RX-576C; Tr. at 605:25-610:8.) XKGC says that this third analysis provided the necessary confirmation. (Citing *id.*; RX-585C at 31, 35.)

XKGC reasons that since XKGC does not obtain microbial cells containing at least 70 mole % reduced coenzyme Q10, XKGC's process necessarily does not perform the step of "disrupting the microbial cells to obtain reduced coenzyme Q10." (Citing RX-623C, Qs. 269-71.) Additionally, XKGC says that Dr. Connors provided no evidence that XKGC's { } which he identified as the disruption step, caused surface structures of the bacterial cells to break. (Citing RX-626C, Q. 59.)

In its reply brief, XKGC says that Kaneka cites Mr. Wu's trial testimony concerning the conditions that indicate the end of culturing to assert that XKGC meets this limitation, but the testimony has nothing to do with { } (Citing Tr. at 851:20-852:2, 854:6-855:25, 857:11-858:18, 868:2-11.) XKGC continues that the deposition testimony of Mr. Wu (CX-202C) and XKGC's operating procedures (CX-199C) concerning { } are consistent with Mr. Wu's trial testimony and say nothing about { } "breaking the surface structure" to obtain or release reduced coenzyme Q10.

XKGC asserts that its process does not include a step of oxidizing reduced coenzyme Q10, as required by all claims. XKGC says that Dr. Connors did not testify that XKGC's process meets these limitations under Respondents' proposed construction, which requires a step to actively convert all or substantially all of the reduced coenzyme Q10 to oxidized coenzyme Q10, either before or after extraction. XKGC continues that Dr. Connors did not identify any data supporting his conclusions. (Citing Tr. at 257:5-258:1.) XKGC reasons that an oxidizing step is unnecessary because XKGC's process does not culture microbial cells having at least 70 mole % reduced coenzyme Q10. XKGC says that Mr. Wu, an employee of one of XKGC's manufacturing subsidiaries, testified that {

} (Citing RX-626C, Qs. 6, 59, 115-117; RX-640C.) Dr. Spormann, XKGC's expert, likewise testified that XKGC's process does not include an oxidizing step before extraction. (Citing RX-623C, Qs. 272-79, 282-83; RX-640C.)

In its reply brief, XKGC says that Kaneka's NSF analysis of a single sample from XKGC's { } is inconsistent with the Alliance Technologies results. (Citing CIB at 59; RX-585C at 10, 15, 19, 28-29.) XKGC continues, explaining that XKGC's analysis of post-extraction samples { } and { } showed { } and { } reduced coenzyme Q10, respectively, whereas NSF reported { } based on analysis of a single sample { } (Citing RX-585C at 10, 15, 19, 28-29.) XKGC says that Dr. Connors never attempted to reconcile these inconsistent data sets, which demonstrate that Dr. Connors' data is not sufficiently reliable to prove infringement. (Citing RX-623C, Qs. 276-277, 283-284.)

XKGC asserts that Kaneka did not identify a single step before or after extraction that

converts all or substantially all of the reduced coenzyme Q10—obtained from microbial cells at a ratio of not less than 70 mole %—to oxidized coenzyme Q10. (Citing *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1342-43 (Fed. Cir. 2007).) XKGC says that Dr. Spormann testified that the data obtained by Kaneka's laboratory and Alliance Technologies does not show consistent evidence that oxidation occurs in the { } (Citing RX-623C, Q. 276.) XKGC contends that Kaneka's test data for one of four samples does not concur with the results obtained by Alliance Technologies for three different samples, two of which were collected at the same time as Kaneka's samples. (Citing RX-623C, Q. 276; RX-585C at 15, 19, 28-29.)

XKGC asserts that Kaneka provided no proof of anything that increases the rate at which obtained reduced coenzyme Q10 converts to oxidized coenzyme Q10. (Citing Tr. at 259:5-261:22.) XKGC says Kaneka offers no evidence of a baseline rate of oxidation other than for human plasma in hexane. (Citing Tr. at 260:24-261:3, 358:7-9.) XKGC reasons that because its process involves no human plasma, the base line is inapplicable. (Citing Tr. at 261:4-8.) XKGC continues that without a baseline, it is not possible to determine if a rate is increasing, decreasing, or staying the same. (Citing RX-623C, Qs. 272, 276-277; RX-585C at 15, 19, 28-29; Tr. at 358:7-9.) Further, XKGC says that Dr. Connors did not account for the duration of any particular step, and therefore provides no calculation of the rate of supposed conversion for any particular point in XKGC's process. (Citing Tr. at 259:1-260:23.) XKGC contends that dividing one percentage by another, as Dr. Connors has done, provides a dimensionless number, not a rate. (Citing RX-623C, Q. 277.)

XKGC says that it does not extract either oxidized or reduced coenzyme Q10 by an organic solvent under an inert gas atmosphere. XKGC says that its {

} (Citing RX-623C, Q. 290; RX-626C, Qs. 84-89; RX-640C at XKGCITC0418891-893; Tr. at 232:5-233:6.) XKGC continues that extraction then proceeds by {

} (Citing *id.*; RX-626C, Qs. 90-93; Tr. at 233:7-234:1.) XKGC asserts that the {

} (Citing *id.*; RX-626C, Qs. 94-95; Tr. at 234:2-24, 240:2-6.) XKGC reasons that once the { } (Citing Tr. at 234:25-235:5, 237:4-17, 237:25-238:24.) XKGC says that Dr. Connors admitted on cross examination that XKGC's { } (Citing Tr. at 238:6-21.)

XKGC says that {

} (Citing *id.*; RX-626C, Q. 102.) XKGC continues that {

}

(Citing *id.*; RX-626C, Qs. 103-105.) XKGC says that the {

} (Citing *id.*; RX-626C, Q. 106; Tr. at 239:5-18.) XKGC says that Dr. Spormann testified that the { } (Citing RX-623C, Q. 290.) XKGC continues that Dr. Connors and Kaneka { } and therefore have no evidence that the { } (Citing Tr. at 236:7-237:3.) XKGC concludes, as a result, that its { } does not contain an atmosphere of inert gas that is free or substantially free of oxygen. (Citing RX-623C, Qs. 285-

295.)

XKGC says that Dr. Connors admitted during cross-examination that XKGC does not extract either oxidized or reduced coenzyme Q10 "under an inert gas atmosphere" or any atmosphere at all. (Citing Tr. at 232:16-234:10; 238:6-24.) XKGC says that neither XKGC's process documents nor its witnesses stated that "the extract" is collected in { } as Kaneka argues. (Citing CIB at 62.) XKGC continues that Kaneka cites no evidence for the proposition that "[e]xtraction is not complete until all of the liquid is purged form the extraction tank using nitrogen gas." (Citing CIB at 63.) XKGC says that Mr. Wu directly contradicted this assertion at trial, stating: { } (Citing Tr. at 864:21-865:4.)

XKGC asserts that it does not extract either oxidized or reduced coenzyme Q10 by an organic solvent in a "sealed tank." XKGC says that the relief valve at the { } (Citing RX-626C, Qs. 75, 95; RX-639C; RX-640C at XKGCITC0418891-893; RX-623C, Qs. 301-303.) XKGC continues that the { } (Citing RX-626C, Qs. 90-91.) XKGC says that the { } (Citing RX-626C, Qs. 78-79, 95-96; RX-639C; RX-640C at XKGCITC0418891-893.) Alternatively, XKGC says that its { } (Citing RX-623C, Qs. 304-305.) XKGC concludes that it does not perform extraction in a sealed tank, as a result. (Citing RX-623C, Qs. 296-305.)

In its reply brief, XKGC says that Kaneka ignores the contrary documentary evidence and testimony of Mr. Wu, Dr. Spormann and even Dr. Connors that the { } (Citing RX-623C, Qs. 290-294, 301-302; RX-626C, Qs. 85-87, 91; RX-640C; RDX-58C; Tr. at 232:5-233:1, 356:11-357:8.) XKGC continues that Kaneka does not deny that, during extraction, the { } but nonetheless argues that the { } XKGC says that it is undisputed that { } (Citing RX-623C, Qs. 144-146, 300-303; RX-626C, Q. 91; RX-639C; RDX-58C.) XKGC continues that Kaneka's argument ignores that under *Dippin' Dots*, the entire extraction process must be performed "in a sealed tank" to satisfy the "extracting" step. 476 F.3d at 1343. XKGC says that { } (Citing RX-626C, Qs. 75, 95; RX-639C; RX-640C at XKGCITC0418891-893; RDX-58C; RX-623C, Qs. 301-303; Tr. at 234:11-235:5, 590:25-591:7.)

XKGC asserts that it does not use a hydrophilic solvent. XKGC says that it uses only { } (Citing RX-626C, Q. 92; RX-640C; RX-623C, Q. 319; Tr. at 1139:24-1140:1.)

XKGC asserts that it does not use an oxidizing agent and does not use manganese dioxide. (Citing RX-626C, Qs. 115-117; RX-640C; RX-641C; RX-623C, Qs. 312-315.) XKGC says that Dr. Connors admitted that he could not identify any oxidizing agent in XKGC's process and agreed that XKGC does not use manganese dioxide. (Citing Tr. at 258:9-259:4.)

In its reply brief, XKGC says that Kaneka bears the burden to prove infringement, and presented no evidence that XKGC uses an oxidizing agent other than Dr. Connors' conclusory opinion. (Citing Tr. at 258:9-259:4.) XKGC continues, saying that although Kaneka apparently no longer asserts dependent claims 5, 16 or 38 against XKGC, Kaneka's brief suggests that it still asserts claim 26. (Citing CIB at 7-8.) XKGC says that Kaneka presented no evidence or argument that XKGC's process uses manganese dioxide, and did not specifically argue that XKGC infringed claim 26.

XKGC asserts that its process does not perform "continuous extraction." XKGC says that { } (Citing RX-626C, Qs. 70-71, 79-83; RX-639C; RX-640C; RX-623C, Qs. 321-324.) XKGC continues, saying that, as Dr. Connors admitted, the { } (Citing RX-626C, Q. 82; RX-623C, Q. 326; Tr. at 240:7-12.)

XKGC says that the { } (Citing RX-626C, Q. 96; RX-640C; RX-623C, Qs. 321-324.) XKGC continues that after collecting { } (Citing RX-626C, Qs. 108-109; RX-640C.) XKGC says that next, the { } (Citing *id.*) XKGC continues that Dr. Spormann testified that "[t]hese are all hallmarks of a batch extraction process, not a continuous extraction process." (Citing RX-623C, Q. 324.) Alternatively, XKGC argues that even if its process performed "continuous extraction,"

it does not perform "countercurrent multistage extraction." (Citing RX-623C, Qs. 329-330; RX-639C; RX-640C.)

XKGC asserts that Kaneka did not present any evidence that XKGC's process meets the 70 mole % limitation after disruption or extraction when measured as required by claims 8, 19, 32, or 45. (Citing RX-623C, Qs. 331-332.)

XKGC asserts that it does not perform extraction in a sealed tank under a deoxygenized atmosphere. XKGC says that since its {

} (Citing RX-623C, Qs. 285-295, 307-311; Tr. at 235:6-24.) In its reply brief, XKGC says that Dr. Connors admitted that {

} (Citing Tr. at 232:16-234:10; 238:6-24.)

Staff's Position: Staff says that there is no real dispute that XKGC's process is a process for producing on an industrial scale oxidized coenzyme Q10.

Staff says that Kaneka has disclaimed { } which XKGC uses in its process, and therefore cannot be found to meet the "microorganisms" limitation of the claims of the '340 patent under any of the proposed claim constructions.

Staff asserts that because{ } produces a proportion of reduced Q10, to the extent Kaneka is able to show that the "microorganisms" limitation is satisfied, Kaneka has demonstrated that this limitation is met under Kaneka's proposed claim construction.

Staff asserts that under the construction of Staff and Respondents, Kaneka must demonstrate that when the bacteria from the seed tanks is cultured and assayed according to the method disclosed in column 4 line 51 to column 5 line 43 and Example 1 of the patent, it is

found to produce reduced Q10 in at least 70 mole %. Staff says that although Kaneka tested the percentage of reduced Q10 in material from XKGC's fermentation tank, the collection and storage of these samples suffers from the same errors and problems as the samples from Shenzhou, and thus the evidence shows that their reliability is suspect. Staff continues that these samples were not from the seed tanks, and the testing not that as in columns 4-5 and Example 1 of the '340 patent and therefore this limitation is not met under the construction proposed by Staff and Respondents.

Staff says that the culture medium used by XKGC contains { } (a carbon source), { } (a nitrogen source), { } (a phosphorus source) and { } a micronutrient. (Citing CX-653C, Q. 123; Tr. at 848:10-849:6.)

Staff asserts that Kaneka has failed to prove that XKGC cultures microorganisms to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10. Staff says that Kaneka initially offered two sets of testing to support its allegation that the XKGC process meets this limitation—testing done by Dr. Kittendorf and testing done by NSF Shanghai. Staff says that Dr. Kittendorf's testing with respect to XKGC was stricken and there is no testimony discussing his results or methodology.

Staff says that the XKGC samples tested by NSF Shanghai were refrigerated after collection and shipped to NSF Shanghai in the refrigerated state and there is no information as to how the samples were stored once they reached NSF. (Citing Tr. at 254:20-255:10.) Staff reasons that because the samples were merely refrigerated upon collection rather than frozen, and also were flushed with argon, the NSF testing suffers from the same deficiencies as does the Kittendorf testing and is similarly unreliable.

Staff says that XKGC collected and tested samples of its own products using procedures much less likely to skew the results. Staff says that in February of 2012, samples were collected by Alliance Technologies. (Citing RX-626C, Qs. 120-155.) Staff says that these samples were taken from the { } (Citing RX-626C, Qs. 126-129.) Staff says that the XKGC samples were frozen immediately after collection and were later freeze-dried under a vacuum. (Citing Tr. at 961:3-962:12; RX-626C, Qs. 131, 155.) Staff says that XKGC's testing indicates that the XKGC bacteria have less than { } of reduced Q10 at the end of the fermentation process. (Citing RX-623 C, Q. 175; RX-585C at 15, 35; RX625C, Q.60, Table III.)

In its reply brief, Staff says that Kaneka relies on testing described in Dr. Connors' expert report relating to XKGC which are identified by "NSF Log Number." (Citing CIB at 59.) Staff says that there were not two sets of testing on XKGC samples; rather, there was only one set that was overseen by Dr. Kittendorf but performed at the NSF labs. Staff reasons that the test results Kaneka relies on are the same Kittendorf test results that were excluded from Dr. Kittendorf's witness statement and therefore, the procedures used to analyze the XKGC samples, and the test results, suffer from the same deficiencies noted previously with Dr. Kittendorf's testing. For this reason, and those detailed in the corresponding section of Staff's Posthearing Brief, Staff submits that the evidence does not show that the XKGC process meets this limitation.

Staff asserts that the evidence demonstrates that the { } in the XKGC process have the effect of disrupting the cells in the broth. According to Staff, to the extent that Kaneka is able to show that the cells in the broth meet the 70 mole % ratio, the evidence demonstrates that the XKGC process meets this limitation under the constructions of Staff and Kaneka.

Staff says that the Respondents' construction requires the disruption take place under conditions preventing oxidation. Staff reasons that as the { } the evidence does not show that this limitation is met under Respondents' proposed construction.

Staff asserts that XKGC's process does not include a step of oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10. Staff says that measurements of the amounts of reduced Q10 at various steps of the XKGC process indicate that during the XKGC process the amount of reduced Q10 peaks during { } { } (Citing RX-585C.) Staff continues that the { } (Citing *id.*) Staff says that Kaneka has identified the { } as the disruption step. Staff reasons that the tests conducted by Alliance for XKGC demonstrate that the { } (Citing RX-585C.) Staff says that the construction of Staff and Respondents requires that all or substantially all of the reduced Q10 must be oxidized after disruption, but the evidence shows that it is oxidized before or during disruption. Staff concludes that if the proposed construction of Staff or Respondents is adopted the evidence does not show that the XKGC process satisfies this limitation.

Staff says that Kaneka's proposed construction requires that the rate at which "the obtained reduced coenzyme Q10" oxidizes be increased. Staff asserts that the "obtained" Q10 is that obtained from the disruption step, and under Kaneka's proposed construction the oxidation

must take place after disruption. Staff reasons that as the evidence demonstrates that after the disruption step there is little or no reduced Q10 remaining, and that the rate of oxidation was increased either prior to or during, but not after, disruption, even if Kaneka's proposed construction is adopted, the evidence does not show that the XKGC process meets this limitation.

Staff asserts that XKGC's process includes a step of oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10. Staff says that Kaneka argues that the post-extraction washing of the Q10 in the XKGC process satisfies this limitation. (Citing CIB at 50-51.) Staff says, however, that Dr. Connors does not identify either which step of the process he believes meets this limitation or what part of the XKGC process produces this oxidation. Staff says that Dr. Connors relies on the fact that the amount of reduced Q10 in the finished product is zero to support his allegations. Staff continues that Kaneka's brief states that post-extraction the Q10 contains { } reduced Q10 and that after the { } it contains no reduced Q10 and the normal rate of oxidation is much slower, so the fact that the amount of reduced Q10 decreases by { } in one step indicates that the rate of oxidation has increased, thereby satisfying the limitation under their proposed claim construction. (Citing CIB at 50-51.)

Staff concludes that the evidence shows that the { } step oxidizes any reduced coenzyme Q10 in the { } and thereby satisfies this limitation under the constructions proposed by all of the parties.

Staff says that Kaneka has not proven that XKGC's process includes a step of extracting the oxidized coenzyme Q10 by an organic solvent under an inert gas atmosphere. Staff says that XKGC uses { } (an organic solvent) and the Q10 extracted is primarily in the oxidized form. (Citing CX-653C, Q. 181.) Staff says that Kaneka argues that XKGC's process conducts extraction under a {

} (Citing CX-653C, Q. 133.) Staff contends that Kaneka's understanding of the XKGC process is flawed because {

} Staff says that during the extraction process the {

} and, as a result, there is no "gas atmosphere." Staff says that to the extent {

} (which Dr. Connors characterizes as "a potentially combustible mixture") and the { } (Citing RX-623C, Qs. 290-291; CX-653C, Q. 133; Tr. at 233:9-235:3.) Staff continues that Dr. Connors further admitted that the {

} (Citing Tr. at 237:3-17, 238:11-24.)

