APPENDIX E — OPINION OF THE UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA, DATED FEBRUARY 22, 2017

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CV 11-02389 SJO (SSx)

CIVIL MINUTES - GENERAL UNDER SEAL

KANEKA CORP.

v.

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

February 22, 2017

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

Victor Paul Cruz	Not Present
Courtroom Clerk	Court Reporter

PROCEEDINGS (in chambers): ORDER RE: WEBSTER, SPORMANN/LIEVENSE, AND SHERMAN *DAUBERT* MOTIONS [ECF Nos. 568, 571, 590]

These matters are before the Court on the following three motions *in limine*: (1) Plaintiff Kaneka Corporation's ("Kaneka") Motion in Limine No. 1 to Preclude Admission

of Portions of the Expert Report and Testimony of Shirley Webster ("Webster Motion"), filed December 30, 2016; (2) Kaneka's Motion in Limine No. 2 to Preclude Admission of Portions of Reports on Defendants' Infringement and Invalidity Experts and Related Testimony ("Spormann/ Lievense Motion"), also filed December 30, 2016; and (3) Defendants Shenzhou Biology and Technology Co., Ltd. ("Shenzhou"), Xiamen Kingdomway Group Company ("XKGC"), Pacific Rainbow International, Inc. ("PRI"), Sojitz Corporation of America ("Sojitz"), and Rochem International, Inc.'s ("Rochem") (collectively, "Defendants") Motion in Limine No. 1, *Daubert* Motion to Exclude the Testimony of David Sherman, PhD ("Sherman Motion"), filed January 6, 2017.[1] The parties filed their respective opposition papers on January 16, 2017, and filed their respective reply papers on January 23, 2017. For the following reasons, the Court **DENIES** the Webster Motion and **GRANTS IN PART** and **DENIES IN PART** both the Spormann/Lievense and Sherman Motions.

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1. Although Defendants filed two *Daubert* motions on December 30, 2016, these motions failed to comply with paragraph 26(b)(6)(e) of the Court's Initial Standing Order, which expressly limits points and authorities to ten (10) pages. The Court struck these two motions on January 4, 2017, ordered Defendants to file compliant *Daubert* motions on or before January 6, 2017. (*See* January 4, 2017 Minute Order, ECF No. 589.) The Court will issue a separate order concerning Defendants' Motion in Limine No. 2 regarding the opinions and testimony of Kaneka's damages expert, Sam Rosenfarb.

Appendix E

I. FACTUAL AND PROCEDURAL BACKGROUND

A. General Background

This is a patent infringement action involving U.S. Patent No. 7,910,340 (the "'340 Patent"), titled "Processes for Producing Coenzyme Q_{10}." Coenzyme Q10 ("CoQ_{10}") exists in animal cells, which use CoQ_{10} to produce adenosine triphosphate ("ATP"), which aids cellular respiration. CoQ_{10} assists ATP production through redox reactions, in which the coenzyme gives up and gains electrons. Both oxidized and reduced CoQ_{10} are sold as dietary supplements.

The '340 Patent, which is owned by Kaneka, contains forty-five (45) process claims, of which three—claims 22, 33, and 36—are asserted against Defendants. Shenzhou and XKGC are Chinese entities that Kaneka accuses of directly infringing the asserted claims. (*See generally* Second Am. Compl. ("SAC"), ECF No. 412.) The Court refers to Shenzhou and XKGC collectively as "Manufacturing Defendants." Defendants PRI, Sojitz, and Rochem are American distributors of CoQ_{10} produced by Shenzhou and XKGC's manufacturing processes. (*See, e.g.,* SAC ¶ 19.)

B. The Relevant Expert Reports and Testimony

To paraphrase former Magistrate Judge Paul Grewal, there are three certainties in the world: death, taxes, and *Daubert* motions in patent litigations. As is often the case in patent matters, each side challenges the

methodology and opinions of the other side's technical and damages experts. An overview of relevant portions of the challenged reports and testimony are provided below.

1. Dr. Shirley Webster, Defendants' Damages Expert

Dr. Shirley Webster ("Dr. Webster") disclosed her Rebuttal Expert Report on damages issues ("Webster Report") on November 30, 2016. (*See* Decl. Gerald W. Griffin in Supp. Webster Mot. ("Griffin Webster Decl."), Ex. B, ECF No. 570-2.) In her report, Dr. Webster opines that XKGC, which is alleged to induce infringement of the asserted claims under 35 U.S.C. Section 271(b), can only be liable for damages beginning on the date the Federal Circuit issued its opinion affirming in part, vacating in part, and remanding Judge Pfaelzer's decision granting summary judgment of noninfringement in favor of defendants because "[a]t least until that date, XKGC would have reasonable held a good faith belief that it did not infringe the '340 patent[.]" (Webster Report 4.) Dr. Webster opines that the damages period for Shenzhou is from March 22, 2011 (the date Kaneka filed its Complaint) through the present, and provides an alternative opinion with respect to XKGC's potential damages exposure using this same damages period in the event the jury determines XKGC was on notice from the date it received a copy of the complaint in this action. (Webster Report 5.)

Dr. Webster further opines that compensation for any infringement by XKGC and Shenzhou should be based on a reasonable royalty, of which the royalty base, which

"should reflect the contribution of the '340 patent to the revenues generated from the sale of the accused CoQ_{10}," is $743,679. (Webster Report 4.) She further opines that the patented invention resulted in a "cost savings" between 2.6 and 19.7 percent for XKGC and between 1.5 and 12.1 percent for Shenzhou, and that the reasonable royalty rate should be no more than 3 percent for either of these defendants. (Webster Report 4-5.) Based on these opinions, Dr. Webster believes that XKGC should pay no more than $171,843 in reasonable royalty damages and that Shenzhou should pay no more than $447,898 in reasonable royalty damages. (Webster Report 4-5.)

In reaching these conclusions, Dr. Webster examined the purported differences between Kaneka's "NX process," which Kaneka claims is covered by the '340 Patent, and its older "QX process," which Kaneka claims is not covered by the '340 Patent. (Webster Report 26.) Dr. Webster relied on Kaneka's "four categories of advantages of [its] NX process over its QX process" that are attributable to the invention claimed in the '340 Patent in determining what "benefits" might be attributable to the '340 Patent. (Webster Report 26-27.)

2. Drs. Alfred Spormann and Jefferson C. Lievense, Defendants' Technical Experts

Dr. Alfred Spormann ("Dr. Spormann"), who was retained by both Shenzhou and XKGC on the issue of invalidity and was retained by XKGC on the issue of noninfringement, disclosed his opening expert report on invalidity on November 8, 2016. (*See* Decl. Keith D. Nowak

in Supp. Spormann/Lievense Mot. ("Nowak Spormann/Lievense Decl."), Ex. F ("Spormann Invalidity Report"), ECF Nos. 573-2, 573-8.) Dr. Spormann and Jefferson C. Lievense ("Dr. Lievense"), who was retained by Shenzhou on the issue of noninfringement, disclosed their rebuttal expert reports on noninfringement on November 30, 2016. (*See* Nowak Spormann/Lievense Decl., Exs. A ("Spormann Noninfringement Report"), B ("Lievense Noninfringement Report"), ECF Nos. 573-3, 573-4.)