Staff says that the {

} (Citing RX-623C, Q. 301.) Staff says that as soon as {

}

(Citing RX-623C, Qs. 144, 153.)

Staff says that the evidence demonstrates that { } is hydrophobic, and therefore that the XKGC process satisfies the limitation requiring that the extraction of the oxidized coenzyme Q10 is carried out using a hydrophobic organic solvent. (Citing CX-653C, Q. 182.)

Staff says that Kaneka's sole basis of support for its contention that the extracted reduced Q10 is oxidized, and oxidized using an oxidizing agent, is that the amount of reduced Q10 decreases as the XKGC process progresses. Staff continues that Kaneka does not identify an oxidizing agent, and does not provide any evidence to demonstrate that the oxidation is not due

to ambient air. (Citing Tr. at 258:8-22.) Staff says that Dr. Connors presented no evidence regarding the rate at which Q10 oxidizes in ambient air, so there is no way to determine if the rate of oxidation has increased. (Citing Tr. at 259:12-20.)

Staff contends that Kaneka has not proven that the oxidized coenzyme Q10 is extracted by continuous extraction in XKGC's process. Staff says that XKGC uses a batch extraction process where {

} (Citing CX-206C, Q. 162.)

Staff asserts that XKGC's process does not conduct extraction in an inert gas atmosphere that comprises nitrogen gas. Staff says that there is no evidence that the extraction step of the XKGC process takes place under an inert gas atmosphere, or even one containing { }

Staff says that there is no real dispute that the limitation requiring the culture medium is at least 750L is met in XKGC's process.

Staff contends that Kaneka has not proven that XKGC's process uses a sealed tank that is sealed under a deoxygenized atmosphere. Staff says that the { } of the XKGC process is {

} Staff says that under Kaneka's construction of "deoxygenized atmosphere," which requires only that some amount of oxygen be displaced, this limitation would be met because it is likely that some of the oxygen in it was displaced by the solvent vapor. Staff contends that if the constructions offered by Staff and Respondents, which require that all or substantially all of the oxygen be displaced, the evidence does not show that this limitation is met.

Discussion and Conclusions: Kaneka has failed to prove by a preponderance of the evidence that XKGC's process of producing coenzyme Q10 infringes any asserted claim of the '340 patent. Although there are other minor disputes between the parties, the key disputes between Kaneka and XKGC are whether or not XKGC's process meets the 70 mole % limitation (as required by all asserted independent claims), whether or not XKGC's process meets the limitations requiring extraction of coenzyme Q10 under an inert gas atmosphere (as required by asserted independent claims 1 and 11), and whether or not XKGC's process meets the limitations requiring extraction of coenzyme Q10 in a sealed tank (as required by asserted independent claims 22 and 33). I find that Kaneka has failed to carry its burden of proof on all of these issues.

First, Kaneka has failed to show by a preponderance of evidence that XKGC's process of producing coenzyme Q10 includes a step of "culturing reduced coenzyme Q10-producing microorganisms . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by each asserted independent claim (claims 1, 11, 22, and 33). Kaneka has not introduced reliable evidence showing that this limitation is met. As explained in section V.C, *supra*, the evidence raises serious questions regarding whether or not Kaneka's handling of the samples caused the test results to not accurately represent the contents of the fermentation tanks from which the samples were taken.

Dr. Connors asserted that the same collection, handling, and testing protocol was used for XKGC as was used for all other respondents. (Tr. at 242:5-8.) Thus, assuming Kaneka's handling procedure was the same for all Respondents' samples, there are serious doubts regarding the accuracy of Kaneka's testing of XKGC's process.

Moreover, other than Dr. Connors' testimony that the same procedure was used for all respondents, Kaneka's evidence regarding the actual sampling, storage, and testing procedure used for XKGC's samples (CX-71C) was excluded as a result of Kaneka's failure to comply with the deadlines imposed in the procedural schedule. (*See* Tr. at 240:13-245:3; Order No. 22.) As discussed in section V.C, *supra*, the sampling, storage, and testing procedure materially impacts the testing results for the 70 mole % limitation. Without information regarding the actual sampling, storage, and testing procedure used for XKGC's samples, there is no way to determine whether or not Kaneka's test results accurately reflect the conditions in XKGC's fermentation tanks, further raising questions regarding the reliability of Kaneka's testing data.

In contrast with Kaneka's lack of reliable testing data, XKGC has provided three sets of testing data that demonstrate XKGC's process does not meet the 70 mole % limitation. Samples taken in February of 2012 from the { } (RX-625C, Qs. 27-30), but before any subsequent processing steps were conducted (*See* RX-625C, Q. 31), showed between { } reduced coenzyme Q10. (RX-625C, Qs. 60-62; RX-585C at XKGCITC0445109.) Samples taken in March of 2012 from the { } (RX-625C, Q. 71), but before any subsequent processing steps were conducted showed between approximately { } reduced coenzyme Q10. (RX-625C, Q. 84; RX-585C at XKGCITC0445122.) Samples taken in April of 2012 from { } (RX-625C, Qs. 95-96), but before any subsequent processing steps were conducted (*See* RX-625C, Q. 97), found approximately { } reduced coenzyme Q10. (RX-625C at Q107; RX-585C at XKGCITC0445129.) Thus, XKGC's measurements of end of fermentation samples show less than 70 mole % reduced coenzyme Q10.

XKGC was correct to rely upon data for end of fermentation samples. The sampling

point to determine whether or not the 70 mole % ratio limitation is satisfied is at the end of culturing, which is the end of fermentation. Each of the independent claims requires "culturing reduced coenzyme Q10-producing microorganisms…to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10." From this claim language, it is clear that the culturing is done "to obtain" the 70 mole % ratio. The claim language therefore requires that the end result of the culturing are microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10. There is nothing in the specification to suggest anything other than this plain language reading of the claim terms.

The specification equates the culturing step to fermentation. This can be seen in the following passages from the specification:

> In the present invention, at first, reduced coenzyme Q10-producing microorganisms are cultured to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole %, preferably not less than 75 mole %, among the entire coenzymes Q10 (fermentation).

(JX-1 at 4:40-44.)

> In the processes of the present invention, high productivity of reduced coenzyme Q10 in the fermentation production on the industrial scale can be achieved partially by using the microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10 and, partially, by using the suitable conditions of culture (fermentation) for increasing a productivity of reduced coenzyme Q10 per unit culture medium as described below. It is particularly preferable to combinedly use suitable microbial cells described above and the suitable conditions of culture (fermentation) as described below.

(*Id.* at 7:55-65.)

> In the fermentation production on the industrial scale, although it depends on the microorganism species, the concentration of the carbon sources (including the produced alcohols) during the culture is preferably controlled to a concentration that no adverse effects are substantially caused on the productivity of reduced coenzyme Q.sub.10. Accordingly, it is preferable to control the culture so as to

> have the concentration of the carbon sources that no adverse effects are substantially caused on the productivity of reduced coenzyme Q.sub.10, that is, generally to not more than 20 g/L, preferably not more than 5 g/L, and more preferably not more than 2 g/L in the broth.

(*Id.* at 8:29-40.)

Based on the claim language and the foregoing passages in the specification, I find that the '340 patent clearly instructs that compliance with the 70 mole % ratio be tested at the end of the culturing step, which is equivalent to the end of fermentation. Kaneka's expert Dr. Connors does not dispute this conclusion. (Tr. at 363:14-364:5.)

Kaneka's only response to XKGC's testing of the end of fermentation samples is to assert that the first two sets of XKGC's testing data showed that the 70 mole % limitation was met, and XKGC conducted the third set of testing with sampling and testing procedures updated to find less than 70 mole % reduced coenzyme Q10. Kaneka's allegations, however, are baseless. None of the testing data included in the three sets of data found the 70 mole % limitation was met for end of fermentation samples, as required by the claims. It its reply brief, Kaneka asserts that XKGC's self test shows { } reduced coenzyme Q10 in "early culturing" and { } reduced coenzyme Q10 in "late culturing." The numbers cited by Kaneka, however, actually correspond to late culturing (approximately{ }) and { } (approximately { }). (*See* RX-585C at XKGCITC0445109; RX-625C, Qs. 27-31.) As discussed above, the relevant testing point is the actual end of fermentation, which shows less than 70 mole % reduced coenzyme Q10. Because none of the test data found the 70 mole % limitation was met at the relevant sampling point, Kaneka's allegation that the testing procedure was manipulated is baseless.

Based upon the foregoing, I find that Kaneka has failed to prove by a preponderance of the evidence that XKGC's process of producing coenzyme Q10 includes a step of "culturing

reduced coenzyme Q10-producing microorganisms . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by all asserted independent claims.

Second, Kaneka has also failed to prove by a preponderance of the evidence that XKGC's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by asserted independent claims 1 and 11. XKGC's { } does not have an inert gas atmosphere while microbial cells are being added. {

} (RX-626C, Qs. 84-89; *See* RX-640C at XKGCITC0418891 (Step 3); Tr. at 232:5-233:6, 233:4-234:10.) Because the atmosphere at this point is ambient air, this portion of the extraction is not being conducted under an atmosphere of inert gas such as nitrogen, as required by the construction of "inert gas atmosphere" reached herein.

{

} (RX-626C, Qs. 90-94; Tr. at 234:25-235:5.) Because {

} as Kaneka's expert Dr. Connors admitted, there is no gas atmosphere in the extraction tank. (Tr. at 238:6-24.) Because there is no gas atmosphere in the extraction tank at this point, this portion of the extraction likewise is not being conducted under an atmosphere of inert gas such as nitrogen, as required by the construction of "inert gas atmosphere."

{

} (RX-626C, Q. 95; See RX-626C, Q. 102.) {

}

{ } (RX-626C, Qs. 97-98.) {

}

(RX-626C, Qs. 100-102.) Dr. Connors admitted there is no gas atmosphere in the {

} (Tr. at 268:6-24 (*see* RDX-58C-10 for context).) Because there is still no gas atmosphere at this point, this portion of the extraction likewise is not being conducted under an atmosphere of inert gas such as nitrogen, as required by the construction of "inert gas atmosphere."

Once the {

} (RX-626C, Qs. 102-106; Tr. at 235:24-236:6.) This is after completion of the extraction process, however, because this {

} (*Id.*; *see also* Tr. at 239:11-240:1.) Moreover, Dr. Connors admitted that he has no data regarding whether or not the { } contains any coenzyme Q10. (Tr. at 236:12-237:3.) As a result, Kaneka has no evidence to assert coenzyme Q10 is extracted by the { } As a result, Kaneka has failed to show that any portion of XKGC's extraction process takes place under an inert gas atmosphere.

Kaneka sets forth two arguments that extraction in XKGC's process takes place under an inert gas atmosphere, neither of which is persuasive. First, Kaneka says that no atmosphere is an "inert gas atmosphere." This directly conflicts with the construction of "inert gas atmosphere," as discussed in section III.B.7, *supra*, which requires an atmosphere of inert gas. Second, Kaneka asserts that the use of { } is extraction under an inert gas atmosphere. However, this is incorrect because, as discussed above, Kaneka has failed to

establish that the { } Since Kaneka has not shown that the { } contains any coenzyme Q10, Kaneka has not shown that the { } is a part of the extraction step. Based on the foregoing, I find that Kaneka has failed to prove by a preponderance of the evidence that XKGC's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by asserted independent claims 1 and 11.

Third, Kaneka has also failed to prove by a preponderance of the evidence that XKGC's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent in a sealed tank," as required by asserted independent claims 22 and 33. The evidence shows that throughout the extraction process, at least {

} allowing the entry or exit of materials.

After {

} (RX-626C, Qs. 90-94; Tr. at 234:25-235:5.) {

} (RX-626C, Q. 95; *See* RX-626C, Q. 102.) {

} (RX-626C, Qs. 97-98.) {

} (RX-626C, Qs. 100-102.) {

} (RX-626C, Qs. 102-106; Tr. at 235:24-236:6.) Although this is after completion of the extraction process (as explained above), the {

} (*Id.*; *See also* Tr. at 239:11-240:1.)

Thus, at all times during the extraction process, { } which permits materials to enter or exit the extraction tank.

Kaneka argues that XKGC's extraction process is conducted in a sealed system, and therefore meets this claim limitation. This is incorrect. First, to the extent Kaneka is attempting to argue that a sealed ***system*** is equivalent to a sealed tank, Kaneka waived any arguments of infringement under the doctrine of equivalents. (Tr. at 23:23-24.) Second, Kaneka's argument fails to address the fact that, as discussed above, for at least a portion of XKGC's extraction process the { } { } (Tr. at 234:25-5.)

Based on the foregoing, Kaneka has failed to prove by a preponderance of the evidence that XKGC's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent in a sealed tank," as required by claims 22 and 33.

Kaneka has likewise failed to demonstrate by a preponderance of the evidence that XKGC's process of producing coenzyme Q10 infringes asserted claims 4-6, 9, 15-17, 20, 25, 27, 29, 30, 37-39, 41, 43, and 45 of the '340 patent because those claims depend variously from claims 1, 11, 22, and 33. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.").

E. ZMC Respondents

Kaneka's Position: Kaneka asserts that ZMC's process of producing coenzyme Q10 infringes at least claims 1, 3, 4, 9-11, 13-15, 20-22, 24, 25, 29-31, 33, 35-37, and 41-44 of the '340 Patent.

Kaneka asserts that ZMC's process is "a process for producing on an industrial scale the oxidized coenzyme Q10 . . ." as required by the preambles of all of the asserted independent claims. {

} Kaneka concludes that this scale of operation represents an "industrial scale" effort.

Kaneka contends that ZMC's process includes "culturing reduced coenzyme Q10 producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient," as required by the first element of all of the asserted independent claims. {

}

Kaneka asserts that ZMC cultures{ }"to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by the first element of all of the asserted independent claims.

{

}

Kaneka contends that ZMC's process includes a step of "disrupting the microbial cells to obtain reduced coenzyme Q10" as required by the second element of claims 1 and 22 and "disrupting the microbial cells" as required by claims 14 and 36. Kaneka says that ZMC's

{

}

In its reply brief, Kaneka asserts there is no reason why a person of ordinary skill in the art would create this limitation that required that disruption must occur under protection from oxidation when construing claims directed to production of oxidized coenzyme Q10.

Kaneka contends that ZMC's process includes a step of "oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10," as required by the third element of claims 1 and 22 and "oxidizing the extracted reduced Coenzyme Q10 to oxidizing Coenzyme Q10" as required by the third element of claims 11 and 33. {

} at ¶¶

{

} Kaneka compares this to reduced Coenzyme Q10 in a hexane extract of human plasma, which oxidizes at a rate of 156 micrograms/hour.

In its reply brief, Kaneka disagrees with ZMC's argument that exposure to ambient air cannot be considered oxidation within the meaning of the claims ignores the specification. Kaneka says that the specification states that when producing oxidized coenzyme Q10, "it is not necessary to carry out the recovery of oxidized coenzyme Q10 under the 'condition that reduced coenzyme Q10 is protected from an oxidation reaction.'" (Citing JX-1 at 17:20-23.) Kaneka continues that the specification emphasizes the preference for protecting against oxidation when

producing reduced coenzyme Q10. (Citing JX-1 at 16:27-34.) Kaneka reasons that in light of these disclosures, a person of skill in the art would easily understand that oxidized coenzyme Q10 can simply be obtained by not protecting from oxidation, including exposure to ambient air and if this were not the case, there is no point in protecting from oxidation when producing reduced coenzyme Q10.

Likewise, Kaneka says that ZMC's argument that no oxidation can occur before extraction where the claims require oxidizing the extracted reduced Coenzyme Q10 to oxidizing Coenzyme Q10 is incorrect. Kaneka says that under ZMC's argument, if any oxidation occurs before extraction, the "oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10" can never be met, even if oxidation also occurs after extraction. Kaneka says that ZMC provides no justification for such a narrow construction.

Kaneka contends that ZMC's process includes a step of "extracting the oxidized coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by the third element of claim 1 and "extracting the reduced coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by the second element of claim 11. {

}

{

}

Kaneka asserts that ZMC's process includes a step of "extracting the oxidized coenzyme Q10 by an organic solvent in a sealed tank," as required by the third element of claim 22 and "extracting the reduced coenzyme Q10 by an organic solvent in a sealed tank," as required by the second element of claim 33. (Citing CX-653C, Q. 186; CX-242C at ¶¶ 182-183, 188-189.)

{

}

{

}

Kaneka asserts that the ZMC process uses a hydrophobic organic solvent for extraction, as required by claims 3, 13, 24, and 35. (Citing CX-653C, Q. 182; CX-242C at ¶ 174.) {

}

Kaneka asserts that ZMC's process oxidizes reduced coenzyme Q10 "with an oxidizing agent," as required by claims 4, 15, 25, and 37. (Citing CX-653C, Q. 180; CX-242C at ¶ 172.) {

}

Kaneka asserts that in ZMC's process, "the sealed tank is sealed under an inert gas atmosphere" and "under a deoxygenized atmosphere," as required by claims 29 and 41. (Citing CX-653C, Qs. 181-186; CX-242C at ¶¶ 173-183, 188-189.) {

}

Kaneka says that ZMC's process meets the additional limitation of dependent claims 9, 20, 30, 43, { } (Citing CX-232C.004-005; CX-239C; CX-226C at 503:13-507:6.)

Kaneka says that ZMC's process meets the additional limitation of dependent claim 42 and 43 { } (Citing CX-232C.004-005; CX-239C; CX-226C at 503:13-507:6.)

Kaneka says that ZMC currently produces Coenzyme Q10 in { } as required by claims 10, 21, 31, and 44. (Citing CX-653C, Q. 190; CX-242C at ¶155-15; CX-224C; CX-228C; CX-229C.)

ZMC's Position: ZMC asserts that its process does not utilize "reduced coenzyme Q10 producing microorganisms," as required by each asserted independent claim. ZMC says that Kaneka never tested its microorganisms under the standard screening method explicitly set forth in the '340 patent at col. 4, line 51 to col. 5, line 43. (Citing RX-473C, Q. 163; RX-348C, Qs. 243-248.) {

}

ZMC asserts that it does not use "microorganisms," as required by each asserted independent claim. {

} ZMC says this argument was rejected by Kaneka's own expert. (Citing Tr. at 316:14-317:4.) ZMC additionally asserts that Kaneka waived this doctrine of equivalents argument. (Citing Tr. at 22:12-23:24.)

ZMC also asserts that its process does not meet the 70% reduced coenzyme Q10 limitation included in each of the asserted independent claims. First, ZMC criticizes Kaneka's collection and sample handling procedures for the same reasons as Shenzhou and XKGC. Second, ZMC criticizes its own testing, which Kaneka relied upon, as being flawed for the same reasons as Kaneka's testing. (Citing RX-348C, Qs. 259-277.)

ZMC asserts that its process does not include a step of "disrupting the microbial cells to obtain reduced coenzyme Q10." {

}

ZMC asserts that its process does not include a step of "oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10." {

}

ZMC says that Dr. Connors admitted that his claim construction requires a baseline to determine whether the rate of oxidation has increased, but he has no data to determine whether or how much the rate of oxidation is increased from the "baseline." (Citing Tr. at 357:20-25.) ZMC continues that Dr. Connors provided no evidence of the rate of oxidation at any step in ZMC's process, and the "baseline" rate he provided of a hexane extract from human plasma is wholly inapposite. (Citing *id.* at 359:1-17.)

ZMC contends that claims 1 and 22, as properly construed, require a three step process: first disruption, then oxidation, then extraction. ZMC reasons that all or substantially all of the reduced coenzyme Q10 obtained from the disruption step must be oxidized to oxidized coenzyme Q10 in a step before beginning the extraction step. ZMC says {

} As a result, ZMC concludes that its process does not infringe under the Respondents' or Staff's proposed constructions, {

} (Citing RX-348C, Q. 301.)

ZMC asserts that its process does not include a step of "extracting the reduced coenzyme Q10." {

} (Citing RX-251C at ZMC104945-46; RX-345C at ZMC107497.) Based on this, ZMC reasons that {

}

ZMC asserts that its process does not include a step of "oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10." ZMC contends that Kaneka cannot meet its burden of proof, even under its own flawed construction. (Citing RX-348C, Q. 309.) ZMC likewise asserts that ZMC does not infringe this limitation under Respondents' or Staff's proposed constructions. (Citing *id.*, Qs. 301-311.) ZMC says that if properly construed, Claims 11 and 33 require a two-step process: first the reduced coenzyme Q10 must be extracted, then the extracted reduced coenzyme Q10 must be oxidized to oxidized coenzyme Q10. ZMC reasons that {

} ZMC's manufacturing process does not convert "all or substantially all" of the coenzyme Q10 after extraction. (Citing *id.* at Q. 311.)

ZMC asserts that its process does not include a step of extracting under an inert gas atmosphere. {

}

{

ZMC contends that its process does not include a step of extracting in a sealed tank.

}

ZMC alternatively argues that Kaneka has provided no evidence that ZMC's tank prevents the direct exposure of its contents to the atmosphere, and the evidence shows just the opposite. {

}

ZMC contends that its process does not use an oxidizing agent to oxidize the reduced coenzyme Q10. {

}

ZMC contends that it does not have a sealed tank sealed under a deoxygenized atmosphere. {

} ZMC asserts that one of ordinary skill in the art would understand that an atmosphere is only "substantially free of oxygen" when it contains less than 1% oxygen. (Citing RX-348C, Q. 230.) {

}

Staff's Position: Staff asserts that there is no real dispute that the ZMC process is a process for producing on an industrial scale the oxidized coenzyme Q10.

Staff asserts that ZMC does not culture reduced coenzyme Q10 producing microorganisms for the same reasons identified regarding Shenzhou's and XKGC's processes.

Staff says that the evidence demonstrates that the culture medium used by ZMC in its fermentation tank contains {

} (Citing CX-653C at Q176.)

Staff contends that ZMC's process does not obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10. {

} but the samples tested by NSF Shanghai were kept refrigerated until the time they were tested, not frozen. (Citing Tr. at 184:21-185:6.) As a result, Staff says that the data has the same problems as the testing Kaneka performed on Shenzhou's samples, and that the testing results are similarly unreliable.

{

} As a result, Staff concludes that

Dr. Kittendorf's testing, when conducted using reliable handling, actually shows non-infringement.

Staff says that ZMC's process includes a step of disrupting the microbial cells to obtain reduced coenzyme Q10 under Staff's and Kaneka's constructions, but not under respondents' construction. {

} Staff says that because the construction proposed by Respondents requires that the disruption be performed under conditions that prevent oxidation, the evidence does not show that this limitation is met under the Respondents' proposed construction.

Staff asserts that ZMC's process includes a step of oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10 under Kaneka's construction, but not under Staff's and Respondents' constructions. {

} Staff concludes that if Kaneka's proposed construction is adopted and the data found to be reliable, the evidence shows that ZMC's process meets this limitation.

Staff says that to satisfy the constructions proposed by Staff and Respondents, all or substantially all of the reduced Q10 from the disruption step must be oxidized. {

} Staff concludes that if the constructions proposed by Staff or Respondents are adopted, the evidence does not show that the ZMC process meets this limitation.

Staff asserts that ZMC's process includes a step of oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10 under any construction. {

}

Staff says that ZMC's process does not include a step of extracting the oxidized coenzyme Q10 by an organic solvent under an inert gas atmosphere. {

} Thus, the evidence does not show that the ZMC process meets this limitation under any of the parties' proposed constructions.

Staff asserts that ZMC's process does not include a step of extracting the oxidized coenzyme Q10 by an organic solvent in a sealed tank under Respondents' and Staff's construction, but is met under Kaneka's construction. {

} As a result, Staff concludes that the evidence shows that this limitation is satisfied under Kaneka's proposed construction, but is not satisfied under the construction proposed by Staff and Respondents.

Staff says that {

} ZMC's process includes a step of extracting the oxidized coenzyme Q10 using a hydrophobic organic solvent.

Staff says that {

} Kaneka has failed to prove that the reduced coenzyme Q10 is oxidized with an oxidizing agent is ZMC's process.

Staff says that {

} ZMC's extraction tank does not have an inert gas atmosphere that comprises nitrogen gas and is not a sealed tank sealed under an inert gas atmosphere.

Staff says that there is no real dispute that {

}

Discussion and Conclusions: Kaneka has failed to prove by a preponderance of the evidence that ZMC's process of producing coenzyme Q10 infringes any asserted claim of the '340 patent. Although there are other minor disputes between the parties, the key disputes between Kaneka and ZMC are whether or not ZMC's process meets the 70 mole % limitation (as required by all asserted independent claims), whether or not ZMC's process meets the limitations requiring extraction of coenzyme Q10 under an inert gas atmosphere (as required by asserted independent claims 1 and 11), and whether or not ZMC's process meets the limitations requiring extraction of coenzyme Q10 in a sealed tank (as required by asserted independent claims 22 and 33). I find that Kaneka has failed to carry its burden of proof on all of these issues.

First, Kaneka has failed to show by a preponderance of the evidence that ZMC's process of producing coenzyme Q10 includes a step of "culturing reduced coenzyme Q10-producing

microorganisms . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by each asserted independent claim (claims 1, 11, 22, and 33). Kaneka has not introduced reliable evidence showing that this limitation is met. Rather, as explained in sections V.C and V.D, *supra*, the evidence raises serious questions regarding whether or not Kaneka's handling of the samples caused the test results to not accurately represent the contents of the fermentation tanks from which the samples were taken. {

}

Kaneka's attempts to rely on { } do not overcome Kaneka's own adverse data, especially in view of the testimony regarding Respondents' testing. {

}

Kaneka has not introduced any evidence to establish the amount of skew in favor of reduced coenzyme Q10 in Respondents' testing. As a result, { } the evidence does not support a conclusion that those results accurately reflect the level of reduced coenzyme Q10 at the end of culturing.[15]

Based on the foregoing, I find that Kaneka has failed to prove by a preponderance of evidence that ZMC's process of producing coenzyme Q10 includes a step of "culturing reduced

[15] This data can be relied upon to show non-infringement where the test results find less than 70 mole % reduced coenzyme Q10 since the skew, if any, would be in favor of the reduced form.

coenzyme Q10-producing microorganisms . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by all asserted independent claims.

Second, Kaneka has also failed to prove by a preponderance of evidence that ZMC's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by asserted independent claims 1 and 11. The disputes between Kaneka and ZMC regarding when extraction begins and when extraction ends are irrelevant to the question of infringement because, even assuming Kaneka is correct, {

}

{

} Moreover, Kaneka offered no alternative evidence regarding the oxygen percentage in ZMC's extraction tank. (*See id.*; Tr. at 351:25-352:5.)

Based on the foregoing, I find that Kaneka has failed to prove by a preponderance of evidence that ZMC's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by asserted independent claims 1 and 11.

Kaneka has also failed to prove by a preponderance of evidence that ZMC's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent in a sealed tank," as required by asserted independent claims 22 and 33. {

}

The remaining issue is whether {

} is sufficient to meet the "sealed tank" limitation. It is not. {

} In view of this evidence, it is unreasonable to say that the coenzyme Q10 is extracted in a sealed tank {

}

{

} Based on the foregoing, I find that Kaneka has failed to prove by a preponderance of the evidence that ZMC's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent in a sealed tank," as required by asserted independent claims 22 and 33.

Kaneka has likewise failed to demonstrate by a preponderance of evidence that ZMC's process of producing coenzyme Q10 infringes asserted claims 3, 4, 9-10, 13-15, 20-21, 24, 25, 29-31, 35-37, and 41-44 of the '340 patent because those claims depend variously from claims 1, 11, 22, and 33. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.").

F. MGC

Kaneka's Position: Kaneka contends that MGC's process for manufacturing coenzyme Q10 infringes at least claims 1, 2, 4, 9-12, 14-15, 20-23, 25, 27, 29-31, 33-34, 36-37, 41-43, and 45 of the '340 patent.

Kaneka asserts that MGC's process is "a process for producing on an industrial scale the oxidized coenzyme Q10 . . ." as required by the preambles of all of the asserted independent claims. Kaneka says that the main fermentation tanks at MGC's C3 and C5 manufacturing plants have a total volume of { } and { } respectively. (Citing CX-653C, Q. 92; CX-110C.004; CX-114C at 55:19-56:25.) Kaneka continues that the size of all equipment used in the process is scaled accordingly. (Citing CX-161C.060 at ¶ 175; CX-111.009 at (a).)

Kaneka asserts that MGC's process includes "culturing reduced coenzyme Q10 producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient," as required by the first element of all of the asserted independent claims. Kaneka says that MGC cultures { }to produce oxidized Coenzyme Q10. (Citing CX-109C at 27:1-13; CX-111C.010 at (b) and (c).) Kaneka continues that some of this coenzyme Q10 will be in the reduced form. (Citing CX-653C, Q. 93; CX-110C.004; CX-135C.005.) Kaneka says that the culture medium used in MGC's process to

manufacture Coenzyme Q10 contains sources of carbon, nitrogen, phosphorus and micronutrients. (Citing CX-653C, Q. 95; CX-110C.005; CX-111.010 at (d).)

Kaneka asserts that MGC cultures { }"to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by the first element of all of the asserted independent claims. Kaneka says that between April 8, 2011 and April 14, 2011, MGC performed a test measuring the ratio of reduced Coenzyme Q10 among total Coenzyme Q10. (Citing CX-653C, Qs. 97-98; CX-106C.002.) Kaneka continues that the twice replicated testing showed that MGC's culturing step produces { } reduced Coenzyme Q10 among total Coenzyme Q10. (Citing CX-653C, Qs. 97-98; CX-106C.002.)

In its reply brief, Kaneka disagrees with MGC's criticisms of Dr. Connors' testimony, saying that Dr. Connors supports his opinion of infringement based on MGC's testing of its products to determine that MGC's industrial fermentation of { }results in over 70 mole % reduced coenzyme Q10 among all the coenzymes. (Citing CX-653C, Qs. 97-98; CX-106C.002.)

Kaneka also disagrees with MGC's arguments that Kaneka cannot rely on CX-106C. Kaneka says that the document itself shows that it was produced by MGC. (Citing CX-106C.002.) Kaneka continues that the document shows on its face that it was from Mr.{ } of MGC's intellectual property group, it was prepared on { } and it references instructions made on { } and states that according to such instructions {

}

(Citing CX-106C.002.) Kaneka says that these admissions are not controverted with any evidence.

Kaneka says that MGC has proffered no one with knowledge of the results to dispute what the document shows, the results are not what they purport to represent, that the results are not reliable, why the English translation produced by MGC would necessarily have MGC stamps on it, or even that MGC's process to produce oxidized CoQ10 is any different for products that may be exported to the United States.

Kaneka contends that MGC's process includes a step of "disrupting the microbial cells to obtain reduced coenzyme Q10" as required by the second element of claims 1 and 22. Kaneka says that MGC's process of producing coenzyme Q10 includes a step in which {

}

(Citing CX-653C, Q. 99; CX-115C.005; RX-99C.013; CX-116C at 69:1-23; CX-111C.010 at (f).) Kaneka asserts that this is a disruption step to one of ordinary skill in the art. (Citing CX-653C, Q. 99; CX-115C.005; RX-99C.013; CX-111C.010 at (f); CX-117C at 43:2-21; Tr. at 851:20-852:2, 854:6-855:25.) Kaneka says that witnesses for other respondents testified that { } acts to disrupt the cells and facilitates the subsequent extraction process. (Citing CX-117C at 40:3-43.)

Kaneka says that this disruption makes the remaining reduced Coenzyme Q10 more easily obtained from the microbial cells that have had the surface structures broken, and thus, obtains reduced coenzyme Q10. (Citing CX-161C at ¶ 190.) Kaneka says that despite the { } Coenzyme Q10 at or near the same time the cell is disrupted in { } all of the reduced Coenzyme Q10 is not oxidized, and thus at least

some of the reduced Coenzyme Q10 is protected from oxidation during MGC's disruption step. (Citing CX-156C at 72:3-20; CX-111C.010 at (f) and (g).)

In its reply brief, Kaneka disagrees with MGC's argument that Kaneka's only evidence that MGC practices the disruption step is Dr. Connors' testimony. Kaneka says it relies on Dr. Connors' testimony, which is based upon evidence from MGC, to show that this step is met by MGC's process. Kaneka continues that it also relies directly on the evidence produced by MGC. (Citing CIB at 81-82.) Kaneka says that one of the MGC process documents that it cites states that { } (Citing RX-99C.013 (MGC00008080) at ¶ 2; see also CX-111C.010 at ¶¶ (f) and (g).)

Kaneka contends that MGCs process includes a step of "oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10," as required by the third element of claims 1 and 22. Kaneka says that {

} (Citing CX-122C at 59:1-60:17; CX-115C.005; RX-99C.013 (MGC00008080).) Kaneka continues, saying that {

} (Citing CX-122C at 59:1-60:17) and {

} (Citing CX-122C at 59:1-60:17; CX-123C.011.) Kaneka says that {

} (Citing CX-122C at 59:1-60:17; CX-123C.011.) Kaneka explains that { } is then used in ZMC's extraction step. (Citing CX-161C at ¶ 158.) Kaneka asserts that the use of { }

increase of the rate at which reduced Coenzyme Q10 obtained from the disruption step is converted to oxidized Coenzyme Q10. (Citing CX-161C at ¶ 194.)

In its reply brief, Kaneka disagrees with MGC's assertion that Dr. Connors did not address the step of "oxidizing thus-obtained reduced CoQ10" in his witness statement. (Citing CX-653C, Qs. 104-105.) Kaneka says that MGC ignores additional factual evidence adduced at the hearing which supports Dr. Connors' conclusion. (Citing Tr. at 650:15-651:11.)

Kaneka contends that MGC's process includes a step of "extracting the oxidized coenzyme Q10 by an organic solvent," as required by the third element of claims 1 and 22. Kaneka says that the extraction step of the MGC process uses {

} to collect the oxidized Coenzyme Q10 from { } (Citing CX-653C, Q. 100; CX-161 at ¶¶ 159-163; Tr. at 996:14-997:20; CX-132C.046, .053, .058, .076; CX-133C.014; CX-115C.005 at (5); RX-99C.013.)

In its reply brief, Kaneka asserts that MGC misrepresents the evidence by asserting it does not { } (Citing RX-360C, Qs. 4-49, 4-54.) Kaneka contends that MGC cannot dispute that it is oxidized CoQ10 that is being extracted. Kaneka says that MGC's own documents show that {

} (Citing RX-99C.013 at ¶¶ 2-5; CX-111C.010 at ¶¶ (f),(g) and (h).) Kaneka continues that MGC { } (Citing CX-653C, Q. 100; CX-161 at ¶¶ 159-163; Tr. at 996:14-997:20; CX-132C.046, .053, .058, .076; CX-133C.014; CX-115C.005 at (5); RX-99C.013.)

Kaneka asserts that this extraction takes place "under an inert gas atmosphere," as required by the third element of claim 1. Kaneka says that during extraction step MGC {

} (Citing CX-653C, Q. 101; CX-130C at 140:7-10; CX-128C at 135:4-19.) In addition to questioning the methodology employed by MGC in testing the atmosphere of its extraction tank, Kaneka says that {

} (Citing CX-653C, Q. 101; CX-157C; CX-128C at 134:7-135:16; CX-129C.) Kaneka continues that the { } (Citing *id.*)

In its reply brief, Kaneka disagrees with MGC's argument that Dr. Connors' opinion is insufficient to prove infringement of the "extracting… under an inert gas atmosphere" claim limitation. Kaneka said it cited to evidence in its Initial Post-trial Brief. (Citing CIB at 83 ¶ f.) Kaneka continues that under the construction proposed by Staff, and according to Dr. Trumpower, the presence of some air in the atmosphere would not cause oxidation. (Citing Tr. at 1068:8-24.)

Kaneka asserts that MGC's extraction takes place "in a sealed tank," as required by the third element of claim 22. (Citing CX-653C, Q. 103.) Kaneka acknowledges that {

} (Citing CX-653C, Q. 102.) Kaneka says that MGC's extraction tank { } (Citing CX-653C, Q. 102.) Kaneka continues that {

} (Citing Tr. at 997:12-998:8.)