In these reports, Drs. Spormann and Lievense opine that tests performed by Kaneka intended to determine whether defendants practice the "70 mole % ratio" are unreliable because, according to these experts, tests performed by Shenzhou employees revealed that Kaneka's mobile laboratory sampling procedure—under which an "extraction solvent" is added to test tubes containing cells and glass beads and five (5) minutes later the test tubes are shaken—permitted some cells to live up to ten (10) minutes, artificially increasing the mole % of reduced CoQ_{10} by more than 5%. (*See, e.g.*, Spormann Invalidity Report ¶¶ 723-733; Lievense Noninfringement Report ¶¶ 145-163.) Neither Dr. Spormann nor Dr. Lievense was present during Shenzhou's testing. (*See* Nowak Spormann/Lievense Decl., Ex. C at 118:14-119:15, Ex. D at 15:7-10, 150:2-21.)

3. Dr. David Sherman, Ph.D., Kaneka's Technical Expert

Dr. David Sherman ("Dr. Sherman"), Kaneka's technical expert, disclosed his Expert Report on Patent

Infringement ("Sherman Infringement Report") on November 8, 2016 and disclosed his Rebuttal Expert Report on the Issue of Patent Validity ("Sherman Validity Report") on November 30, 2016. (*See* Decl. Robert M. Bowick in Opp'n Defs.' Mot. for Summ. J. ("Bowick MSJ Opp'n Decl."), Ex. 2 ("Sherman Infringement Report"), ECF No. 605-5; Decl. Harold H. Davis, Jr. in Supp. Sherman Mot. ("Davis Sherman Decl."), Ex. N ("Sherman Invalidity Report"), ECF No. 591-3.) In his Infringement Report, Dr. Sherman opines that Shenzhou and XKGC's manufacturing processes practice the 70 mole % limitation, relying on certain tests conducted by PharmaForensics and other tests performed by Shenzhou. (*See generally* Sherman Infringement Report.) Dr. Sherman also opines that the 70 mole % limitation is a novel aspect of the '340 Patent that confers the ability to produce a "higher yield" of CoQ_{10} on an industrial scale. (*See* Sherman Validity Report ¶ 10.) Finally, Dr. Sherman offers opinions concerning induced infringement. (*See* Sherman Infringement Report ¶¶ 453-526.)

II. LEGAL STANDARDS

A. Motions in Limine

Motions in limine are "important tool[s] available to the trial judge to ensure the expeditious and evenhanded management of the trial proceedings." *Jonasson v. Lutheran Child & Family Servs.*, 115 F.3d 436, 440 (9th Cir. 1997). "A party may use a motion in limine to exclude inadmissible or prejudicial evidence before it is actually introduced at trial." *Barnett v. Gamboa*, No. CV 05-01022

BAM, 2013 WL 174077, at *1 (E.D. Cal. Jan. 16, 2013) (citing *Luce v. United States*, 469 U.S. 38, 40 n.2 (1984)). Regardless of a court's initial decision on a motion in limine, however, it may revisit the issue at trial. *See Luce*, 469 U.S. at 41-42 ("[E]ven if nothing unexpected happens at trial, the district judge is free, in the exercise of sound judicial discretion, to alter a previous *in limine* ruling."). "The Supreme Court has recognized that a ruling on a motion in limine is essentially a preliminary opinion that falls entirely within the discretion of the district court." *United States v. Bensimon*, 172 F.3d 1121, 1127 (9th Cir. 1999) (citing *Luce*, 469 U.S. at 41-42).

B. Relevance and Unfair Prejudice

Under the Federal Rules of Evidence ("FRE"),[2] all relevant evidence is admissible. Fed. R. Evid. 402. Evidence is relevant if it has "any tendency to make a fact [that is of consequence in determining the action] more or less probable than it would be without the evidence." Fed. R. Evid. 401. Evidence that cannot meet this standard is inadmissible. *See* Fed. R. Evid. 402. Even if relevant, evidence may be excluded "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. "A district court is accorded a wide discretion in determining the admissibility of evidence under the Federal Rules." *United States v.*

2. Unless otherwise indicated, in text references to particular Federal Rules of Evidence are hereinafter abbreviated as "FRE [X]," where [X] is the number of the referenced rule.

Abel, 469 U.S. 45, 54 (1984). Nevertheless, "[i]n making a determination under [FRE] 403, the balance in close cases is struck in favor of admission" of the evidence. *United States v. Crosby*, 75 F.3d 1343, 1347 (9th Cir. 1996) (quoting *United States v. Payne*, 805 F.2d 1062, 1066 (D.C. Cir. 1986)) (internal quotation marks omitted).

C. Expert Testimony

The Federal Rules of Evidence "assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation, and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 597(1993). In serving this "gatekeeper" function, a district court performs a two-part analysis. *Domingo v. T.K.*, 289 F.3d 600, 605 (9th Cir. 2002). First, a district court "must determine nothing less than whether the experts' testimony reflects scientific knowledge, whether their findings are derived by the scientific method, and whether their work product amounts to good science." *Daubert v. Merrell Dow Pharms. (Daubert II)*, 43 F.3d 1311, 1315 (9th Cir. 1995) (internal quotations and citations omitted). "*Daubert*'s general holding—setting forth the trial judge's general 'gatekeeping' obligation—applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). Second, the court "must ensure that the proposed expert testimony is 'relevant to the task at hand' i.e., that it logically advances a material aspect of the proposing party's case." *Daubert II*, 43 F.3d at 1315 (citation omitted).

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When considering whether expert testimony is reliable, a trial court should consider the factors laid out by the United States Supreme Court in *Daubert*, 509 U.S. at 593-595, including: (1) "whether the theory or technique employed by the expert is generally accepted in the scientific community;" (2) whether "it's been subjected to peer review and publication;" (3) "whether it can be and has been tested;" and (4) "whether the known or potential rate of error is acceptable." *Daubert II*, 43 F.3d at 1316-17 (citing *Daubert*, 509 U.S. at 593-595). The Supreme Court acknowledged in *Daubert* that the trial judge's reliability inquiry is "flexible," and therefore trial courts are encouraged to consider other factors not specifically mentioned by the Supreme Court in *Daubert*. *Daubert*, 509 U.S. at 594. To that end, trial courts have also considered other potentially relevant factors, including (1) "whether the expert is proposing to testify about matters growing directly out of independent research he or she has conducted or whether the opinion was developed expressly for the purposes of testifying;" (2) whether the expert has "unjustifiably extrapolated from an accepted premise to an unfounded conclusion;" (3) "whether the expert has adequately accounted for obvious alternative explanations;" (4) "whether the expert is being as careful as he would be in his regular professional work;" and (5) "whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion offered." *In re Silicone Gel Breast Implants Litigation*, 318 F. Supp. 2d 879, 890 (C.D. Cal. 2004) (citing Fed. R. Evid. 702 Advisory Committee's Notes).