In its reply brief, Kaneka disagrees with MGC's argument that Dr. Connors' opinion is insufficient to prove infringement of the "extracting . . . in a sealed tank" claim limitation. Kaneka says that it cited evidence supporting infringement in its brief. (Citing CIB at 83 ¶ g.)

Kaneka contends that MGC's process includes a step of "extracting the reduced coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by the second element of claim 11 and "extracting the reduced coenzyme Q10 by an organic solvent in a sealed tank" as required by the second element of claim 33. Kaneka says that this claim element is the same in the MGC process as those in claims 1 and 22, and therefore meets this element for the same reasons. (Citing CX-161C at ¶¶ 160-164; CX-128C -142C; CX-161C at ¶ 206.)

In its reply brief, Kaneka disagrees with MGC's argument that the reduced CoQ10 being extracted must be at least 70 mole % of the total CoQ10 enzymes. Kaneka says that MGC does not point to any claim language where such a limitation exists and there is no sequential limitation included for this step such as "and then." {

} (Citing CX-161C at ¶¶ 160-164; CX-161C at ¶ 207; CX-653C, Qs. 104-105; CX-111C.010 at ¶¶ (f), (g) and (h); CX-133C.014, .015, .021.)

Kaneka contends that MGC's process includes "oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10," as required by the third element of claims 11 and 33. Kaneka says that after the extraction step, the MGC process has {

} (Citing CX-161C at ¶¶ 160-164; CX-161C at ¶ 207; CX-653C, Qs. 104-105; CX-111C.010 at (g); CX-133C.014, .015, .021.) Kaneka concludes that, as a result, the MGC process {

} (Citing CX-653C, Qs. 104-105.)

Kaneka asserts that in MCG's process {

} Kaneka says that the MGC process utilizes {

} during extraction. (Citing CX-653C, Q. 107.)

Kaneka asserts that MGC's process includes a step of "disrupting the microbial cells," as required by claims 14 and 36. Kaneka says that MGC's process includes a step of disrupting the microbial cells. (Citing CX-653C, Qs. 108-109.)

Kaneka asserts that MGC's process oxidizes reduced coenzyme Q10 "with an oxidizing agent," as required by claims 4, 15, 25, and 37. Kaneka represents that the parties have agreed on the definition of oxidizing agent as "a reagent other than ambient air that is used to oxidize the reduced Coenzyme Q10." (Citing CX-653C, Q. 111; CX-161C at ¶ 213.) Kaneka says that {

} Kaneka continues that MGC's process also includes a {

} (Citing CX-653C, Q. 111; CX-161C at ¶ 213; CX-111C.010 at (g).)

Kaneka asserts that in MGC's process, "the inert gas atmosphere comprises nitrogen gas," as required by claims 9 and 20. Kaneka says that during extraction, MGC {

} (Citing CX-653C, Q. 112; CX-130C at 140:7-10; CX-128C at 135:4-19; CX-157C; CX-158C.) Based on this evidence, Kaneka concludes that the MGC process meet this limitation. (Citing CX-653C, Q. 112.)

Kaneka asserts that in MGC's process, "the sealed tank is sealed under an inert gas atmosphere" and "under a deoxygenized atmosphere," as required by claims 29 and 41. Kaneka argues that a person of ordinary skill in the art would understand "deoxygenated atmosphere" in the context of the '340 Patent to mean "[a] gas atmosphere from which some oxygen has been displaced." (Citing CX-653C, Q. 113.) Kaneka says the MGC process extraction does occur under an inert gas atmosphere. (Citing CX-653C, Q. 113.)

Kaneka asserts that in MGC's process, "the inert gas atmosphere comprises nitrogen gas," as required by claims 9, 20 and 30. (Citing CX-653C, Q. 114.)

Kaneka asserts that in MGC's process, "the deoxygenized atmosphere comprises an inert gas" and "nitrogen gas" as required by claims 42 and 43, respectively. Kaneka says that the deoxygenated atmosphere under which extraction occurs in the MGC process comprises of nitrogen, which is an inert gas. (Citing CX-653C, Q. 115; CX-161 at ¶ 198.)

Kaneka asserts that in MGC's process "the culture medium is at least 750 L," as required by claims 10, 21, 31, and 44. Kaneka says that the volumes of the culture media in the main fermentation tanks in the MGC process are { } respectively. (Citing CX-653C, Q. 116; CX-110C.004; CX-114C at 55:19-56:25.)

MGC's Position: MGC asserts that Kaneka has failed to prove that the MGC process practices asserted claims 1, 2, 4, 8-12, 14-15, 19-23, 25, 29-34, 36-37, and 41-45 of the '340 patent.

First, MGC says Kaneka failed to carry its burden to show infringement because Kaneka's infringement case against MGC was almost entirely based on the brief testimony of Dr. Connors. (Citing CX-653C, Qs. 88-116.) MGC says that because Dr. Connors was not accepted as an expert in the industrial manufacture of CoQ10, was not offered as an expert in

industrial manufacturing of any other type (Citing Tr. at 226:15-18), only four pages of his witness statement relate to MGC infringement, and the witness statement is conclusory, based on erroneous claim constructions, without citation of specific evidence, incomplete, and without application of reliable principles and methods to the facts, Dr. Connors' testimony should be given no weight. (Citing *Yoon Ja Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1320 (Fed. Cir. 2006); *Rohm and Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1091 (Fed. Cir. 1997).)

Second, MGC asserts that its process does not meet the 70% reduced coenzyme Q10 limitation included in each of the asserted independent claims. MGC says that Kaneka did not obtain or test any samples of MGC's product. MGC continues that Kaneka's only evidence of infringement of the 70% limitation is a single conclusory paragraph of expert testimony in which Dr. Connors refers to CX-106C, a document that merely summarizes the partial results of a non-rigorous test not conducted by or under the supervision of Dr. Connors. (Citing CX-653C, Q.98.) MGC says that no one testified in this investigation regarding the tests discussed in CX-106C. Based on this lack of testimony, MGC reasons that this document is insufficient to establish that the 70% limitation is met because the results reflected in CX-106C likely indicate {

} (Citing RX-360C, Qs. 5-8 to 5-21).

MGC contends there are four problems with the testing relied upon by Dr. Connors. First, MGC says that CX-106C lacks important details regarding the sampling and handling of the samples and analysis. MGC asserts that the lack of such evidence is significant because {

} in which case the coenzyme Q10 will be increasingly in the reduced form over time. (Citing RX-623C, Qs. 202-253; RX-348C, Qs. 259-276, 416-417; RX-473C, Qs. 174-194; Tr. at

594:6-595:22, 607:11-610:8, 1011:7-1012:25, 1060:21-1061:12.) MGC explains that the only way that the percentages reported in CX-106C could be accurate would be if { } MGC says that CX-106C does not report that { } MGC continues that Mr. Ebina explained that { } can be discerned from CX-106C itself because { }

Based on this evidence, MGC argues that the actual percentages would be lower than indicated by CX-106C. (Citing RX-360C, Qs. 5-16 to 5-17.)

Second, MGC notes the lack of evidence of the time between when the samples were collected and when the first analysis was conducted. MGC contends that this time lag is critical because the longer the time lag the higher the percentage of reduced coenzyme Q10 for { } (Citing RX-623C, Qs. 202-253; RX-308C; RX-402C; RX-585C; RDX-59C; RDX-60C; RDX-61C; RDX-62C; RDX-63C; RDX-64C; RDX-65C; RDX-66C; RDX-67C; RX-348C, Qs. 259-276, and 416-417; RX-473C, Qs. 174-194; Tr. at 594:6-595:22, 607:11-610:8, 1011:7-1012:25, 1060:21-1061:12.) MGC reasons that without this information, the actual percentage of reduced coenzyme Q10 at the end of fermentation simply cannot be known. MGC says that all a POSITA could say is that it certainly would be lower { } likely much lower. (Citing RX-360C, Q.5-17).

Third, MGC notes the lack of any evidence concerning the analysis method used. MGC says Mr. Ebina explained that there is no general standard for measuring the percentage of reduced coenzyme Q10. (Citing RX-360C, Qs. 3-12 – 3-17.) MGC continues that because CX-106C is silent on the method used for the analyses, it is impossible to know whether the analysis

specified in the '340 patent was used or whether there is any correlation between the analysis methods that were used and the one specified in the '340 patent. (Citing RX-360C, Qs. 5-18 – 5-21).

Fourth, MGC notes that there is no evidence linking the tested product from CX-106C to the only MGC products that are relevant to this case: those manufactured for importation and sale in the United States. (Citing RX-360C, Q.5-14.) MGC asserts that without this link, the testing results from CX-106C are irrelevant. Based on this evidence, MGC concludes that the results contained in CX-106C are not sufficient to establish that MGC's process infringes the 70% limitation.

MGC asserts that its process does not include a step of "disrupting the microbial cells to obtain reduced coenzyme Q10." MGC says that Kaneka relies upon Dr. Connors' conclusory testimony that this step is met by {

} (Citing CX-653C, Q.99.)

First, MGC argues that the claim language requires that reduced CoQ10 must be the product of the disruption process. MGC contends that Dr. Connors' testimony does not address the requirement that the disruption step must be carried out "to obtain reduced coenzyme Q10." MGC says that as evidence of record in this Investigation establishes without question, {

} (Citing RX-360C, Qs. 4-30, 4-78, 5-31, 5-44.)

Second, MGC says that Dr. Connors ignores that the claims are directed to a process for producing oxidized coenzyme Q10 as the final product and that this product be obtained by disruption. MGC says that its process does not "obtain" any coenzyme Q10 {

} Rather, according to MGC,

{

} (Citing RX-360C, Qs. 4-36 – 4-41.)

Third, MGC says that {

} MGC says that Dr. Connors used the wrong {

} in MGC's process. MGC continues that the actual {

} (Citing CX-653C, Q.99; RX-360C, Q.4-33.) MGC contends that {

} in contrast to the { } conditions used for disruption in Example 1 of Kaneka's own patent application. (Citing RX-14; RX-360C, Q.4-33.) In view of this evidence, MGC concludes that {

} under MGC's process would not fall within the disruption process as described in the '340 patent.

MGC reasons that because, as Mr. Ebina explained, {

} disruption before extraction is not necessary in MGC's process. (Citing RX-360C, Q.4-36.)

In its reply brief, MGC disagrees with Kaneka's argument that the MGC process performs disrupting { } (Citing CIB 81; CX-360C, Q. 99.) MGC says that the other Respondent's { } referenced by Kaneka's Brief involved that different microorganisms and different conditions from the MGC process. (Citing *Id.*; RX-360C, Qs. 4-24 – 4-37; Tr. at 994:13 – 995:3.)

MGC says that the {

} (Citing RX-33 at SHENZITC790_114997; Tr. at 522:1:48 – 522:2:4) and

Mr. Ebina explained the step was used to improve { } (Citing RX-360C, Qs. 4-26–4-28; Tr. at 990:10-21, 994:13 – 995:3) MGC continues that it is conducted at { } and Mr. Ebina explained that there is a significant difference between { } (Citing Tr. at 991:15 – 992:8, 994:13 – 996:7, 1004:12-24). MGC explains that { } (Citing RX-360C, Q. 4-41; Tr. at 995:12-22.)

MGC disagrees with Kaneka's argument regarding the disrupting limitation, saying it is based on the conclusory opinion of Dr. Connors without any sample testing or other factual evidence { } MGC says that the only document cited is page 2 of CX-101C at 59, from another Respondent. The testimony and experience of the other Respondent was not shown to be relevant.

MGC says that Mr. Ebina testified that MGC's { } and the '340 patent specifically says that disrupting is not necessary { } (Citing RX-360C, Qs. 4-24, 4-33, 4-36; Tr. at 994:13, 995:3, 1004:12-24; JX-1 at 9:27-29).

MGC says that Kaneka ignores the literal requirement of Claims 1 and 22 that the "disrupting" must be "to obtain reduced coenzyme Q10" and ignores the sequence of steps in this limitation and the next, which requires "oxidizing thus-obtained reduced Coenzyme Q10 …." MGC says that this language requires that CoQ10 be "obtained" in a disrupting step and that it be in the reduced form.

MGC says that Mr. Ebina testified that CoQ10 was not released in MGC's { } (Citing RX-360C, Qs. 3-27, 3-32 to 3-41, 4-40 to 4-41, 5-28, 5-31, 5-34; Tr. at

995:21-22.) MGC continues that it is undisputed that the result of MGC's {

} (Citing RX-360C at 4-30; Tr. at 992:9 – 993:19.)

MGC says that Dr. Connors' witness statement is silent regarding infringement of the "thus-obtained" requirement in this limitation. (Citing CX-653C, Qs.88-116.) MGC contends that Dr. Connors' silence alone is adequate to defeat Kaneka's assertion of infringement of this limitation.

MGC says that coenzyme Q10 is not "obtained" in { } as noted above. MGC explains that coenzyme Q10{

} MGC reasons, as a result, that no coenzyme Q10 is "thus-obtained" to be oxidized in this step. (Citing RX-360C, Qs. 4-36 – 4-41.)

MGC reasons that because the result of MGC's { } is {

} (Citing RX-360C, Qs. 4-30, 4-78, 5-31, 5-44), { }

MGC asserts that the limitations of claim 1 require that reduced coenzyme Q10 first be obtained by disrupting and then be oxidized. According to MGC, Kaneka has not offered any evidence that the sequence is satisfied in MGC's process. MGC says that its process does not proceed in this sequence.

MGC disagrees with Kaneka's argument that { } in MGC's Process result in an increase of the rate at which reduced CoQ10 obtained {

} because it is based on Kaneka's construction of this limitation, which is incorrect. MGC says that Kaneka makes no effort to show infringement under the correct

construction of Respondents nor does it argue that this limitation is satisfied by { } discussed above. MGC says that Kaneka's argument ignores the fact that { } and does not cite any factual evidence of oxidation in the { }

MGC asserts that its process does not include a step of "extracting the oxidized coenzyme Q10 by an organic solvent." First, MGC says that it is undisputed that the MGC process requires { } (Citing RX-360C, Qs. 4-49 – 4-50, 4-54)). MGC concludes, as a result, that extraction is not "by an organic solvent" in MGC's process. Second, MGC says that this claim limitation requires extraction oxidized CoQ10 after the disruption and oxidation are complete, by virtue of the words "and then." MGC continues that Dr. Connors omitted the words "the oxidized coenzyme Q10" from his testimony about this limitation. (Citing CX-653C, Q. 100.) MGC reasons that because the MGC process does not employ the claimed disrupting, it also does not extract "the oxidized coenzyme Q10."

In its reply brief, MGC asserts that the evidence proffered by Kaneka does not prove that the extracting is "by an organic solvent," because MGC's process { } (Citing RX-360C, Qs. 4-49 – Q. 4-50.) MGC says that this limitation requires that "extracting" be "by an organic solvent," not that the extraction medium "comprises" or "includes" an organic solvent. MGC argues that the ordinary meaning of that phrase is equivalent to "consisting of," precluding inclusion of a necessary material other than "an organic solvent" and Kaneka has failed to prove that the MGC process satisfies this limitation. MGC notes that Kaneka cannot argue under the doctrine of equivalents. (Citing Tr. at 22:12 – 23:24.)

MGC asserts that its process does not include a step of "extracting … under an inert gas atmosphere." MGC says that in its process, {

} MGC continues that Mr. Ebina explained that {

} MGC explains that the {

} (Citing RX-360C, Qs. 4-60 – 4-70.)

MGC says that its test data shows that {

} (RX-124C; RX-125C; RX-360C, Qs. 4-68 – 4-79.) MGC continues that the {

} (Citing RX-360C, Qs. 5-48–5-49.) MGC concludes that when "inert gas atmosphere" is construed in accordance with its plain and ordinary meaning, MGC's Process does not practice this limitation because {

} the atmosphere is not one of "inert gas." (Citing RX-360C, Q.5-46; RX-124C and RX-125C.)

MGC contends that assuming, arguendo, that Dr. Connors' construction can be meaningfully applied in an infringement analysis, Dr. Connors fails to address all of the relevant facts about the MGC process that would be necessary to satisfy this limitation. (Citing CX-653C, Qs. 38-39, 42, 49, 53, 100-101.) MGC says that Dr. Connors never expressly says that this limitation is infringed by the MGC process; rather, Dr. Connors mentions {

} ignores {

} and then concludes {

} without further explanation or citation to any relevant documents. (Citing CX-653C, Q. 101.)

MGC asserts that Kaneka's brief concedes the issue of the "extracting … under an inert gas atmosphere" limitations of Claims 1 and 11 under Respondents' construction, by not mentioning it.

MGC disagrees with Kaneka's reliance on Dr. Connors' conclusion that {

} because it ignores the evidence that {

}

(Citing RX-360C, Q. 4-70; Tr. at 997:21 – 1003:10.)

MGC asserts that its process does not include a step of "extracting the reduced coenzyme Q10." First, MGC says that its process { } and thus does not literally infringe the requirement in claim 11 of "extracting … by an organic solvent." Second, MGC disagrees with Kaneka's suggestion that the "extracting" claim limitation in claim 11 is the same as "extracting" claim limitation in claim 1. MGC says that claim 1 includes limitations requiring oxidizing the reduced coenzyme Q10 before extracting oxidized coenzyme Q10 whereas claim 11 requires extracting reduced coenzyme Q10 before oxidizing. MGC contends that considering these limitations as equivalent would render the words "oxidized" and "reduced" meaningless. (Citing CX-653C, Q. 100.) Third, MGC says that "the reduced coenzyme Q10" that is in the cells in these limitations refers to the "reduced coenzyme Q10 at a ratio of not less than 70 mole % …" in the cells following culturing and the claims have no intervening oxidation between the fermentation and extraction steps. MGC says in its process { } (Citing RX-360C, Qs. 4-30, 4-78, 5-31, 5-44); and concludes, as a result, that this limitation is not satisfied. Fourth, MGC says that Dr. Connors' testimony does not address the claim 11 requirement that

the extracting be performed with "the reduced coenzyme Q10." (CX-653C, Qs. 101–102.) MGC concludes that because the coenzyme Q10 in the MGC process is {

} this claim limitation is not infringed.