III. DISCUSSION

A. Webster Motion

Kaneka raises two arguments as to why Dr. Webster's damages opinions are unreliable. First, it contends Dr. Webster improperly apportioned Shenzhou and XKGC's royalty bases to reflect what she and Defendants' technical experts assert as Defendants' "hypothetical cost savings" in using processes allegedly covered by the '340 Patent over older processes that are not covered. (Mem. of Ps & As in Supp. Webster Mot. ("Webster Mem.") 4, ECF No. 570-1.) Second, it submits that even if Dr. Webster could reliably apportion the royalty base, because she apportions the alleged "hypothetical cost savings" differently for Shenzhou and XKGC based on their actual manufacturing costs while admitting the alleged savings to each defendant is the same, her testimony should be stricken. (Webster Mem. 8.) Finally, it argues Dr. Webster should be precluded from testifying that the damages period for XKGC began on June 10, 2015. (Webster Mem. 9-10.).

1. Dr. Webster's Apportionment of the Royalty Base Does Not Run Afoul of Rule 702

With respect to the issue of apportionment, the Court agrees with Defendants that Dr. Webster's methodology underlying her royalty base calculation is sufficiently reliable to pass muster under Rule 702. In *AstraZeneca AB v. Apotex Corp.*, the Court of Appeals for the Federal Circuit reiterated the longstanding principle that even when the EMVR does not apply, "[w]hen a patent covers

the infringing product as a whole, and the claims recite both conventional elements and unconventional elements, the court must determine how to account for the relative value of the patentee's invention in comparison to the value of the conventional elements recited in the claim, standing alone." 782 F.3d 1324, 1338 (Fed. Cir. 2015) (citing *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1233 (Fed. Cir. 2014) for the proposition that "the patent holder should only be compensated for the approximate incremental benefit derived from his invention").

The companion litigation that proceeded in the Southern District of Texas is highly illuminating. In that action, the court, in denying Kaneka's motion to exclude Webster's substantially similar damages opinions, found "Kaneka's arguments regarding the EMVR [to be] inapposite" because "Dr. Webster's royalty base calculation is not premised on an application of the EMVR, or even on an application of a 'reverse' form of the EMVR." (Decl. Harold H. Davis in Opp'n Webster Mot. ("Davis Webster Decl."), Ex. A ("Texas Webster Ruling") at 9, ECF No. 614-2.) Instead, Webster "correctly apportioned [defendant's] total revenue from its accused sales, according to 'the contribution of the '340 Patent to the coenzyme Q_{10} production process." (Texas Webster Ruling 10.) Indeed, the court noted Webster relied on statements and opinions from Kaneka's own witnesses, employees, and experts in reaching her conclusion regarding the proper royalty base, and concluded that challenges regarding the weight of her testimony are properly challenged through cross-examination. (Texas Webster Ruling 10-11.) Moreover, the court found that "it is clear

that the '340 Patent is an improvement to older processes of manufacturing coenzyme Q_{10}" and that Webster's "apportionment of the royalty base adequately represents what [defendant] may have been willing to pay to obtain a license to the '340 Patent." (Texas Webster Ruling 11.) Although Kaneka argues that the judge in the Southern District of Texas erred in her application of *AstraZeneca* to exclude Dr. Webster, this Court nevertheless finds Judge Milloy's reasoning to be persuasive.

Kaneka argues that apportionment is not proper where the "patented feature creates the 'basis for customer demand' or 'substantially create[s] the value of the component parts[,]'" citing to *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1318 (Fed. Cir. 2011). (*See* Webster Mem. 4.) This argument is wholly misplaced, as it is **Kaneka's** burden to demonstrate that the EMVR applies, not Defendants' burden to demonstrate that it does not.

To the extent Kaneka argues Dr. Webster's opinions are unreliable because the asserted claims cover "an entire process" rather than a multi-component product such that "the EMVR, and the related line of cases" do not apply, such an argument misunderstands that apportionment is a fundamental concept in patent damages that is not limited to the EMVR context. This is because a "key inquiry" in the reasonable royalty analysis "is what it would have been worth to the [infringer], as it saw things at the time, to obtain the authority to use the patented technology, considering the benefits it would expect to receive from using the technology and the alternatives it might have

pursued." Carnegie *Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1304 (Fed. Cir. 2015). Indeed, Dr. Webster points to testimony from Kaneka's own witnesses and experts indicating Kaneka's old QX process is not covered by the patented claims and analyzing the cost savings Kaneka has realized by switching to the patented NX process, after taking into account cost savings that might be attributable to features other than those covered in the '340 Patent. (*See generally* Webster Report 47-55.) Kaneka cites no authority in support of its argument that apportionment of the royalty base is inappropriate where process claims, rather than multi-component product claims, are concerned.

To the extent Kaneka decries Dr. Webster's decision to calculate the "hypothetical cost savings" of Shenzhou and XKGC based on their actual costs, the Court disagrees that this decision renders her methodology unreliable. Dr. Webster first attempts to calculate the cost savings in costs per kilogram that Kaneka achieved by switching to the patented process. (Webster Report 50-52.) After opining that there was "no indication that the same or similar benefits are experienced by XKGC or Shenzhou in their production processes," Dr. Webster then examined the "hypothetical cost savings" each defendant may have achieved if they had used the alleged patented invention. (Griffin Webster Decl., Ex. C at 132:14-133:7, 135:13-136:22.) She then compared these potential cost savings with each defendant's cost of sales, determining that the hypothetical cost savings was 2.6% of XKGC's production costs and 1.9% of Shenzhou's costs. (*See* Webster Report 53-54.) The Court finds nothing fundamentally unsound

about opining that each defendant's royalty base should reflect the incremental benefit it might have realized through switching from an unpatented process to the patented process given its unique manufacturing processes, cost structure, and sales practices. Kaneka can challenge the conclusions reached by Dr. Webster in employing her apportionment and hypothetical cost methodologies through cross-examination.

2. Whether XKGC Had a Good-Faith Belief of Noninfringement Prior to the Federal Circuit Issuing Its Opinion Is a Question for the Jury

Kaneka next argues that Dr. Webster should be precluded from testifying as to her opinion that XKGC is not liable for any infringement prior to the date the Federal Circuit issued its opinion affirming in part, vacating in part, and remanding Judge Pfaelzer's decision granting summary judgment of noninfringement in favor of defendants because Dr. Webster "may not use counsel's opinions as a sword to limit damages, and then as a shield to prevent discovery of the facts allegedly supporting her own opinions." (Webster Mem. 10.)

In *Commil USA, LLC v. Cisco Systems, Inc.*, 720 F.3d 1361 (Fed. Cir. 2013), *vacated on other grounds*, 135 S. Ct. 1920 (2015), the Federal Circuit implicitly held that although an accused infringer's good-faith belief of noninfringement could negate the requisite intent for induced infringement, that determination is reserved for the fact finder:

> We now hold that evidence of an accused inducer's good-faith belief of [noninfringement] may negate the requisite intent for induced infringement. This is, of course, not to say that such evidence precludes a finding of induced infringement. Rather, it is evidence that should be considered by the fact-finder in determining whether an accused party knew "that the induced acts constitute patent infringement."