In its reply brief, MGC says it does not dispute that the MGC process {

} MGC says that the limitation of claims 11 and 33 actually requires "oxidizing the extracted reduced Coenzyme Q10," referring back to extraction of the not less than 70 mole % reduced CoQ10 in the cells obtained by culturing. MGC reasons that {

} as required by claims 11 and 33.

MGC asserts that its process does not include a step of "extracting … coenzyme Q10 … in a sealed tank." MGC says that its extraction tank is not sealed because {

} (Citing RX-360C, Qs. 4-70, 4-72 – 4-74, 5-50 – 5-53.) MGC says that Dr. Connors admits that there are many valves and pipes going in and out of the extraction tank used by MGC, including {

} (Citing CX-653C Q. 102.) MGC disagrees, {

}

MGC asserts that Kaneka's brief concedes that the MGC process does not perform "extracting … in a sealed tank" under Respondents' construction. MGC says that Kaneka mischaracterizes { } (Citing CIB at 83-84; RX-360C, Qs. 4-62–4-65; RIB at 48-49.)

MGC says that Kaneka's arguments ignore { } when it says, { } (Citing CIB at 83.) MGC says that { } (Citing RX-360C, Qs. 5-50–5-53.)

MGC says that claim 22 mirrors claim 1, except that instead of requiring extraction "under an inert gas atmosphere" claim 22 requires extraction "in a sealed tank." MGC contends that Kaneka has failed to show that MGC's process meets the following limitations of Claim 22: (1) the 70% limitation; (2) "disrupting the microbial cells to obtain reduced coenzyme Q10"; (3) "and oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10"; (4) "and then extracting the oxidized coenzyme Q10 by an organic solvent"; and (5) "extracting . . . in a sealed tank."

MGC says that claim 33 mirrors claim 11, except that instead of requiring extraction "under an inert gas atmosphere" claim 33 requires extraction "in a sealed tank." MGC contends that Kaneka has failed to show that MGC's process meets the following limitations of Claim 33: (1) the 70% limitation; (2) "extracting the reduced coenzyme Q10 by an organic solvent"; and (3) "extracting . . . in a sealed tank."

MGC asserts that its process does not include a step of "disrupting," as required by claims 14 and 36. MGC says that Kaneka has not proffered any credible evidence that MGC's process includes a step of "disrupting." (Citing RX-360C, Qs. 3-22 – 3-41, 4-24 – 4-37, 5-25 – 5-31.) MGC continues, saying that Mr. Ebina explained that MGC's process does not include a "disrupting" step. (Citing RX-360C, Qs. 3-22 – 3-41, 4-24 – 4-37, 5-25 – 5-31.)

MGC asserts that its process does not include a step of continuous extraction, as required by claims 6, 7, 17, 18, 27, 28, 39, and 40. MGC says that Mr. Ebina explained that the extraction step in MGC's process is {

} (Citing RX-360C, Qs. 3-84 – 3-89, 5-54.) Based on this testimony, MGC concludes that its process does not utilize "continuous extraction."

Staff's Position: Staff says that there is no real dispute that the MGC process is a process for producing on an industrial scale the oxidized coenzyme Q10. Staff says that MGC admits that it has manufactured oxidized Q10 on an industrial scale since 1979. (Citing RX-360C, Q.5-5.)

Staff says that the evidence shows that MGC's process includes culturing reduced coenzyme Q10 producing microorganisms under Kaneka's construction, but not under Respondents' and Staff's construction. Staff says that{ } is not a photosynthetic bacteria and is not capable of growing photosynthetically. (Citing CX-653C, Q.94.) Based on this evidence, Staff concludes that MGC cultures microorganisms under all of the proposed constructions of the term microorganisms.

Staff says that MGC admits that{ }produces a mixture of reduced and oxidized Q10. (Citing RX-360C, Q.5-6.) Staff concludes that the evidence shows that MGC satisfies this limitation under Kaneka's proposed construction for reduced coenzyme Q10 producing microorganisms. Staff says that Kaneka has provided no evidence that prior to the fermentation step the{ }strain used by MGC contains reduced coenzyme Q10 at a ratio of not less than 70 mole % as determined by the assay described in Example 1 or col. 5:8-43 of the '340 patent. As a result, Staff concludes that the evidence does

not show that MGC meets this limitation under the construction proposed by Staff and Respondents.

Staff asserts that MGC cultures "in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient." Staff says that MGC does not deny, and the evidence shows, that its process meets this limitation. (Citing RX-360C, Q.5-7.)

Staff says that Kaneka was not able to obtain a sample from MGC until shortly before the hearing, and relies on the testing in CX-106C to demonstrate that the MGC process meets the 70 mole % limitation. (Citing CX-653C, Q. 98.) Staff continues, saying that Kaneka asserts that this document reports the result of testing performed by MGC in April 2011 measuring the ratio of reduced coenzyme Q10 among total coenzyme Q10 and that the test found { } (Citing *id.*) Staff says that CX-106C states that the ratio of reduced Q10 { } (Citing CX-106C.)

Staff reasons that although the testing addressed in CX-106C seems to have been performed on a sample taken at the proper step in the MGC process, Kaneka has not offered any information about how these tests were conducted or how the samples were collected and stored. Staff says that because the testing protocol, sample collection, and storage procedures impact the ratio of Q10, Staff does not believe that Kaneka has offered sufficient evidence relating to the testing described in CX-106C to meet its burden of demonstrating infringement under any of the parties' proposed constructions of this limitation.

Staff asserts that MGC's process includes a step of disrupting the microbial cells to obtain reduced coenzyme Q10 under Kaneka's construction but does not under Respondents'

construction. Staff submits that the evidence shows that the MGC's {

} (Citing CX-101C at p.59.)

Staff says that the construction urged by Respondents requires that the reduced Q10 be protected from an oxidation reaction throughout the disruption step. Staff continues that Kaneka has not provided any evidence that during {

} Rather, according to Staff, the evidence demonstrates that {

} (Citing RX-360C at 4-30.)

Staff asserts that MGC's process includes a step of "oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10." Staff says that the evidence demonstrates that the MGC process meets this limitation under Kaneka's proposed construction. Staff says that under its construction (and Respondents'), all or substantially all of the Q10 from the disruption step must be either actively converted or oxidized. Staff explains that these constructions require that the cells be disrupted prior to oxidation and require active conversion. Staff says that the evidence shows that {

} Staff reasons that {

}

Staff asserts that MGC's process includes a step of "oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10." {

}

(Citing Tr. at 992:9-22.) Staff notes that although the evidence demonstrates that {

} any increase in the rate of oxidation of any amount of extracted Q10 would be sufficient to satisfy this

limitation under Kaneka's proposed construction. Staff says that {

} the MGC process satisfies this limitation under the constructions proposed by Staff and Respondents.

Staff asserts that MGC's process does not include a step of "extracting the oxidized coenzyme Q10 by an organic solvent under an inert gas atmosphere." Staff says that MGC uses { } in its extraction process. (Citing CX-653C, Q. 100.) Staff continues, noting that during the extraction step MGC { } (Citing CX-653C, Q. 101.) Staff says that the { } (Citing CX-157C; CX-158C; RX-360C, Q.5-46.)

Staff contends that Kaneka's construction for this limitation, requiring that the gas atmosphere be less readily reactive with the organic solvent, is unclear. Staff reasons that if the reactivity of the atmosphere in the extraction tank is being compared to the reactivity of ambient air, Kaneka should have provided evidence that the atmosphere was less readily reactive than ambient air. Staff says that Kaneka failed to do so and therefore the evidence does not show that this limitation is met under Kaneka's proposed construction.

Staff says that because { } the evidence does not show that this limitation is met under the constructions proposed by Staff and Respondents, which require the atmosphere be free or substantially free of oxygen or not cause oxidation of coenzyme Q10. (Citing CX-157C; CX-158C.)

Staff asserts that MGC's process includes a step of "extracting the oxidized coenzyme Q10 by an organic solvent in a sealed tank" under Kaneka's construction, but not under Staff's and Respondents' constructions. Staff says that the MGC extraction tanks have {

} (Citing RX-360C, Q.5-53.) Staff says that Kaneka asserts that the MGC extraction tank is sealed because {

}

(Citing CX-653C, Q. 102.) Based on this evidence, Staff concludes that MGC's process meets this limitation under Kaneka's proposed construction. Staff reasons that because the evidence demonstrates that multiple components enter and exit the extraction tank during the extraction process, the evidence does not show that this limitation is met under the constructions proffered by Staff and Respondents.

Staff asserts that in MGC's process the extraction of the oxidized coenzyme Q10 is carried out by using { } Staff says that MGC uses {

} to perform extraction of oxidized Q10. (Citing CX-653C, Q. 107.) Staff continues that { } (Citing CX-653C, Q. 107.)

Staff says that in the MGC process, the reduced Q10 is oxidized by {

}

Staff contends that under Kaneka's construction of inert gas atmosphere, the inert gas atmosphere comprises { } gas in MGC's process. (Citing RX-360C, Q.5-49.) Staff concludes that, to the extent Kaneka's proposed construction for inert gas atmosphere is adopted,

the evidence shows that the atmosphere in the extraction tank meets the inert gas atmosphere limitation and this limitation.

Staff contends that the culture medium is at least 750L in MGC's process. Staff says that the volume of the fermentation tanks used by MGC is { } (Citing RX-360C, Qs. 4-20, 4-22.)

Staff contends that under Kaneka's constructions of deoxygenized atmosphere, MGC's process uses a sealed tank that is sealed under a deoxygenized atmosphere. Staff says that the { } (Citing CX-157C; CX-158C.) Staff says that to the extent the sealed tank limitation is satisfied, the evidence shows that this limitation is met under Kaneka's proposed construction. Staff continues that as the constructions proposed by Staff and Respondents require an atmosphere free or substantially free of oxygen, the evidence does not show that the MGC process satisfies this limitation under the constructions of Staff and Respondents.

Discussion and Conclusions: Kaneka has failed to prove by a preponderance of evidence that MGC's process of producing coenzyme Q10 infringes any asserted claim of the '340 patent. Although there are other minor disputes between the parties, the key disputes between Kaneka and MGC are whether or not MGC's process meets the 70 mole % limitation (as required by all asserted independent claims), whether or not MGC's process meets the limitations requiring extraction of coenzyme Q10 under an inert gas atmosphere (as required by asserted independent claims 1 and 11), and whether or not MGC's process meets the limitations requiring extraction of coenzyme Q10 in a sealed tank (as required by asserted independent

claims 22 and 33.) I find that Kaneka has failed to carry its burden of proof on all of these issues.

First, Kaneka has failed to show by a preponderance of evidence that MGC's process of producing coenzyme Q10 includes a step of "culturing reduced coenzyme Q10-producing microorganisms . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by each asserted independent claim (claims 1, 11, 22, and 33). Kaneka has relied upon a document produced by MGC, CX-106C, to assert that this limitation is met. CX-106C provides that {

} MGC performed a test to measure the ratio of reduced coenzyme Q10 among total coenzyme Q10 immediately after culturing, which showed {

} (CX-106C.)

CX-106C states that "amounts of Coenzyme Q10 in microbial cells in respective steps in Coenzyme Q10 manufacturing devices in Niigata factory were analyzed . . . ." (CX-106C.) CX-106C includes a chart {

} (CX-106C.)

Although these test results show {

} Kaneka has not tied these results to the products actually imported by MGC. MGC raised this argument in the Respondents' post hearing brief. (RIB at 45.) In response, Kaneka only asserts that MGC has not provided any evidence to prove the results reported in CX-106C do ***not*** correspond to products actually imported. (CRB at 38.) Kaneka does not identify any representations by MGC regarding this test data. (*See id.*) Kaneka's argument overlooks the fact that Kaneka, as the complainant, bears the burden to prove infringement by a preponderance of the evidence. *SmithKline Diagnostics, Inc.*, 859 F.2d at 889. Because there is

no evidence linking the test results reported in CX-106C to products actually imported by MGC (which are the only relevant products for this Investigation) rather than products that are produced for markets other than the United States, the test results reported in CX-106C are insufficient to meet the preponderance of the evidence standard.

Based on the foregoing, I find that Kaneka has failed to prove by a preponderance of the evidence that MGC's process of producing coenzyme Q10 includes a step of "culturing reduced coenzyme Q10-producing microorganisms . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by all asserted independent claims.

Second, Kaneka has also failed to prove by a preponderance of the evidence that MGC's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by asserted independent claims 1 and 11. Test data provided by MGC shows that {

} (RX-360C, Q. 5-46; RX-124C; RX-125C.) When compared to ambient air, which has approximately 21% oxygen (RX-348C, Q. 65), this is not an atmosphere that is "free or substantially free of oxygen."

Kaneka's criticism of MGC's oxygen meter data as not accurately representing the oxygen content of the extraction tank is not persuasive. Although Kaneka's brief criticizes MGC's testing as having "questionable methodology," Kaneka cites no evidence for this argument. (See CIB at 83.) Moreover, Kaneka also offered no alternative evidence regarding the oxygen percentage in MGC's extraction tank. (*See id.*)

In view of MGC's testing and Kaneka's failure to rebut this test data, I find that Kaneka has failed to prove by a preponderance of the evidence that MGC's process of producing

coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by asserted independent claims 1 and 11.

Kaneka has also failed to prove by a preponderance of the evidence that MGC's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent in a sealed tank," as required by asserted independent claims 22 and 33. During MGC's extraction process, MGC's extraction tanks {

} (RX-360C, Q.4-62; RX-97C.) {

} (RX-360C, Q.4-62.)

{

} (RX-360C, Q.4-62.) Thus, MGC's extraction tank permits materials, { } to exit the tank during extraction {

} Kaneka admits that gases escape from the extraction tank { } (CIB at 83 {

} As a result, the extraction tank in MGC's process is not "a tank that is closed to prevent the entry or exit of materials."

Based on the foregoing, I find that Kaneka has failed to prove by a preponderance of the evidence that MGC's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent in a sealed tank," as required by asserted independent claims 22 and 33.

Kaneka has likewise failed to demonstrate by a preponderance of the evidence that MGC's process of producing coenzyme Q10 infringes asserted claims 2, 4, 9-10, 12, 14-15, 20-21, 23, 25, 27, 29-31, 34, 36-37, 41-43, and 45 of the '340 patent because those claims depend

variously from claims 1, 11, 22, and 33. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.").

VI. DOMESTIC INDUSTRY

A. Applicable Law

In patent-based proceedings under section 337, a complainant must establish that an industry "relating to the articles protected by the patent...exists or is in the process of being established" in the United States. 19 U.S.C. § 1337(a)(2) (2008). Under Commission precedent, the domestic industry requirement of Section 337 consists of an "economic prong" and a "technical prong." *Certain Data Storage Systems and Components Thereof*, Inv. No. 337-TA-471, Initial Determination Granting EMC's Motion No. 471-8 Relating to the Domestic Industry Requirement's Economic Prong (unreviewed) at 3 (Public Version, October 25, 2002).

The "economic prong" of the domestic industry requirement is satisfied when it is determined that the economic activities set forth in subsections (A), (B), and/or (C) of subsection 337(a)(3) have taken place or are taking place. *Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, USITC Pub. No. 3003, 1996 ITC LEXIS 556, Comm'n Op. at 21 (Nov. 1996). With respect to the "economic prong," 19 U.S.C. § 1337(a)(2) and (3) provide, in full:

> (2) Subparagraphs (B), (C), (D), and (E) of paragraph (1) apply only if an industry in the United States, relating to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established.
>
> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned-

(A) significant investment in plant and equipment;

(B) significant employment of labor or capital; or

(C) substantial investment in its exploitation, including engineering, research and development, or licensing.

Given that these criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the domestic industry requirement. *Certain Integrated Circuit Chipsets and Products Containing Same*, Inv. No. 337-TA-428, Order No 10, Initial Determination (Unreviewed) (May 4, 2000), citing *Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, Commission Op. at 15, USITC Pub. 3003 (Nov. 1996).

To meet the technical prong, the complainant must establish that it practices at least one claim of the asserted patent. *Certain Point of Sale Terminals and Components Thereof*, Inv. No. 337-TA-524, Order No. 40 (April 11, 2005). "The test for satisfying the 'technical prong' of the industry requirement is essentially same as that for infringement, i.e., a comparison of domestic products to the asserted claims." *Alloc v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). The technical prong of the domestic industry can be satisfied either literally or under the doctrine of equivalents. *Certain Excimer Laser Systems for Vision Correction Surgery and Components Thereof and Methods for Performing Such Surgery*, Inv. No. 337-TA-419, Order No. 43 (July 30, 1999). The economic prong and technical prong showings must be made for the same product or products.

B. Economic Prong

Kaneka's Position: {

}

Kaneka alleges that Respondents have not refuted any of the facts supporting Kaneka's economic activity as to employment of labor and capital.

In its reply brief, {

}

Respondents' Position: {

}

Respondents cite *In re Certain Polyimide Films, Products Containing Same, and Related Methods*, Inv. No. 337-TA-772, Initial Determination, 2012 WL 2131128 (May 10, 2012), and say that the Administrative Law Judge issued an Initial Determination that Kaneka had failed to the economic prong under similar circumstances. (Citing *id.* at 173.) Respondents assert that the Administrative Law Judge found that Kaneka did not meet the economic prong, because it "provide[d] only generalized figures regarding the overall investment made at the KTC facility." (*Id.* at 174.) Respondents quote the decision to say that "[i]n order to demonstrate that the economic prong is met, it was necessary for Kaneka to provide detail regarding the investments made related specifically to the products alleged to practice the patents." (Citing *id.*)

Respondents argue that the same result is warranted here because Kaneka has failed to produce any evidence regarding the cost of plant and equipment related specifically to the oxidized form of coenzyme Q10 and merely relies on expenditures for coenzyme Q10 as a whole. {

}

In their reply brief, Respondents say that, in describing its domestic industry, Kaneka touts its role as a manufacturer of coenzyme Q10, and in the background facts, it uses the term interchangeably. Respondents argue that this ignores the fact that it is only *oxidized* coenzyme Q10 that is covered by the '340 patent, and {

}

Respondents contend that Kaneka cites no evidence to support its claim regarding its investments in a domestic industry. {

}

Respondents say that Kaneka relies solely on the fact that {

} Respondents argue that Kaneka can only rely on prior investments in plant and equipment to the extent they are used in producing oxidized CoQ10 after March 22, 2011, the date of issue of the '340 patent. (Citing *Alloc, Inc. v. Int'l Trade Comm'n,* 342 F.3d 1361, 1375 (Fed. Cir. 2003).)