Id. at 1368-69. Although Kaneka claims Dr. Webster improperly "refused to testify about [the opinions of XKGC's counsel regarding noninfringement] on the grounds of attorney client privilege," the Court declines to prophylactically limit Dr. Webster's testimony on this issue at this juncture. First, Dr. Webster offered an alternative opinion regarding XKGC's damages exposure in the event it is determined that the jury determines XKGC's alleged infringement of the '340 Patent began on March 22, 2011. (*See* Webster Report 55.) Moreover, in order to prevail on its good-faith defense, XKGC will need to present evidence regarding why it believed, in good faith, that it did not infringe the asserted claims between the date it received notice of Kaneka's Complaint and the date on which the Federal Circuit issued its opinion. Kaneka will be afforded an opportunity to cross-examine XKGC and its witnesses if such testimony is offered. To the extent Kaneka claims XKGC improperly denied Kaneka discovery into the issue of why XKGC believed it did not infringe the asserted claims after receiving notice of its alleged infringement, Kaneka should have raised the issue with the assigned Magistrate Judge.

3. Conclusion

For the foregoing reasons, the Court **DENIES** the Webster Motion in its entirety.

B. Spormann/Lievense Motion

In the Spormann/Lievense Motion, Kaneka asks the Court (1) to exclude these experts' opinions to the extent they center on Shenzhou's data and cell viability tests performed by Shenzhou's employees; and (2) to exclude Dr. Spormann's noninfringement opinions to the extent they are based on incorrect claim constructions. (*See generally* Mem. of Ps & As in Supp. Spormann/Lievense Mot. ("Spormann/Lievense Mem."), ECF No. 573-1.) These two arguments are addressed in turn.

1. Drs. Spormann and Lievense's Reliance on the Shenzhou Tests

The Court disagrees with Kaneka to the extent it argues that because neither Dr. Spormann nor Dr. Lievense participated in or observed the employee-run testing at Shenzhou's facility, they are unable to demonstrate that the data or cell viability test results "are based on sound science." Before turning to the merits of this argument, the Court notes that these opinions were offered to challenge the reliability of the "mobile laboratory" sampling method created and used by Dr. Sherman and are not solely based on the testing performed by Shenzhou employees.

Although it is true that Drs. Spormann and Lievense admit they were not physically present during the "mobile laboratory" testing conducted by Shenzhou employees, both testified that they spoke with the employees who performed the tests about the sampling procedures they followed. (Nowak Spormann/Lievense Decl., Ex. C at 118:5-120:3, Ex. D at 150:2-25; cf. Spormann/Lievense Mem. 4 (contending that these experts' opinions were "based solely on their review of data and photographs").) Federal Rule of Evidence 703 provides that "[a]n expert may base an opinion on facts or data in the case that the expert **has been made aware of** or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted." Fed. R. Evid. 703 (emphasis added). Indeed, in *Monsanto Co. v. David*, the Federal Circuit permitted an expert's "reliance on seed report tests that were produced by [Plaintiff's] scientific team but not by [the expert] personally." 516 F.3d 1009, 1015 (Fed. Cir. 2008).

In any event, Kaneka's challenges concerning whether the proper protocol was followed and whether Shenzhou's production strain of *Rhodobacter sphaeroides*, rather than a different strain, was used go to the weight of these experts' opinions rather than the admissibility of such opinions. Indeed, both sides will have an opportunity at trial to lay the foundation for and/or challenge the methods used in the Shenzhou tests. Kaneka's reliance on Dr. Sherman's testimony concerning the "errors" allegedly made by the Shenzhou employees is therefore misplaced—Dr. Sherman's challenges go to the weight

of the opinions offered by Drs. Spormann and Lievense, rather than the admissibility of their opinions. *See, e.g., Microfinancial, Inc. v. Premier Holidays Int'l, Inc.*, 385 F.3d 72, 81 (1st Cir. 2004) ("The objection regarding the scope of Killion's investigation of the accounts goes to the weight, not the admissibility, of his testimony.") (citing *Int'l Adhesive Coating Co. v. Bolton Emerson Int'l*, 851 F.2d 540, 545 (1st Cir. 1988) for the following language: "When the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony—a question to be resolved by the jury."). The Court therefore **DENIES** the Spormann/Lievense Motion on this basis.

2. Kaneka's Arguments Regarding Claim Construction Issues

Kaneka next raises a host of arguments concerning whether the opinions of Drs. Spormann and Lievense rely on impermissible claim constructions. It is a bedrock principle of patent law that testimony that is contrary to or ignores the court's claim construction is unhelpful to the trier of fact and is therefore inadmissible. *See, e.g., MarcTec, LLC v. Johnson & Johnson*, 664 F.3d 907, 913 (Fed. Cir. 2012); *see also Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1224 & n. 2 (Fed. Cir. 2006) (holding that the district court did not err in excluding expert testimony inconsistent with the court's claim construction ruling).

Kaneka principally argues that Drs. Spormann and Lievense should be precluded from offering opinions that

apply different constructions in the noninfringement and invalidity contexts. (*See* Spormann/Lievense Mem. 4-5.) Kaneka next contends that these experts should be precluded from offering opinions that apply constructions inconsistent with those applied by Judge Pfaelzer and by the Federal Circuit. (Spormann/Lievense Mem. 6.) Although "[i]t is axiomatic that claims are construed the same way for both invalidity and infringement," the Court does not find these issues to be as black and white as Kaneka suggests. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (citation omitted).

At his deposition, Dr. Spormann made clear that his opinions relied on different constructions of the terms "oxidation," "microorganism," and "sealed tank" in the noninfringement and invalidity contexts. (Nowak Spormann/Lievense Decl., Ex. F at 159:19-162:22.) Defendants contend that to the extent these experts' opinions applied different constructions in these different contexts, they only did so because their noninfringement opinions were offered specifically to rebut Kaneka's characterization of the Federal Circuit's construction of these terms. (*See* Mem. of Ps & As in Opp'n Spormann/Lievense Mot. ("Spormann/Lievense Opp'n") 9-10, ECF No. 621-1.) In an effort to ensure that the parties and there experts do not attempt to argue claim construction to the jury, the Court clarifies the proper construction of these three terms. *Cf. Apple, Inc. v. Samsung Elecs. Co., Ltd.*, No. 12-CV-00630-LHK, 2014 WL 660857, at *3 (N.D. Cal. Feb. 20, 2014) ("Arguing claim construction to the jury is inappropriate because it risks confusion and the likelihood that a jury will render a verdict not supported by substantial evidence.").

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With respect to the terms "**microorganisms**" and "**reduced coenzyme Q_{10}-producing microorganisms,**" the Court rules (1) that photosynthetic bacteria and yeast may fall within the scope of the term "microorgamisms," and rejects Defendants' prosecution history disclaimer argument; and (2) that the claims do not require testing of the bacteria pursuant to the standard assay set forth between column 4, line 51 and column 5, line 43 of the '340 Patent. Defendants and their experts are thus **PRECLUDED** from offering opinions that seek to import such limitations into these claim terms.