Staff's Position: {

} Staff believes that Kaneka has shown significant investment related to the domestic industry product.

{

}

In its reply brief, Staff says that Respondents allege that Kaneka has failed to demonstrate that it satisfies the economic prong of the domestic industry requirement due {

}

Staff submits that the total investments in plant, equipment, capital, and labor {

} Staff reasons that allocation on the basis of percentage of sales is an accepted proxy for determining whether the specific investments made by a Complainant in a patent-based Section 337 investigation are related to an article protected by the patent. 19 U.S.C. § 1337(a)(3). Staff says, for example, in *Certain Digital Televisions and Certain Products Containing the Same,* Funai, the patentee, demonstrated that it engaged in substantial investments with respect to the patents-in-suit using a percentage of sales allocation method. (Citing Inv. No. 337-TA-617, Final Initial Determination at 159 (Nov. 17, 2008) (unreviewed in relevant part).)

Staff applies the same method to this case, {

} Staff argues that these investments are substantial in view of the industry and the

product, and the evidence demonstrates that Kaneka has satisfied the economic prong of the domestic industry requirement.

Discussion and Conclusions: Based on the evidence in the record, I find that Kaneka has demonstrated by a preponderance of evidence that it satisfies the economic prong of the domestic industry requirement for the '340 patent.

Kaneka filed its complaint on June 17, 2011. Kaneka only asserts that a domestic industry exists, and it does not assert that a domestic industry is in the process of being established. Therefore, the domestic industry analysis is limited to determining whether or not Kaneka's domestic industry existed as of June 17, 2011. *Certain Video Game Systems & Controllers*, Inv. No. 337-TA-743, Comm'n Op. at 5 (Jan. 20, 2012).

To determine whether or not Kaneka satisfies the economic prong, I must examine Kaneka's domestic investments "with respect to the articles protected by the patent[s]." 19 U.S.C. § 1337(a)(3). The analysis is therefore focused on the investments related to the product that Kaneka claims practices the '340 patent. Kaneka claims that the process used to make its oxidized Coenzyme Q10 product practices the '340 patent.

Kaneka asserts that it satisfies the economic prong under subsection (a)(3)(B) of Section 337.

Plant & Equipment

Kaneka discusses "plant and equipment" in its brief, and that form of investment may satisfy the economic prong by demonstrating "significant investment in plant and equipment" related to the articles protected by the asserted patents. 19 U.S.C. § 1337(a)(3)(A). Nevertheless, Kaneka does not actually make an argument in its brief that this type of investment satisfies the economic prong, and Kaneka's intent is unclear. Assuming *arguendo* that Kaneka

intended to argue that its investment in "plant and equipment" satisfies the economic prong, I will discuss that element here.

The evidence supports a finding that in June 2004, Kaneka established KNL and began the construction of the KNL plant in Pasadena, Texas for large-scale Coenzyme Q10 manufacturing in the United States. (CX-652C, Q. 18; CX-58C.) {

}

The case cited by Respondents, *In re Certain Polyimide Films, Products Containing Same, and Related Methods*, Inv. No. 337-TA-772, Initial Determination (May 10, 2012), actually highlights the difference between a total lack of specificity which in that case did not meet the standard for demonstrating that Kaneka met the economic prong, and the showing here in which Kaneka has provided a reasonable connection between the expenses claimed and the product they allege to practice the '340 patent.

I find that the evidence concerning Kaneka's investments into what has become the KNA facility is sufficient to demonstrate a domestic industry based on plant and equipment. {

.}

While Respondents argue that expenses incurred prior to the issuance of the patent may not be considered, they cite no authority to support that position. The one case cited, *Alloc, Inc. v. Int'l Trade Comm'n,* 342 F.3d 1361, 1375 (Fed. Cir. 2003), does not even hint at such a position. Domestic industry in that decision is a brief discussion that affirms a finding that the complainants failed to meet the technical prong.[16] I note, too, that the Commission has specifically found otherwise. In *Certain Video Game Systems and Controllers,* Investigation No. 337-TA-743, I declined to consider the Complainant's pre-issuance activities and granted Respondent's motion for summary determination that the Complainant had not demonstrated that it met economic prong of the domestic industry requirement. In reversing and remanding my decision, the Commission found that engineering and research and development activities that preceded issuance of a patent could be considered in determining whether or not the economic prong is met. The Commission did indicate that certain pre-issuance activities (*e.g.* patent prosecution, licensing and litigation) related to the patent may not be germane to the domestic industry requirement under the facts and circumstances established by the complainant in a particular investigation. *See* Comm'n Op. in *Certain Video Game Systems and Controllers,* Investigation No. 337-TA-743 at *5, *7-8 (April 13, 2011).

In the present case, in my view the early investments in real estate, construction, maintenance, even those investments that predated the issuance of the '340 patent, coupled with the continued operation of a manufacturing plant through the date of filing of the complaint, is properly considered in determining whether or not the economic prong is met.

[16] In *Alloc* the Administrative Law Judge actually found that the economic prong was met.

Labor or Capital

Kaneka may satisfy the economic prong by demonstrating "significant employment of labor or capital" related to the articles protected by the asserted patents. 19 U.S.C. § 1337(a)(3)(B). Kaneka clearly argues that this element is met and satisfies its burden regarding the economic prong. I concur.

{

}

Based on all of the foregoing, I find that Kaneka has demonstrated by a preponderance of evidence that it satisfies the economic prong of the domestic industry requirement for the '340 patent.

{

}

C. Technical Prong

Kaneka's Position: Kaneka asserts that KNA practices claims 11-15, 17-18, 20-21, 33-37, and 39-44 of the '340 patent. Kaneka asserts that KNA's process is "a process for producing on an industrial scale the oxidized coenzyme Q10 . . ." as required by the preambles of all of the asserted independent claims. Kaneka says that KNA's manufacturing facility has an annual capacity of 9 million liters. (Citing CX-651C, Qs. 10-11.)

Kaneka contends that KNA's process includes "culturing reduced coenzyme Q10 producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient," as required by the first element of all of the asserted independent claims. Kaneka says that KNA utilizes yeast cells to produce Coenzyme Q10. Kaneka continues that this culture medium contains a carbon source, a nitrogen source, a phosphorus source and a micronutrient. (Citing CX-651C, Qs. 12-16; CX-63C through CX-67C.)

In its reply brief, Kaneka contends that there can be no real dispute that the microorganisms used by Kaneka produce CoQ10. Kaneka disagrees with Respondents' challenge to this claim element based on the requirement that one must also perform an additional test not recited in the claims, namely a separate independent assay of the microorganism under a standardized test. Kaneka says that this is directly contrary to the language of the claims which require the actual obtaining of 70 mole % on an industrial scale.

{

}

Kaneka says that KNA's commercial process cultures a reduced Coenzyme Q10 producing

microorganism to obtain microbial cells containing reduced Coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10 as shown by Dr. Kittendorf's testing. (Citing CX-73C.)

Kaneka contends that Dr. Kittendorf's results are further bolstered by the testing data submitted in support of the Complaint in this investigation. {

}

Kaneka disagrees with Respondents' argument that sampling to determine mole percentage should be taken "at the end of fermentation." Kaneka says that the proposed language that "the microbial cells must be analyzed at the end of the fermentation process" finds no support in the claims, specification nor file history of the '340 Patent and thus cannot be correct. {

}

Kaneka says that Respondents offer no proposal for determining the "end of fermentation" and Respondents' experts admitted at the "end of fermentation" occurs when the cells are actually killed. (Citing Tr. at 717:19-718:18.) {

}

{

}

In its reply brief, Kaneka says that Kaneka and Respondents submitted claim construction positions for this claim element that did not include any reference to "end of fermentation." Kaneka continues, explaining that Kaneka and Respondents developed sampling and testing protocols, {

}

Kaneka disagrees with Respondents' argument that testing must be done at "the end of fermentation." {

}

Second, Kaneka says that the claims recite "culturing" and as all of the experts agree, the microorganisms in the {

}

Third, Kaneka says that Respondents have argued that the purpose of the culturing step is to deliver CoQ10 above 70 mole % at the end of this step for use in the next step, as asserted by Respondents in devising the "end of fermentation" argument. Based on this argument of Respondents, Kaneka reasons that the end of the culturing step is when the microorganisms are transferred over for disruption in the milk tank. Kaneka argues that Respondents cannot devise a clever "end of fermentation" argument and then disavow its proper application.

Kaneka disagrees that Respondents measurement was taken at the end of fermentation { } Rather, Kaneka says that the sample was obtained without any supervision and was transported to the testing lab during Dr. Kittendorf's absence and as such was suspect. Kaneka continues, saying that, { } there was no attempt to hide this sample and the test results which were fully and timely disclosed to Respondents. (Citing Tr. at 943:5-944:8, 975:17-976:5.)

Kaneka disagrees with Respondents' assertion that the { }

Kaneka contends that KNA's process includes a step of "extracting the reduced coenzyme Q10 by an organic solvent under an inert gas atmosphere," and "in a sealed tank" as

required by the second element of claims 11 and 33. {

} Kaneka concludes that KNA's extraction process establishes the extraction elements of claims 11 and 33 of the '340 Patent. (Citing CX-651C, Q. 17; CX-68C.)

Kaneka contends that KNA's process includes "oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10," as required by the third element of claims 11 and 33. {

.}

Kaneka contends that KNA also practices dependent claims 12-13 and 34-35 {

}

Kaneka contends that KNA also practices dependent claims 14 and 36 {

}

Kaneka contends that since KNA's process embodies all of the elements of claims 11 and 33, it is undisputed that it embodies claims 15-16 and 37-38 of the '340 Patent.

Kaneka contends that {

.}

Respondents' Position: Respondents contend that Kaneka has failed to establish that KNA uses "reduced coenzyme Q10-producing microorganisms" within the meaning of the claims, KNA's process meets the 70% limitation, KNA extracts reduced coenzyme Q10 under an inert gas atmosphere, or KNA extracts reduced coenzyme Q10 in a sealed tank.

Respondents assert that Kaneka has cited no evidence that when cultured by the method described in the '340 patent, KNA's cells produce a ratio of greater than 70% reduced coenzyme Q10. {

)

Respondents assert that the evidence shows that Kaneka's alleged domestic industry process at KNA does not include "culturing reduced coenzyme Q10 producing microorganisms in a culture medium . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10" for two reasons. First, Respondents argue that, like Kaneka's testing for infringement purposes, Kaneka's testing methods for domestic industry are fatally flawed. (Citing RX-348C, Qs. 415-417.)

Second (and alternatively), Respondents argue that Kaneka's data does not show that its process produces 70 mole % reduced coenzyme Q10 at the relevant point in the process.

{

}

{

}

{

}

In their reply brief, Respondents contend that their proposed construction of "culturing reduced coenzyme Q10-producing microorganisms . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10" has two aspects: (1) to qualify as a "reduced coenzyme Q10-producing microorganism," the microorganism must produce 70 mole % reduced coenzyme Q10 when cultured and measured according to the method set forth in the '340 patent; and (2) the industrial process must culture the microorganisms to obtain 70 mole % reduced coenzyme Q10, *i.e.* it must result in at least 70 mole % reduced coenzyme Q10 at the end of culturing or fermentation. Respondents say that Kaneka's brief ignores Respondents' proposed construction of "reduced coenzyme Q10-producing microorganisms." Respondents reason that Kaneka therefore concedes that should Respondents' and Staff's claim construction be adopted, Kaneka's process does not meet this limitation.

Respondents assert that KNA does not produce 70% reduced coenzyme Q10 under any party's construction {

} First, Respondents contend that because Kaneka's testing method is fatally flawed, Kaneka cannot meet its burden of proof in establishing a domestic industry, just as it cannot meet its burden of proving infringement.

Second, Respondents say that the plain language of the claims mandates when a sample must be taken to determine whether an accused process infringes. Respondents continue that the claims require that to infringe, a process must culture microorganisms to obtain microbial cells containing 70 mole % reduced coenzyme Q10. Based on this language, Respondents conclude

that the only logical reading is that the sample must be taken from the end of the culturing process.

Respondents disagree with Kaneka's argument that Respondents are adding language to the claims of the '340 patent. Respondents say they merely seek to have this language interpreted based on the plain and ordinary meaning of the claim term. In contrast, Respondents say that Kaneka disregards the claim language "culturing . . . to obtain," and suggests that cells from virtually any point in the process would satisfy the 70% limitation. Respondents assert that Kaneka's reading would render the limitation virtually meaningless and leave the public wholly unable to ascertain the scope of the claims.

{

} Respondents continue that both Dr. Trumpower and Dr. Taylor explained that the notion of "culturing" requires affirmative steps to encourage the cells to grow. (Citing

Tr. at 680:14-682:15, 715:19-718:18, 796:7-17, 1020:20-1022:19.) {

}

Respondents say that Kaneka glosses over testing results obtained by the experts in

{

} Respondents assert that Kaneka has provided no reason why those testing data should be believed over those of Dr. Lee.

Respondents contend that Dr. Lee's methodology was shown at the hearing to be more scientifically sound. (Citing RX-348C, Qs. 390-395; RX-365C, Qs. 54-88.) Respondents say that although Dr. Trumpower testified that he did not notice the anomalies in Dr. Kittendorf's results, Dr. Trumpower was not offered or accepted as an expert in analytical chemistry, while Dr. Lee and Dr. Taylor both were. (Citing Tr. at 671:15-572:2, 733:25-734:5, 739:6-7, 907:7-16.) Respondents continue, saying that Dr. Taylor agreed that Dr. Lee's testing was more accurate than Dr. Kittendorf's. (Citing RX-348C, Qs. 392-395; Tr. at 1021:9-15.) {

}

Respondents disagree with Kaneka's argument that it extracts reduced coenzyme Q10 under an inert gas atmosphere because it is based on an assertion that {

}

Respondents contend that this is no more than a bald assertion that Kaneka meets the claim limitations, and it is insufficient to meet Kaneka's burden of proof under any claim construction. Respondents say that Dr. Connors admitted that he had no knowledge of the atmosphere in Kaneka Nutrients' extraction tanks {

}

{

}

Respondents say they have contested this issue throughout this investigation. Respondents say that Kaneka's only argument is that its "extraction process is carried out under a nitrogen atmosphere," but Kaneka cites no supporting evidence. Respondents continue, saying that the only evidence Kaneka cites regarding either this limitation or the "sealed tank" limitation {

}

Respondents say that Dr. Connors admitted that he had no knowledge {

}

Respondents disagree with Kaneka's argument that it extracts in a sealed tank because Kaneka's only proffered "evidence" on this issue is Dr. Connors' conclusory testimony.

{

}

In their reply brief, Respondents disagree with Kaneka's argument that this claim limitation is "undisputed." Respondents say that Kaneka claims that the "extraction tanks do not allow the direct exposure of their contents to the atmosphere because it would violate both environmental and safety regulations." (Citing CIB at 90.) {

} Respondents say that Kaneka provides no explanation, let alone a citation to the record, for this proposition. Respondents say their experts have explained that the use of a sealed tank is inconsistent with the use of continuous processes, since the plain meaning of the term means that nothing is going in, and nothing is going out. (Citing RX-367C, Q. 141.)

{

}

Staff's Position: Staff contends that there is no real dispute that the KNA process is a process for producing on an industrial scale oxidized coenzyme Q10.

Staff contends that KNA's process includes a step of "culturing reduced coenzyme Q10 producing microorganisms" under Kaneka's construction, but not under Respondents' and Staff's construction. Staff says that{ }is a non-photosynthetic microorganism that produces some amount of Q10, which Staff contends satisfies Kaneka's proposed construction of microorganism. Staff argues, however, that to demonstrate this

limitation is met under the construction of Staff and Respondents, a sample from the seeding tank must be cultured and assayed as described in the '340 patent, and these assays must show that the seed strain produces at least 70 mole % reduced Q10. Staff says that Kaneka has not supplied any evidence showing the testing results from a seed sample that was cultured and assayed this way; {

} and Dr. Kittendorf did not follow the testing procedure described in the patent. Staff concludes that if the construction proposed by Staff and Respondents is adopted the evidence does not show that this limitation is satisfied.

{

}

Staff contends that Kaneka has failed to prove that KNA cultures to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10. Staff says that Kaneka relies on two sets of testing to demonstrate that its process meets this limitation.

Staff argues that the proper time for testing to determine whether or not the 70 mole % limitation is met is at the end of fermentation. {

.}

Additionally, Staff contends that Dr. Kittendorf's testing of the samples from KNA suffers from the same fundamental flaws that mar the testing performed on the samples from Respondents. {

} As a result, Staff concludes that, { } Dr. Kittendorf's testing is unreliable.

{

}

Staff contends that there are two problems with this evidence. {

} Staff says that the experts testified that the fermentation step ends when the broth is taken from the fermentation tank. (Citing Tr. at 718:3-18.) Staff says that Dr. Spormann states that growth is culturing, a living organism per se is not culturing, and without growth there is no culturing. (Citing Tr. at 573:3-13, 575:7-9, 576:4-19.) Staff continues, saying that Dr. Trumpower testified that culturing requires that the microorganisms be dividing and multiplying and requires actively taking steps to encourage the bacteria to grow. (Citing Tr. at 680:25-681:10, 716:12-19.) Staff says that Dr. Trumpower stated that culturing ends when the steps taken to promote microbial growth cease and the aeration stops because many organisms, such as *Rhodobacter sphaeroides*, require oxygen to grow and divide, so once the broth is no longer aerated or sparged, growth ceases. (Citing Tr. at 229:22-25.) Staff says that Dr. Taylor defines culturing as the propagation of microorganisms in a media that is conducive to their growth. (Citing Tr. at 796:14-17.)

Staff says that Dr. Spormann agreed that the culturing step ends when aeration is stopped, because without aeration the cells stop growing. (Citing Tr. at 614:2-14.) Staff continues that when the broth leaves the fermentation tank it is no longer being aerated. {

} Staff says that Kaneka did not disclose these results, alleging that its reason for doing so was that the collection of the sample was flawed. Staff disagrees, saying that Kaneka has not identified any specific flaws in the sampling process.

Staff contends that Kaneka has proven that KNA's process includes a step of oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10. {

}

Staff says that Kaneka has proven that KNA's process includes a step of extracting the oxidized coenzyme Q10 by an organic solvent under an inert gas atmosphere. {

} Based on this evidence and the fact that little, if any, oxidation takes place in the extraction step, this limitation is met under the construction proposed by Kaneka or the construction proposed by Staff and Respondents.

Staff contends that Kaneka has proven that KNA's process includes a step of extracting the oxidized coenzyme Q10 by an organic solvent in a sealed tank under Kaneka's construction, but has failed to do so under the construction proposed by Staff and Respondents. Staff says that

{

} does not satisfy this limitation under the construction proposed by Staff and Respondents, but does show that this limitation is met under Kaneka's proposed construction.

Staff contends that in { } the extraction of the oxidized coenzyme Q10 is carried out using a hydrophobic organic solvent. {

}

Staff contends that in { ,} the reduced coenzyme Q10 is oxidized with an oxidizing agent. Staff says that after extraction {

} which contains numerous oxidizing substances. (Citing CX-653C, Q.76.)

{

.} Staff argues that because Kaneka's construction only requires that some oxygen be displaced, to the extent the sealed tank limitation is found to be satisfied, the evidence shows that this limitation is met under Kaneka's proposed construction. Staff continues that the atmosphere in the extraction tank is free or substantially free of oxygen, and therefore if the construction of Staff and Respondents is adopted, this limitation is met.

Discussion and Conclusions: Kaneka has failed to prove by a preponderance of the evidence that KNA's process of producing coenzyme Q10 practices at least one valid claim of the '340 patent because KNA's process does not meet the 70 mole % limitation (as required by all independent claims Kaneka uses to allege there is a domestic industry), the limitations requiring extraction of coenzyme Q10 under an inert gas atmosphere (as required by independent claim 11), and the limitations requiring extraction of coenzyme Q10 in a sealed tank (as required by independent claim 33).

First, Kaneka has failed to show by a preponderance of the evidence that KNA's process of producing coenzyme Q10 includes a step of "culturing reduced coenzyme Q10-producing microorganisms . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by claims 11 and 33. For the same reasons discussed in Sections V.C – V.E, *supra*, Kaneka's testing { } does not prove by a preponderance of evidence that the 70 mole % limitation is met by KNA's process. As discussed *supra*, Kaneka's testing data confirms that, under Kaneka's storage and testing protocol, the amount of reduced coenzyme Q10 in samples increased over time when refrigerated. {

} As a result, the evidence raises serious questions regarding whether or not Kaneka's handling of the samples from KNA caused the test results to not accurately represent the contents of the fermentation tanks from which the samples were taken.

The accuracy of Kaneka's test data is further called into question by Respondents' test data {

} Based on questions raised by Kaneka's flawed methods and the conflicting test data provided by Respondents, I cannot rely on Kaneka's testing data as an accurate reflection of the amount of reduced coenzyme Q10 in {

}

Additionally, Even if Kaneka's test data from the fermentation tank could be relied upon, it does not show that this limitation is met.[18] As explained in Section V.D, *supra*, the 70 mole % limitation must be met at the end of culturing, not at some earlier point or later point. {

} Respondents obtained similar results at this sampling point. (RX-353C at ZMC103379.) Thus, the test data from Kaneka's fermentation tank does not show this limitation is met.

Based on Kaneka's flawed sampling, storage, and testing methods, Kaneka's incorrect timing of sampling { } and the contrary test results provided by Respondents, I find that Kaneka has failed to prove by a preponderance of the evidence that KNA's process of producing coenzyme Q10 includes a step of "culturing reduced coenzyme Q10-producing microorganisms . . . to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10," as required by independent claims 11 and 33.

Kaneka has also failed to prove by a preponderance of evidence that KNA's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by independent claim 11. Kaneka has not offered

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any evidence regarding the atmosphere in KNA's extraction tanks other than testimony from Dr. Connors that nitrogen is introduced. (CIB at 90.) However, Dr. Connors admitted he did no testing on the oxygen concentration in KNA's extraction tanks and reviewed no documents regarding the oxygen content of the extraction tanks. (Tr. at 371:4-371:18.) Because an "inert gas atmosphere" requires "an atmosphere of inert gas (such as nitrogen, carbon dioxide, helium, argon, or hydrogen) that is free or substantially free of oxygen," and Kaneka has provided no evidence regarding the amount of oxygen in KNA's extraction tanks, I find that Kaneka has failed to prove by a preponderance of the evidence that KNA's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent under an inert gas atmosphere," as required by independent claim 11.

Third, Kaneka has also failed to prove by a preponderance of the evidence that KNA's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent in a sealed tank," as required by independent claim 33. {

} Kaneka has failed to prove by a preponderance of evidence that KNA's process of producing coenzyme Q10 includes a step of "extracting . . . coenzyme Q10 by an organic solvent in a sealed tank," as required by claim 33.

Because Kaneka has failed to prove by a preponderance of evidence that KNA practices independent claims 11 or 33, Kaneka likewise has failed to prove by a preponderance of the evidence that KNA practices any of the dependent claims 12-18, 20-21, 34-37, and 39-44.

Based on all of the foregoing, I find that Kaneka has not demonstrated by a preponderance of evidence that it satisfies the technical prong of the domestic industry requirement for the '340 patent.

VII. REMEDY & BONDING

A. General Exclusion Order

Kaneka's Position: Kaneka asserts that a general exclusion order should be granted in this case because "a good amount" of Coenzyme Q10 products enter the U.S. via downstream products. (CIB at 153.) Kaneka says that it is difficult to stop the majority of infringement without a general exclusion order. Kaneka continues, saying that to allow downstream products to enter the U.S. in this case would not effectuate the purpose of an exclusion order, which aims to eliminate unfair competition.

In its reply brief, Kaneka asserts that a general exclusion order is necessary to prevent Respondents from importing goods under alternative names or through alternate channels. Kaneka says that each of the four manufacturing Respondents MGC, Shenzhou, XKGC and ZMC have already demonstrated the use of alternative avenues of import, e.g., Maypro and Pacific Rainbow. As a result, Kaneka concludes that a limited exclusion order directed only at the present Respondents would not prevent any of the four manufacturing respondents from establishing new channels of import through non-parties to this investigation.

Respondents' Position: Respondents contend that the conditions required for a general exclusion order to be issued are not present in this investigation. Respondents say that Kaneka has not established that such an order is necessary to prevent the circumvention of a limited exclusion order. Respondents say that they served interrogatories seeking Kaneka's basis for requesting a general exclusion order. Respondents' continue that Kaneka's response cited only excerpts from the

Complaint and depositions of Respondents' witnesses, none of which show that a general exclusion order is necessary to prevent circumvention of a limited exclusion order, or that it is difficult to identify the source of the infringing products. Respondents assert that Kaneka has no basis for alleging circumvention by the Respondents and there is no evidence of a pattern of violation of Section 337, nor is it difficult to identify the source of the allegedly infringing articles. As a result, Respondents conclude that Kaneka cannot meet the high burden of proof required to establish the necessity of a general exclusion order.

Staff's Position: Staff says that the section of Kaneka's pre-hearing brief explaining why it believes issuance of a general exclusion order is warranted is extremely brief. Staff continues that Kaneka does not state which of the prongs of Section 1337(d)(2) it believes are satisfied here and makes no clear allegation that there is a widespread pattern of violation or that it is difficult to identify the source of infringing products. As a result, Staff does not believe the evidence shows that issuance of a general exclusion order is warranted.

Staff says that Kaneka appears to be requesting a hybrid exclusion order, one that excludes any product containing Q10 produced by the Respondents, regardless of whether the product is manufactured by a third party, but that does not exclude products containing Q10 made by non-Respondent producers. Staff asserts that the evidence does not show that the issuance of such an order is warranted. (Citing *Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-605, Comm'n Op. at 69, 70 (June 3, 2009).)

In its reply brief, Staff says that the Commission has recently rejected a general exclusion order request similar to the one proposed by Kaneka. (Citing *Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-605, Comm'n Op. at 69, 70 (June 3, 2009).) Staff says that, as the Commission found in the 605 investigation, Kaneka

does not identify any evidence that would indicate that it is entitled to a general exclusion order under the statutory requirements of section 337(d). Staff concludes that the facts here are similar to those in the 605 investigation and the Complainant's request should similarly be denied.

Discussion and Conclusions: I have found that, in this case, there is no violation of Section 337. Should the Commission find a violation of Section 337, however, I do not recommend that the Commission issue a general exclusion order.

Pursuant to 19 U.S.C. § 1337(d), the Commission may issue either a limited or a general exclusion order. A limited exclusion order instructs the U.S. Customs and Border Protection ("CBP") to exclude from entry all articles that are covered by the patent at issue and that originate from a named respondent in the investigation. A general exclusion order instructs the CBP to exclude from entry all articles that are covered by the patent at issue, without regard to source.

A general exclusion order is permitted in certain limited situations. Specifically, the statute provides:

> (2) The authority of the Commission to order an exclusion from entry of articles shall be limited to persons determined by the Commission to be violating this section unless the Commission determines that—
>
> (A) a general exclusion from entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named persons; or
>
> (B) there is a pattern of violation of this section and it is difficult to identify the source of infringing products.

19 U.S.C. § 1337(d)(2); *see also Certain Hydraulic Excavators*, Inv. No. 337-TA-582, Comm'n Op. (Feb. 3, 2009) (describing the standard for general exclusion orders).

Kaneka does not address either of these requirements for a general exclusion order, merely arguing that "[t]o allow downstream products to enter the U.S. in this case would not

effectuate the purpose of an exclusion order, which aims to eliminate unfair competition" (CIB at 153) and "XKGC and ZMC have already demonstrated the use of alternative avenues of import, e.g., Maypro and Pacific Rainbow." (CRB at 58.) Arguing that two named respondents, Maypro and Pacific Rainbow, import products from XKGC and ZMC does not show that a general exclusion order is necessary to prevent circumvention of a limited exclusion order, or that there is a pattern of violation and that it is difficult to identify the source of the infringing products. Thus, Kaneka has not met its burden to demonstrate that the issuance of a general exclusion order is proper in this investigation, should the Commission find a violation of Section 337.

B. Limited Exclusion Order

Kaneka's Position: Kaneka contends that granting the requested remedy will not harm the public health and welfare. Kaneka says that this case is about leveling the playing field and providing protection from unfair competitive advantage. (Citing *Certain Power Supply Controllers and Products Containing Same*, ITC Inv. No. 337-TA-541, Comm'n Op. at 10 (Aug. 29, 2006) (noting that protection of intellectual property is favored).) Kaneka continues, asserting that the same rationale applies equally in this action. Kaneka further contends that the competitive conditions and the production of articles that are directly competitive in the U.S. economy do not weigh against a limited exclusion order. Rather, Kaneka says that a number of competitors exist in the US market, aside from the Respondents and therefore, the competitive conditions in the U.S. will not be harmed. Likewise, Kaneka contends that the United States consumers will not be harmed because they will have continued and undisrupted access to either Kaneka products or non-infringing products. As a result, Kaneka concludes that an analysis of the public interest factors supports the remedy sought by Kaneka in this action.

Kaneka contends that the evidence in this investigation strongly supports the issuance of

a limited exclusion order against importing of non-licensed infringing articles into the U.S. by or on behalf of Respondents in this action. Kaneka says that the following categories of products made by Respondents and/or incorporating CoQ10 produced by Respondents, should be excluded: (1) Coenzyme Q10 in bulk form as a powder, (2) Coenzyme Q10 sold in bulk form as a food additive to companies which add the Coenzyme Q10 to food products and sell the food products to consumers, (3) Coenzyme Q10 sold as a health food supplement in tablet or capsule form, commonly found in nutritional, natural or health food stores, (4) Foods containing Coenzyme Q10 as an added ingredient.

Kaneka says that the Respondents have admitted what Kaneka needs to show for importation. (Citing Joint Stip. Of Contested Issues (05/15/12).) Kaneka says that the Respondents products that have been imported into the U.S. are as follows:

Respondent	Accused Product
ZMC	Coenzyme Q10 (Ubidecarenone) Coenzyme Q10 Powder 10%/20%/40% CWS Coenzyme Q10 Powder 50% TAB Coenzyme Q10 98% Oxidized Coenzyme Q10, in bulk form
XKGC	Coenzyme Q10 nano-emulsion 1%, 5%, and 10% Coenzyme Q10 40% CWS Food Grade Pharmaceutical Grade Coenzyme Q10 Coenzyme Q10 Powder, USP Coenzyme Q10 Powder, water soluble powder 10% United States Pharmaceutical Grade Coenzyme Q10 Coenzyme Q10 10% CWS Food Grade Coenzyme Q10 20% CWS Food Grade

Respondent	Accused Product
MGC	Bio Q10 BioQ10 Coenzyme Q10 Ubidecarenone Microactive CoQ10 PureSorbQ10 BioQ10 EX BioQ10 SA Bulk Ubidecarenone (Coenzyme Q10) Natural Coenzyme Q10 BIO Q10 Emulsifiable concentrate 10% - discontinued prior to 3/22/2011 BioQ10 WD Powder 10% BIOQ10 beads 40% BIOQ10 CD Complext Coenzyme Q10 MIX
Shenzhou	Bulk Ubidecarenone (Coenzyme Q10) Coenzyme Q10

Kaneka's reply brief says that downstream products are not products that may incidentally include CoQ10, but are products which are simply repackaged CoQ10 and as such should be included in any exclusion order. Kaneka continues, asserting that unnamed parties that sell the same goods must also be included in an exclusion order otherwise a simple name change of a party will avoid the exclusion order, rendering it ineffective.

Respondents' Position: Respondents contend that if a violation is found, the only appropriate order would be a limited exclusion order applicable to the allegedly infringing products themselves and not to any downstream products. Respondents continue that in the event that the Commission determines to issue a limited exclusion order with respect to any of the Respondents, the order should be set to terminate based on the expiration date of the '340 patent and should include a certification provision in that order. Respondents say that certification provisions are generally included in exclusion orders where U.S. Customs and Border Protection is unable to easily determine by inspection whether an imported product violates a particular exclusion order. Respondents also contend that any limited exclusion order

should be limited to the Respondents and not extend to unnamed parties. (Citing *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340 (Fed. Cir. 2008).).)

In their reply brief, Respondents contend that Kaneka's request for a limited exclusion order is overly broad. Respondents say that Kaneka lists numerous ZMC products that it requests be covered by a LEO, but these do not match the stipulation regarding importation,

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.} (Citing Stipulations of Fact Regarding ZMC-USA, L.L.C., February 16, 2012.)

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(Citing *id.*)

Staff's Position: Staff says that if a violation of Section 337 is found, Kaneka appears to request that at least a limited exclusion order be issued. Staff continues that Kaneka's pre-hearing brief identified a number of Respondents' products, some of which Respondents deny have been imported or sold in the United States after the date on which this investigation began. Staff asserts that any exclusion order should be limited strictly to the listed products sold by the Respondents, and should not extend to parties that were not named as Respondents. (Citing *Kyocera Wireless Corp. v. USITC*, 545 F.3d 1340 (Fed. Cir. 2008).)

In its reply brief, Staff says that in addition to bulk Q10 sold by Respondents, Kaneka also requests that the exclusion order include: 1) Q10 health supplements in tablet or capsule form and foods containing Q10 sold by Respondents; and 2) bulk Q10, Q10 nutritional supplements, and food containing Q10 manufactured by parties other than Respondents which incorporate some Q10 from Respondents. (Citing CIB at 151-152.) Staff asserts that any exclusion order should be strictly limited to the Q10 products sold by the Respondents, and

should not extend to the products of parties that were not named as Respondents. (Citing *Kyocera Wireless Corp. v. USITC*, 545 F.3d 1340 (Fed. Cir. 2008).)

Discussion and Conclusions: I have found that, in this case, there is no violation of Section 337. Should the Commission find a violation of Section 337, however, I recommend that the Commission issue a limited exclusion order that applies to Zhejiang Medicine Co., Ltd., ZMC-USA, L.L.C., Xiamen Kingdomway Group Company, Pacific Rainbow International, Mitsubishi Gas and Chemical Company, Mitsubishi Gas Chemical America, Inc., Shenzhou Biology and Technology Co., Ltd.,[19] as well as all of their affiliated companies, parents, subsidiaries, other related business entities, and their successors or assigns, and covers the coenzyme Q10 products found to infringe the asserted patent.

I recommend that any such limited exclusion order should not reach products of parties that were not named as respondents. In *Kyocera Wireless Corp. v. USITC*, the Federal Circuit ruled that limited exclusion orders can only apply to named respondents found to violate Section 337. 545 F.3d 1340, 1356-1358 (Fed. Cir. 2008). This decision precludes the issuance of limited exclusion orders directed to unnamed downstream parties. *Id.* Kaneka's argument that unnamed parties that sell the same goods must also be included in the limited exclusion order does not explain why the limitations of *Kyocera* should not be applied here. Moreover, in my view there is nothing here that gives rise to any exception from *Kyocera*.

I recommend that any limited exclusion order include a certification provision. The Commission has explained that "[c]ertification provisions are generally included in exclusion orders where Customs is unable to easily determine by inspection whether an imported product violates a particular exclusion order." *Certain Semiconductor Chips With Minimized Chip*

[19] Pursuant to agreement of the parties at trial, any limited exclusion order should not include Maypro Industries, LLC. (Tr. at 10:21-12:19.)

Package Size & Products Containing Same, Inv. No. 337-TA-605, Commission Opinion (July 29, 2009) (including a certification provision in an exclusion order because of the difficulty of determining whether imported products contain the infringing chipsets); *see also Certain Ground Fault Circuit Interrupters & Products Containing Same*, Inv. No. 337-TA-615, Commission Opinion (Mar. 26, 2009) (noting that a certification provision "gives U.S. Customs & Border Protection the authority to accept a certification from the parties that goods being imported are not covered by the exclusion order."). Here, because Customs would not be able to easily determine by inspection whether or not an imported product violates the exclusion order, I find that a certification provision is appropriate.