With respect to the term "**sealed tank,**" the Federal Circuit's construction of the term requires that extraction be performed "by an organic solvent in a tank that prevents exposure of the tank's contents to the atmosphere." (Opinion 9, ECF No. 352.) The parties dispute whether this construction requires that the extraction tank prevent exposure of the tank's contents to the atmosphere during the entire extraction process. According to the Federal Circuit,

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

(Opinion 8.) The only tenable reading of this limitation is that the tank must prevent exposure of its contents to

the atmosphere for the entire duration of the extraction step, or else the contents of the tank could be exposed to the atmosphere for at least a portion of the extraction step. The Court therefore declines to preclude Drs. Spormann and Lievense from opining that the extraction system must be "sealed . . . all the time." In addition, the Court **PRECLUDES** the parties and their experts from testifying or opining that extraction can be performed in a "sealed tank" even if the contents of the tank are exposed to the atmosphere for a portion of the extraction step.

Finally, the Court addresses the opinions offered by Drs. Spormann and Lievense that a "baseline" for "passive **oxidation**" is required to determine whether a process can be considered one that "actively oxidizes." Although the Court disagrees with Defendants and their experts that such a baseline is "required" under the Federal Circuit's construction of the oxidizing step, it also disagrees with Kaneka that these experts' opinions on this issue are "irrelevant" or are improper attempts to "circumvent" the Federal Circuit's construction of this limitation. The Federal Circuit held that "oxidation requires an active step." (Opinion 10.) The Federal Circuit also held, however, that "because the claims affirmatively recite the step of 'oxidizing,' 'oxidizing' cannot be interpreted as doing nothing, or to simply allow oxidation to occur on its own." (Opinion 10.) Thus, whether certain "actions"—including washing and drying—"simply allow oxidation to occur on its own" or increase the rate of oxidation beyond this "passive" level are questions the parties' experts are capable of addressing at trial. Kaneka and its experts may be able to demonstrate that washing and drying

increase the oxidation rate without reference to a "passive baseline," and Defendants' experts can challenge these conclusions, among other means, by questioning why Kaneka chose not to compare these methods with "passive oxidation."

C. Sherman Motion

Defendants raise a number of arguments with respect to the opinions offered by Kaneka's technical expert, Dr. Sherman. First, they argue that his opinions and testimony based on Kaneka's testing of Defendants' manufacturing processes should be stricken as unreliable in light of his failure to follow his own testing protocol. (Mem. of Ps & As in Supp. Sherman Mot. ("Sherman Mem.") 1-5, ECF No. 591-1.) Second, they contend that Dr. Sherman's opinions and testimony regarding a higher yield of CoQ_{10} should be stricken as unsupported. (Sherman Mem. 6-7.) Finally, they submit that Dr. Sherman should be precluded from offering opinions regarding or testifying about factual disputes in the evidentiary record or providing legal conclusions. (Sherman Mem. 7-9.) These arguments are addressed below.

1. Alleged Issues with the PharmaForensics Protocol and Dr. Sherman's Deviations from the Protocol

Defendants begin by raising a litany of issues concerning the PharmaForensics Protocol and Dr. Sherman's undisputed failure to follow certain aspects of the protocol. These alleged shortcomings include (1) failing

to validate this protocol; (2) failing to place samples on ice between collection and sampling; (3) failing to disrupt the cells at the point of collection; (4) "cherry-pick[ing] the measurements" favorable to Kaneka; (5) failing to show the protocol solved the 70 mole % problems identified in the ITC Proceedings; (6) relying on a rationale "contrary to the scientific literature;" (7) failing to analyze Defendants' test results; and (8) resulting in impermissibly high standard deviations. (*See generally* Sherman Mem. 1-6.)

a. Dr. Sherman's Decisions to Use a Solvent Mixture, Rather than Ice, to Stop Microbial Cell Metabolism and to Wait to Disrupt the Microbial Cells Until Reaching the Mobile Laboratory

Defendants principally challenge Dr. Sherman's decision to add a solvent mixture to the samples containing microbial cells in order to stop the cells' metabolic activity rather than to place the samples on ice, as is required under the PharmaForensics Protocol. (Sherman Mem. 2-4.) Defendants also contend that Dr. Sherman improperly chose not to physically disrupt the microbial cells at the point of collection by vigorous shaking with glass beads, even though this measure could have been taken. (Sherman Mem. 2-4.)

Kaneka does not dispute that Dr. Sherman did not place the samples on ice, but instead argues that placing the samples on ice "would have had no effect" given Dr. Spormann's earlier testimony that it would take thirty-five

to fifty-five minutes for the temperature of a fermentation sample to become cold enough to stop the microbial cells from metabolizing. (Mem. of Ps & As in Opp'n Sherman Mot. ("Sherman Opp'n") 6, ECF No. 618-1.)

The Court agrees with Defendants that Kaneka has failed to meet its burden of demonstrating that Dr. Sherman's decisions (1) to add a mixture of n-hexane and isopropanol to the samples within seconds of collection rather than to place the samples on ice; and (2) to not physically disrupt the cells at the point of collection are the products of "scientifically valid principles." *Daubert*, 509 U.S. at 597. The Court begins by noting that the PharmaForensics Protocol (and Dr. Sherman's deviation from the protocol) were created expressly for the purpose of litigation. (*See* Davis Sherman Decl., Ex. B at 1.) Where, as here, "the proffered expert testimony is not based on independent research, the party proffering it must come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles.'" *Daubert II*, 43 F.3d at 1317-18. "Establishing that an expert's proffered testimony grows out of pre-litigation research or that the expert's research has been subjected to peer review are the two principal ways the proponent of expert testimony can show that the evidence satisfies the first prong of Rule 702." *Id.* at 1318. "Where such evidence is unavailable, the proponent of expert scientific testimony may attempt to satisfy its burden through the testimony of its own experts." *Id.* at 1318-19. "For such a showing to be sufficient, the experts must explain precisely how they went about reaching their conclusions and point to some objective source—a learned treatise, the policy

statement of a professional association, a published article in a reputable scientific journal or the like—to show that they have followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in their field." *Id.* at 1319. Kaneka has failed to make these expert-driven showings.

Although Shenzhou's own expert testified that one known method of quickly stopping a cell's metabolism is to "add some sort of solvent or solvent mixture," (*see* Bowick MSJ Opp'n Decl., Ex. 4 at 129:8-18), Kaneka has not pointed to anything in the scientific literature demonstrating that the addition of a mixture of n-hexane and isopropanol in the amounts used by Dr. Sherman to a broth containing the bacterium *Rhodobacter sphaeroides* under an inert gas atmosphere "immediately kills the microorganisms upon contact" such that refrigeration would be "unnecessary." (Cf. Sherman Infringement Report ¶ 122.) Nor has Kaneka pointed to any studies that it or its experts have conducted showing that the addition of a mixture of n-hexane and isopropanol in the amounts used by Dr. Sherman to a broth containing the bacterium *Rhodobacter sphaeroides* under an inert gas atmosphere, without immediate physical disruption, have the effect of "immediately killing" the microbial cells.

According to Defendants, these evidentiary shortcomings are particularly problematic in light of peer-reviewed literature demonstrating that bacteria may continue to survive after being placed in a mixture of organic solvents. (*See* Decl. Jefferson C. Lievense in Supp. Sherman Mot. ("Lievense Sherman Decl."), Exs.