C. Cease & Desist Order

Kaneka's Position: Kaneka requests that the Commission issue a permanent order, pursuant to Section 1337(f), directing the Respondents to cease and desist from importing, selling, selling for importation, offering for sale, using, demonstrating, promoting, marketing, and/or advertising in the U.S. the Respondents' CoQ10 products that are found to be infringing one or more claims of the Asserted Patents. Kaneka says that the Commission has usually issued cease and desist orders to domestic respondents who maintain a commercially significant inventory of the infringing imported products. (Citing *Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, USITC Pub. 2391 (U.S.I.T.C. June 1991), Comm'n Op. 37-42 ("Cefadroxil").) Kaneka continues, saying that the Commission has inferred the existence of "commercially significant" domestic inventories where a respondent has failed to provide evidence to the contrary. (Citing *Certain Asian-Style Kamaboko Fish Cakes*, Inv. No. 337-TA-378 (U.S.I.T.C. Sept. 1996); *Cefadroxil*, Inv. No. 337–TA–276, USITC Pub. 2196 (U.S.I.T.C. May 1989).) Kaneka concludes by asking that the Commission issue a cease and desist order to

prevent the exploitation by Respondent of any inventories of infringing products that exist or may exist in the U.S.

In its reply brief, Kaneka asserts that even if commercially significant quantities are not currently present, a cease and desist order is necessary in the event that significant quantities are present at the time of entry of a final determination and to prevent Respondents from increasing importation and stockpiling in anticipation of an adverse final determination.

Respondents' Position: Respondents contend that I and the Commission should reject Kaneka's request for the issuance of permanent cease and desist orders against the Respondents as inconsistent with Commission precedent. Respondents say that in order to justify a cease and desist order, the Commission typically requires a complainant to establish the existence of commercially significant inventories of infringing products in the United States and that, absent a cease and desist order, the exclusion order would be circumvented. Respondents continue that limiting cease and desist orders to circumstances in which there are substantial U.S. inventories is based on the notion that exclusion orders alone are usually sufficient to give complainants complete relief.

Respondents say that Kaneka has not demonstrated that the Respondents maintain commercially significant inventories in the United States of their accused products. Respondents continue, saying that Kaneka has put forth no evidence (including expert testimony) that the Respondents' inventory levels are commercially significant. As a result, Respondents conclude that Kaneka is not entitled to a cease and desist order against the Respondents.

In their reply brief, Respondents say that Kaneka has shown no evidence that Respondents have "commercially significant inventories," nor can it be assumed from any facts in the record that such inventories are present. Respondents continue that Kaneka has not even

argued that absent a cease and desist order an exclusion order would be circumvented. Respondents say that, as a result, Kaneka has cited no facts in the record in support for its request for a cease and desist order, and none is warranted.

Staff's Position: Staff says that Commission precedent does not support the issuance of cease and desist orders against Respondents that do not have commercially significant inventories in the United States. As a result, Staff asserts that the evidence does not show that the issuance of a cease and desist order against the foreign manufacturer Respondents (i.e., ZMC, Shenzhou, MGC, and XKGC) is appropriate. Staff says Kaneka has not provided sufficient evidence that the domestic Respondents ZMC America, MGCA, and PRI have commercially significant inventories. Accordingly, Staff submits that the evidence does not show that cease and desist orders should be issued against the domestic Respondents should a violation of Section 337 be found.

In its reply brief, Staff says that Kaneka essentially concedes that it has provided no evidence to show that Respondents maintain commercially significant domestic inventories and asks that the Commission infer that such inventories exist. (CIB at 153-54.) Staff says that the investigations cited by Kaneka are easily distinguishable from the current circumstances. Staff says that in *Fish Cakes*, the Respondents had defaulted and thereby refused to provide any evidence regarding their inventories. (Citing *Certain Asian-Style Kamaboko Fish Cakes*, Inv. No. 337-TA-378, Comm'n Op. (USITC Sept. 1996).) Staff says the second case also presented a situation where no evidence had been presented regarding inventory due to the fact that it was a temporary enforcement proceeding and further had a long and complicated history indicating that domestic inventories were likely. (Citing *Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293 (USITC May 1989.).) Staff contends that Respondents participated and Kaneka had

the opportunity to obtain evidence regarding inventories yet failed to do so. Because commission precedent does not support the issuance of cease and desist orders against Respondents that do not have commercially significant inventories in the United States, Staff says that issuance of a cease and desist order against the foreign manufacturer Respondents ZMC, Shenzhou, MGC, and XKGC and the domestic Respondents ZMC America, MGCA, and PRI is not appropriate.

Discussion and Conclusions: I have found that, in this case, there is no violation of Section 337. Should the Commission find a violation of Section 337, however, I do not recommend the issuance of a cease and desist order. Section 337 provides that the Commission may issue a cease and desist order as a remedy for violation of Section 337. *See* 19 U.S.C. § 1337(f)(1). The Commission generally issues a cease and desist order directed to a domestic respondent when there is a "commercially significant" amount of infringing, imported product in the United States that could be sold so as to undercut the remedy provided by an exclusion order. *See Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, USITC Pub. 2391, Comm'n Op. on Remedy, the Public Interest and Bonding at 37-42 (June 1991); *Certain Condensers, Parts Thereof and Products Containing Same, Including Air Conditioners for Automobiles*, Inv. No. 337-TA-334, Comm'n Op. at 26-28 (Aug. 27, 1997). The complainant bears the burden of proving that a respondent has a commercially significant inventory in the United States. *Certain Integrated Repeaters, Switches, Transceivers & Products Containing Same*, Inv. No. 337-TA-435, Comm'n Op., 2002 WL 31359028 (Aug. 16, 2002). Here, Kaneka has provided no evidence regarding whether or not any of the Respondents have a commercially significant inventory in the United States. In view of this, I find that Kaneka has not met its burden to show that it is entitled to a cease and desist order.

D. Bonding

Kaneka's Position: Kaneka contends that in the present Investigation, the Parties, including Staff, agree that a bond in the amount of 10% of the entered value of any infringing imports is appropriate. In its reply brief, Kaneka says that Respondents have presented no specific arguments against the 10% bond requested by Kaneka.

Respondents' Position: Respondents contend that no bond should be imposed in this investigation. Respondents say that the Commission has recognized that it is "[t]he complainant [that] has the burden of supporting any proposition it advances, including the amount of bond." (Citing *Certain Rubber Antidegradants, Components Thereof & Prods. Containing Same*, USITC Pub. 3975, Inv. No. 337-TA-533, Comm'n Op. at 40 (April 2008).) Respondents continue, saying that I am not required to recommend any bond amount if the complainant fails to establish the need for a bond. (Citing *Certain Liquid Crystal Display Devices and Prods. Containing Same*, Inv. No. 337-TA-631, Final Initial & Recommended Determination at 223-225 (Feb. 2009).)

Respondents say that Kaneka has put forth no evidence regarding the price differentials between its products and Respondents' products. Respondents continue that the only evidence of a royalty rate is Kaneka's license of the patent-in-suit to Kaneka Nutrients LP. (Citing CX-59C.) Respondents say that I previously found that a license between Kaneka and its subsidiary was irrelevant in determining bond and recommended that no bond be imposed, and the same result is warranted here. (Citing *Polyimide Films*, 2012 WL 2131128, at *186-87.) Accordingly, Respondents conclude that Kaneka has not met its burden, and no bond should be imposed if a violation is to be found.

In their reply brief, Respondents disagree with Kaneka's statement that "all parties, including Staff, agree that a bond in the amount of 10% of the entered value of any infringing imports is appropriate." (Citing CIB at 154.) Respondents say that such an agreement was never reached; rather, Staff proposed a stipulation that a 10% bond be applied in order to reduce the number of issues for trial but Respondents never reached consensus, and Kaneka never pursued the matter. Respondents conclude that no stipulation was ever filed, and Kaneka's statement that all parties are in agreement on the bond amount is false.

Staff's Position: Staff says that Kaneka has not explained why a bond is needed, nor has it pointed to any evidence regarding royalty rates or price differentials. Staff continues, saying that in the event that a violation of Section 337 is found, Complainant has not demonstrated that a bond is warranted.

In its reply brief, Staff disagrees with Kaneka's assertion that the Parties, including Staff, agree that a bond in the amount of 10% of the entered value of any infringing imports is appropriate. Staff says that prior to the evidentiary hearing, in the interest of simplifying briefing and the hearing, the parties were negotiating a stipulation as to recommended bond amount. Staff says that the stipulation was never finalized, and thus neither Staff nor Respondents have agreed to a 10% royalty rate.

Staff says that Kaneka bears the burden of establishing the need for a bond and if the burden is not met, then no bond will be ordered. Staff continues that Kaneka has not explained why a bond is needed, nor has it pointed to any evidence regarding royalty rates or price differentials. As a result, Staff concludes that in the event that a violation of Section 337 is found, Complainant has not demonstrated that a bond is warranted.

Discussion and Conclusions: I have found that, in this case, there is no violation of Section 337. Should the Commission find a violation of Section 337, however, I do not recommend the imposition of a bond.

The administrative law judge and the Commission must determine the amount of bond to be required of a respondent, pursuant to section 337(j)(3), during the 60-day Presidential review period following the issuance of permanent relief, in the event that the Commission determines to order a remedy. The purpose of the bond is to protect the complainant from any injury. 19 CFR §§ 210.42(a)(1)(ii), 210.50(a)(3). The complainant has the burden of supporting any bond amount it proposes. *Certain Rubber Antidegradants, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-533, Comm'n Op., 2006 ITC LEXIS 591 (Jul. 21, 2006).

When reliable price information is available, the Commission has often set the bond by eliminating the differential between the domestic product and the imported, infringing product. *See Certain Microsphere Adhesives, Processes for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. a 24 (1995). In other cases, the Commission has turned to alternative approaches, especially when the level of a reasonable royalty rate could be ascertained. *See, e.g., Certain Integrated Circuit Telecommunication Chips and Products Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, Comm'n Op. at 41 (1995).

The Commission has set a bond of 100% when the evidence supported a finding that it would be difficult or impossible to calculate a bond based on price differentials. *Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, Comm'n Op., 1996 WL 1056209 (Sept. 23, 1996) (finding that a bond of 100% was appropriate "because of the difficulty in quantifying the cost advantages of respondents' imported Enercon E-40 wind

turbines and because of price fluctuations due to exchange rates and market conditions."); *Certain Systems For Detecting and Removing Viruses or Worms, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-510, Comm'n Op., 2007 WL 4473083 (Aug. 2007) (imposing a bond of 100% based on a finding that the parties had numerous models and products lines, and that a price comparison would be difficult because respondent's products were a combination of hardware and software while the complainant's products were software only); *Certain Flash Memory Circuits and Products Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 26-27 (July 1997) (a 100% bond imposed when price comparison was not practical because the parties sold products at different levels of commerce, and the proposed royalty rate appeared to be *de minimis* and without adequate support in the record).

In *Certain Rubber Antidegradants*, the Commission did not require a bond. The presiding administrative law judge had set no bond, finding, "no evidence in the record to support any bond to offset any competitive advantage resulting from the unfair acts of [respondents] from their importations." *Certain Rubber Antidegradants*, 2006 ITC LEXIS 591, at *59.

The respondent argued that the lack of pricing information was due to the complainant's failure to adduce such evidence during the hearing and complainant should not be able to benefit from that failure. (*Id.* at 60.) In response, the complainant argued that it had no burden of proof with respect to bonding, and that the existence of a violation is sufficient to support a 100% bond. (*Id.*) In deciding the issue, the Commission stated:

> We find the ALJ's recommendation appropriate in the circumstances here and have determined not to require that a bond be posted for temporary importation. In our view, the complainant has the burden of supporting any proposition it

> advances, including the amount of the bond. [The complainant] did not meet that burden.

(*Id.*)

Kaneka requests a bond of 10%, yet offers no justification to support that amount.[20] (CIB at 154.) Kaneka does not assert that calculating a bond would be difficult or impossible. (*See id.*) Rather, Kaneka says that the parties agreed to a bond in the amount of 10%. (*Id.*) Kaneka did not cite any evidence of this agreement. (*See id.*) Based on Respondents' and Staff's reply briefs, Kaneka appears to be mistaken.

In its reply brief, Kaneka says that "Respondents have presented no specific arguments against the 10% bond requested by Kaneka." (CRB at 58.) However, this attempts to improperly shift the burden from Kaneka to support its bond request, to Respondents to disprove Kaneka's bond request. Because Kaneka failed in its burden to demonstrate the appropriate bond amount, I recommend that the Commission not impose a bond if a violation of Section 337 is found.

VIII. MATTERS NOT DISCUSSED

This Initial Determination's failure to discuss any matter raised by the parties, or any portion of the record, does not indicate that it has not been considered. Rather, any such matter(s) or portion(s) of the record has/have been determined to be irrelevant, immaterial or meritless. Arguments made on brief which were otherwise unsupported by record evidence or legal precedent have been accorded no weight.

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[20] The only evidence cited by any party is CX-59C, which is a license between Kaneka Corporation and Kaneka Nutrients L.P. (CX-59C.) I have previously rejected relying on a license between a parent company and a wholly owned subsidiary to show evidence of a reasonable royalty. *See Certain Polyimide Films, Products Containing Same, and Related Methods*, Inv. No. 337-TA-772, Initial Determination at 324-327 (May 10, 2012) (unreviewed in relevant part).

IX. CONCLUSIONS OF LAW

1. The Commission has subject matter jurisdiction, *in rem* jurisdiction, and *in personam* jurisdiction.

2. There has been an importation into the United States, sale for importation, or sale within the United States after importation of the accused coenzyme Q10 products, which are the subject of the alleged unfair trade allegations.

3. An industry does not exist in the United States that exploits U.S. Pat. No. 7,910,340, as required by 19 U.S.C. § 1337(a)(2).

4. Claims 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 17, 18, 19, 20, 21, 22, 23, 24, 25, 29, 30, 31, 32, 33, 34, 35, 36, 37, 41, 42, 43, and 44 of U.S. Pat. No. 7,910,340 are not invalid pursuant to 35 U.S.C. § 102.

5. Claims 1, 2, 3, 4, 8, 9, 10, 11, 12, 13, 14, 15, 20, 21, 22, 23, 24, 25, 29, 30, 31, 32, 33, 34, 35, 36, 37, 41, 42, 43, and 44 of U.S. Pat. No. 7,910,340 are not invalid pursuant to 35 U.S.C. § 103.

6. Claims 1, 11, 22, and 33, are not invalid as unpatentable under 35 U.S.C. § 101.

7. Claims 22-45 are not invalid pursuant to 35 U.S.C. §§ 112 ¶ 1 and 132(a).

8. Claims1-45 are not invalid pursuant to 35 U.S.C. § 102(f).

9. The accused Shenzhou products do not infringe claims 1, 3-4, 6, 8-11, 13-15, 17, 19-22, 24-25, 27, 29-33, 35-37, 39, and 41-45 of U.S. Pat. No. 7,910,340.

10. The accused Maypro products do not infringe any claims of U.S. Pat. No. 7,910,340.

11. The accused XKGC and PRI products do not infringe claims 1, 4-6, 9, 11, 15-17, 20, 22, 25, 27, 29, 30, 33, 37-39, 41, 43, and 45 of U.S. Pat. No. 7,910,340.

12. The accused ZMC products do not infringe claims 1, 3, 4, 9-11, 13-15, 20-22, 24, 25,

29-31, 33, 35-37, and 41-44 of U.S. Pat. No. 7,910,340.

13. The accused MGC products do not infringe claims 1, 2, 4, 9-12, 14-15, 20-23, 25, 27, 29-31, 33-34, 36-37, 41-43, and 45 of U.S. Pat. No. 7,910,340.

14. There is no violation of 19 U.S.C. § 1337(a)(1) with respect to U.S. Pat. No. 7,910,340.

X. ORDER

Based on the foregoing, and the record as a whole, it is my Final Initial Determination that there is no violation of 19 U.S.C. § 1337(a)(1) in the importation into the United States, sale for importation, and the sale within the United States after importation of certain coenzyme Q10 products.

I hereby **CERTIFY** to the Commission my Final Initial and Recommended Determinations together with the record consisting of the exhibits admitted into evidence. The pleadings of the parties filed with the Secretary, and the transcript of the pre-hearing conference and the hearing, as well as other exhibits, are not certified, since they are already in the Commission's possession in accordance with Commission rules.

It is further **ORDERED** that:

In accordance with Commission Rule 210.39, all material heretofore marked *in camera* because of business, financial and marketing data found by the administrative law judge to be cognizable as confidential business information under Commission Rule 201.6(a), is to be given *in camera* treatment continuing after the date this investigation is terminated.

The initial determination portion of the Final Initial and Recommended Determination, issued pursuant to Commission Rule 210.42(a)(1)(i), shall become the determination of the Commission sixty (60) days after the service thereof, unless the Commission, within that period,

shall have ordered its review of certain issues therein, or by order, has changed the effective date of the initial determination portion. If the Commission determines that there is a violation of 19 U.S.C. § 1337(a)(1), the recommended determination portion, issued pursuant to Commission Rule 210.42(a)(1)(ii), will be considered by the Commission in reaching a determination on remedy and bonding pursuant to Commission Rule 210.50(a).

On or before October 10, 2012, the parties shall submit to the Office of Administrative Law Judges ***a joint statement*** regarding whether or not they seek to have any portion of this document deleted from the public version. The parties' submission shall be made by hard copy and must include a copy of this Initial Determination with red brackets indicating any portion asserted to contain confidential business information to be deleted from the public version. The parties' submission shall include an index identifying the pages of this document where proposed redactions are located. The parties' submission concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.

Issued: 9/27/2012
DATE

Robert K. Rogers, Jr.
Administrative Law Judge

CERTAIN COENZYME Q10 PRODUCTS, AND METHODS OF MAKING SAME

Inv. No. 337-TA-790

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** was served upon **Aarti Shah, Esq.,** the Commission Investigative Attorney, and the following parties via first class mail delivery on November 1, 2012

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CERTAIN COENZYME Q10 PRODUCTS, AND METHODS OF MAKING SAME

Inv. No. 337-TA-790

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