B-D, ECF No. 580.) Kaneka responds by arguing that these articles are inapposite because they involve bacteria other than *Rhodobacter sphaeroides* and also study the addition of solvents at significantly lower amounts "v/v" than that used by Dr. Sherman. (*See* Mem. of Ps & As in Opp'n Sherman Mot. ("Sherman Opp'n") 5-6, ECF No. 618-1; Decl. David H. Sherman in Supp. Sherman Opp'n ("Sherman Sherman Decl.") ¶¶ 4-11, ECF No. 618-6.) Although the Court acknowledges there might be differences, perhaps even substantial differences, between these studies and the methodology employed by Dr. Sherman, the Court agrees with Defendants that these studies demonstrate the scientific principle that "the survivability of some bacteria in solvents has been studied and shown." (Mem. of Ps & As in Reply Sherman Mot. ("Sherman Reply") 2, ECF No. 626-1.)

The existence of this principle is particularly notable in light of Dr. Sherman's decision not to "disrupt" the samples until reaching the mobile laboratory (approximately five minutes away from the sample collection site), coupled with results of testing using the PharmaForensics Protocol conducted by Shenzhou employees and by third-party Chemir Analytical Services ("Chemir"). These results tend to show (1) that bacterial cells survive contact with the solvent mixture used by Dr. Sherman in test tubes for as long as 10 minutes, and that delaying physical disruption of the cells by as little as five minutes causes the mole % of reduced CoQ_{10} to increase by more than 5%; and (2) that if the cells are killed immediately upon collection by physical disruption, the ratio of reduced CoQ_{10} among the entire coenzymes Q_{10} is below 70 mole % even after a day

of sample collection. (*See* Lievense Sherman Decl. ¶¶ 3-13, Ex. K at SHZO_001512-16, Ex. L at SHZO_002288-95; Decl. Rachel Rensing in Supp. Sherman Mot. ("Rensing Sherman Decl.") ¶ 5, Ex. F at SHZO_001553.) Even though Kaneka challenges the accuracy and results of these tests,[3] the point remains that the burden of proving admissibility under Rule 702 **rests with Kaneka,** which has failed to identify any "objective source" demonstrating that the addition of the solvent mixture in the amounts used by Dr. Sherman without immediate physical disruption is sound according to the scientific community. *Daubert II*, 43 F.3d at 1319. Indeed, Dr. Sherman testified that a proper way of determining whether the addition of a solvent mixture would immediately stop microbial cells from growing would be "to have controls" such as a "mock solvent like a buffer." (Davis Sherman Decl., Ex. E at 44:8-25.) For whatever reason, neither Kaneka nor Dr. Sherman performed such a controlled experiment. (*See, e.g.,* Davis Sherman Decl., Ex. E at 23:10-26:2 [claiming there is no need to conduct a study to determine whether microbial cells survive the addition of solvent more for any significant period of time because it is "so fundamental," and analogizing that one does not need to "go into outer space [when] someone tells you there is no oxygen in outer space [and that] you're not going to survive that" to test the hypothesis].)

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3. The Court takes seriously Defendants' argument that because Kaneka refused to permit them to take Dr. Kittendorf's deposition on the grounds of privilege, Kaneka should not be permitted to rely on Dr. Kittendorf's declaration to criticize Chemir's testing methodology while preventing discovery into his underlying opinions.

Dr. Sherman's opinions and testimony on this point are problematic for a second reason: he opines that refrigerating the samples for 5-7 minutes was "unnecessary" in light of the addition of the solvent mixture, notwithstanding that the PharmaForensics Protocol, which he helped design, specifically calls for placing the samples on ice between sample collection and testing. (Davis Sherman Decl., Ex. E at 203:11-22; Ex. B at 3-4; Ex. L at ¶ 14 [calling for placing the samples on ice].) When questioned about this decision at his deposition, Dr. Sherman testified that "[t]here was no upside or downside [to placing the samples on ice] and it was one extra step so we eliminated it at the end," even though he was offered ice by XKGC. (Davis Sherman Decl., Ex. E at 204:4-12.) According to Dr. Sherman, this decision was made because he "**wanted to move as quickly as possible.** We put a lot of time and money into building this laboratory and developing the logistics to work in Inner Mongolia, and once we had our samples, we wanted to move as quickly as possible with the lab to complete the task." (Davis Sherman Decl., Ex. E at 204:13-21 [emphasis added].)

This unsupported explanation defies both logic and the record. Kaneka failed to prove infringement before the ITC in large part because of the undisputed impact that refrigeration and freezing have on the microbial cells' ability to metabolize. Indeed, tests performed by Shenzhou confirmed that when microbial cell samples collected from a fermentation tank are not placed on ice, the results are biased toward a higher ratio of CoQ_{10}. (Davis Sherman Decl., Ex. J at ¶ 143.) This fact, coupled with Kaneka's affirmative decision to include a step in the

PharmaForensics Protocol calling for placing the samples on ice, casts serious doubt on Dr. Sherman's testimony that there was "no upside or downside" to cooling the samples.[4] Moreover, it does not take a person of skill in the art to recognize that good science is not conducted by those who "want[ ] to move as quickly as possible."

In summation, the central problem with Kaneka's position is one squarely addressed in *Daubert II*: "the expert's bald assurance of validity is not enough." 43 F.3d at 1316. Kaneka, as "the party presenting the evidence[,] must show that the expert's findings are based on sound science, and this will require some objective, independent validation of the expert's methodology." *Id.* Kaneka has not even attempted to make this showing, and instead relies on Dr. Sherman's *ipse dixit* based on his "35 years of experience as a microbiologist[.]" (Sherman Sherman Decl. ¶ 10.) The Court accordingly finds Kaneka's July 2016 testing of whether Shenzhou and XKGC's manufacturing processes practice the 70 mole % limitation using the PharmaForensics Protocol—including Dr. Sherman's

4. Kaneka argues that placing the samples on ice "would have had no effect" given Dr. Spormann's earlier testimony that it would take thirty-five to fifty-five minutes for the temperature of a fermentation sample to become cold enough to stop the microbial cells from metabolizing. (Sherman Opp'n 6) This argument fails to consider the distinct possibility that refrigerating or the samples or placing the samples on ice for five to seven minutes could have a significant impact on the cells' ability to metabolize, regardless whether complete metabolic cessation only occurs on a longer timeframe. Kaneka bears the burden of coming forth with "objective evidence" that freezing for five to seven minutes "would have had no effect."

deviation therefrom—to be unreliable under Rule 702. The Court **PRECLUDES** Kaneka and its witnesses from testifying and offering opinions regarding the results of their testing of the 70 mole % limitation under this protocol. This ruling does not, however, bar Kaneka from introducing evidence or argument at trial regarding testing of the 70 mole % limitation performed by others, such as Shenzhou and Chemir, using the PharmaForensics Protocol, as Defendants have not demonstrated that this protocol, if followed, is unreliable.

b. The Data Considered by Dr. Sherman

Defendants next claim that Dr. Sherman "cherry-picked" only favorable measurements that he took, failed to analyze Shenzhou and XKGC's results, and reached conclusions with standard deviations that render his results "insufficiently precis[e]." (Sherman Mem. 5-6.) The Court disagrees that these methods render Dr. Sherman's methodology unreliable.

The Court begins by rejecting the last of these arguments, as Defendants offer no support for their conclusion that because one standard deviation below a particular mole % reduced CoQ_{10} average ratio brings the ratio below the 70% certain threshold, relying on that average renders an expert's opinion unreliable. Attacks on the accuracy of an expert's conclusions, rather than her methodology, are not a basis for exclusion under Rule 702.

The Court next considers Defendants' argument that because Dr. Sherman "picks and chooses" only favorable

testing data and fails to consider unfavorable data from Shenzhou and XKGC, his opinions run afoul of Rule 702. In response to this accusation, Kaneka first argues that "the only test results required to prove infringement were the results taken while the microorganisms were still alive and fermenting" and that "[t]hose results were all over" 70 mole %. (Sherman Opp'n 7.) Kaneka then submits that "Dr. Sherman did refer to Shenzhou's own test results in his expert report because they were at least close to the amounts found by Kaneka," but does not cite to the portion of Dr. Sherman's report that cites to this data. (Sherman Opp'n 7.) Finally, Kaneka contends that "Dr. Sherman was well aware of [XKGC's] test results but did not refer to [these] results . . . because [XKGC's] results were approximately ½ the amounts Kaneka and Shenzhou found during fermentation in Shenzhou's process" such that "one skilled in the art could only conclude that [XKGC] did not correctly follow Kaneka's protocol." (Sherman Opp'n 7 & n. 4.)

Although the Court is troubled by Dr. Sherman's failure to explain in his Infringement Report why he considered certain samples but did not consider others in reaching his conclusions regarding the 70 mole % limitation, it does not find that preclusion is warranted pursuant to Rule 702. Defendants point to a sample taken at 84 hours from XKGC's fermentation tank that showed an average ratio of 65.73% with a standard deviation of 4.13%. (*See* Davis Sherman Decl., Ex. M at KAN-CDCAL-23690.) Kaneka responds that "the only test results required to prove infringement were the results taken while the microorganisms were still alive

and fermenting" and that "[t]hose results were all over 70 mole%." (Sherman Opp'n 7.) Although the particulars of this argument are difficult to glean from Kaneka's opposition papers, the Court understands that this 84-hour sample falls outside the "fermentation" step (i.e., "too late" in the process), while the samples taken at 42 hours and 72 hours fall within this step. Defendants can question Dr. Sherman regarding his decision not to address the 84-hour sample through cross-examination and through their rebuttal experts.

The Court also rejects Defendants' argument that Dr. Sherman inexplicably failed to consider data from Shenzhou and XKGC's testing of their own manufacturing processes. First, Dr. Sherman expressly considered Shenzhou's findings in paragraph 131 of his Infringement Report. (*See* Sherman Infringement Report ¶ 131.) Second, although it is true that Dr. Sherman decided not to reference XKGC's testing of its own plant in his Infringement Report, Kaneka accuses these results of being "so low that one skilled in the art could only conclude that [XKGC] did not correctly follow Kaneka's protocol." (Sherman Opp'n 7 n. 4.) Although it undoubtedly would have been wise for Dr. Sherman to address this point in his Infringement Report, rather than in an opposition to a motion *in limine*, the Court concludes that this argument must be tested through vigorous cross-examination. At the very least, the Court does not find Dr. Sherman's selection of test results to be the sort of "cherry-picking" condemned by courts. *Cf. E.E.O.C. v. Freeman*, 778 F.3d 463, 469-70 (4th Cir. 2015) (collecting cases and finding that the expert's "100% failure rate," which "wildly varie[d]

from the 3.5% failure rate for criminal checks and 9.9% failure rate for credit checks reflected in the rest of the data," which the district court termed "an egregious example of scientific dishonesty," warranted exclusion); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176-77 (N.D. Cal. 2007) (excluding expert's testimony where he wholesale rejected "meta-analysis," notwithstanding that plaintiffs other experts relied on such studies and even found one to be a "good study").

2. Testimony Regarding "Higher Yield"

Defendants next argue that the Court should strike Dr. Sherman's testimony that an industrial- scale process that includes a process step for "culturing reduced coenzyme Q_{10}-producing microorganisms to obtain . . . reduced coenzyme Q_{10} at a ratio of not less than 70 mole % among the entire coenzymes Q_{10}," produces a "higher yield" of oxidized or overall CoQ_{10} because he lacks any scientific testing or technical data to support this opinion. (Sherman Mem. 6.) In particular, Defendants challenge as lacking in support paragraph 10 of Dr. Sherman's Rebuttal Expert Report on the Issue of Patent Validity, in which he opines that "[a] novel discovery of the '340 [P]atent is that the productivity of the microorganisms can be maximized in order to obtain a higher yield [sic] a better purity than that previously known in the prior art," including by culturing microbial cells that meet the 70 mole % limitation. (Sherman Validity Report ¶ 10.)

Kaneka responds that two pieces of evidence support Dr. Sherman's opinion: (1) column 7, lines 55 through 65 of the '340 Patent; and (2) a comparison of Kaneka's new NX process and old QX process, and evidence that switching from QX to NX resulted in a cost savings of 3,410 yen per kilogram. (*See* Sherman Opp'n 8-9.) Although these pieces of evidence support Dr. Sherman's opinion that the patented process improves the productivity and yield of **reduced** CoQ_{10}, they do not lend support to his opinion that the 70 mole % limitation improves the yield of oxidized or overall CoQ_{10}.

Dr. Sherman testified at his deposition that a microorganism's ability to produce at least 70 mole % of CoQ_{10} "enables the high levels of production of the metabolite to make industrial level production viable and achievable." (Davis Sherman Decl., Ex. E at 82:9-20.) When questioned as to what support he had for this proposition, Dr. Sherman cited to the '340 Patent and to his knowledge of "microbial physiology" that because CoQ_{10} is a critical component in the respiration of cells and because "the level of reduced CoQ_{10} reflects the ability of the cells to generate ATP to support it's metabolism . . . if the level of CoQ_{10} is greater than 70 mole %, it's clear that the microorganism is growing under conditions that reflect a high level of reducing power." (Davis Sherman Decl., Ex. E at 79:15-80:11.) Besides the '340 Patent, Dr. Sherman was unable to point to any piece of literature supporting the view that the 70 mole % limitation is a novel feature that leads to higher yield of CoQ_{10} in any form. (Davis Sherman Decl., Ex. E at 77:6-84:17.) Moreover, Dr. Sherman did not perform any experiments to test this hypothesis. (Davis Sherman Decl., Ex. E at 77:6-84:17.)

Appendix E

Column 7, lines 55 through 65 of the '340 Patent provide that "[i]n the processes of the present invention, **high productivity of reduced coenzyme Q_{10}** in the fermentation production on the industrial scale can be achieved partially by using the microbial cells containing reduced coenzyme Q_{10} at a ratio of not less than 70 mole % among the entire coenzymes Q_{10} . . . ." (Decl. Keith D. Nowak in Supp. Sherman Opp'n ("Nowak Sherman Decl."), Ex. J ("'340 Patent") col. 7, ll. 55-65 [emphasis added], ECF No. 618-12.) The specification of the '340 Patent further describes one object of the invention as producing oxidized CoQ_{10} by "**oxidizing the reduced** coenzyme Q_{10} obtained from the microbial cells as an **intermediate substance** in producing oxidized coenzyme Q_{10}." ('340 Patent col. 3, ll. 39-46 [emphasis added].) Nowhere in the '340 Patent is there a discussion of an improved productivity or yield of overall or oxidized CoQ_{10}.

The only other piece of "evidence" Kaneka claims supports Dr. Sherman's opinion regarding the connection between the 70 mole % limitation and "higher yield" of any form of CoQ_{10} is a three- page document that was an exhibit to one of Defendants' employees' depositions that discusses some "[a]dvantages of NX system" vis-a-vis the QX system. (Sherman Opp'n 9; *see also* Nowak Sherman Decl., Ex. L.) Two potentially relevant "advantages" are "high quality" and "high yield." (Nowak Sherman Decl., Ex. L.) Unfortunately for Kaneka, the stated "reason for the[se] advantages" is that the "[p]hysical process [of the NX system] can avoid decomposition of Q_{10} during chemical disruption." (*Id.*) There is no reference to this "advantage" resulting from the culturing of certain microorganisms to meet the 70 mole % limitation.

Because Kaneka fails to point to some "objective source" that the patented process, and in particular the 70 mole % limitation, improves the productivity or yield of overall or oxidized CoQ_{10}, the Court **PRECLUDES** Dr. Sherman from offering opinions or testimony to this effect.

3. Testimony Regarding Factual Disputes and Legal Conclusions

Finally, Defendants ask the Court to preclude Dr. Sherman from offering opinions regarding (1) Shenzhou and XKGC's state of mind vis-a-vis the '340 Patent and whether they induced infringement of the patent; (2) factual statements that go beyond his scientific assessment of the processes at issue and that evaluate the credibility of Shenzhou's evidence. (Sherman Mem. 7-10.)

With respect to the state of mind issue, the Court **PRECLUDES** Dr. Sherman from testifying about anyone's motives, intent, or state of mind, as such "opinions" would invade the province of the jury. *See Oxford Gene Tech., Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 443 (D. Del. 2004). Not only is such testimony generally improper, but Dr. Sherman is a self-proclaimed expert in "the fields of microbial natural products, metabolic engineering, medicinal chemistry, biochemistry, and drug discovery," and is not qualified to provide "expert" opinions on the issues of Defendants' mental states or level of knowledge. (Sherman Infringement Report ¶ 1.) A significant number of the challenged paragraphs in Dr. Sherman's Infringement Report *directly* bear on these issues, and cannot be presented to the jury. (*See, e.g.*, Sherman

Infringement Report ¶¶ 472 ["The fact that Shenzhou has not disclosed its testing results is at least an inference that Shenzhou has actual knowledge that its microorganisms are cultured to obtain a [sic] least 70 mole % reduced coenzyme Q_{10}."]; 482 [opining that "[a]t a minimum, Shenzhou must have subjectively believed there was a high probability that its process infringed upon the '340 patent, and took deliberate actions to avoid learning of its infringement"]; 491 [opining that Shenzhou's customers' concerns "necessarily infers the specific intent to induce patent infringement"]; 498 ["Therefore, [XKGC] has been aware of the '340 patent since as early as March 22-23, 2011, but no later than April 7, 2011."]; 503 ["[XKGC] had actual knowledge that the oxidized . . . ."]; 512 ["The fact that [XKGC] has not disclosed its testing results is at least an inference that [XKGC] has actual knowledge that its microorganisms are cultured . . . . At a minimum, [XKGC] must have subjectively believed there was a high probability that its process infringed upon the '340 patent, and took deliberate actions to avoid learning of its infringement."].)

Kaneka argues that Dr. Sherman "did no more than" caselaw allows in that he testifies as to his understanding of certain facts and then offers his opinion on the ultimate issue of inducement. (Sherman Opp'n 10.) The central case relied upon by Kaneka, *Gen-Probe Inc. v. Becton Dickinson & Co.*, does not support Kaneka's position. In that case, the court expressly precluded the plaintiff's expert, who was "a patent attorney who has advised private companies" and has "worked as in-house counsel responsible for the IP department" at a major company,

from "testify[ing] about anyone's motives, intent and state of mind." No. 09-CV-2319 BEN NLS, 2012 WL 9335913, at *4 (S.D. Cal. Nov. 26, 2012). The court did, however, allow this expert to "testify about [certain opinion] letters' competency," including certain "shortcomings" such as "the letters' failure to define the person of ordinary skill in the art." *Id.* This case offers no help to Kaneka. First, Dr. Sherman's background and area of expertise distinguishable from the expert at issue in *Gen-Probe*, and Kaneka has offered no support for the proposition that Dr. Sherman can offer opinions about whether a defendant has induced infringement given his background in biology. Second, Kaneka glosses over the substantial number of paragraphs in Dr. Sherman's Infringement Report in which he offers opinions about Defendants' state of mind, intent, and knowledge. (*See* Sherman Opp'n 10.) This tactic, beyond being highly disingenous, runs afoul of Rule 702.

The Court rejects, however, Defendants' challenges regarding opinions that purportedly require no scientific, specialized, or technical knowledge. The particular challenges raised do not necessarily fall outside the purview of Dr. Sherman's expertise. Indeed, opinions regarding the sealing and operation of Shenzhou's extraction tanks and potential conflicts between Shenzhou's legal contentions and witness testimony do not fall within "the common knowledge of the average layman." *Mukhtar v. Cal. State Univ. Hayward*, 299 F.3d 1053, 1065 n.9 (9th Cir. 2002). Defendants can challenges Dr. Sherman's opinions through cross-examination and through the testimony and opinions of their own rebuttal

experts, and the Court **DENIES** the Sherman Motion on this basis.

IV. RULING

For the foregoing reasons, the Court:

1. **DENIES** Kaneka's Motion in Limine No. 1 to Preclude Admission of Portions of the Expert Report and Testimony of Shirley Webster;

2. **GRANTS IN PART** and **DENIES IN PART** Kaneka's Motion in Limine No. 2 to Preclude Admission of Portions of Reports on Defendants' Infringement and Invalidity Experts and Related Testimony; and

3. **GRANTS IN PART** and **DENIES IN PART** Defendants' Motion in Limine No. 1, *Daubert* Motion to Exclude the Testimony of David Sherman, PhD.

The Court will issue orders regarding the parties' cross-motions for summary judgment and Defendants' Motion in Limine No. 2, *Daubert* Motion to Exclude the Testimony of Sam Rosenfarb in short order.

IT IS SO ORDERED.

APPENDIX F — DENIAL OF REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, FILED AUGUST 12, 2019

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2018-1892

KANEKA CORPORATION,

Plaintiff-Appellant,

v.

XIAMEN KINGDOMWAY GROUP COMPANY, PACIFIC RAINBOW INTERNATIONAL INC.,

Defendants-Appellees,

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

Defendants.

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

Appendix F

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before PROST, *Chief Judge*, NEWMAN, LOURIE, BRYSON*, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*.

PER CURIAM

ORDER

Appellant Kaneka Corporation filed a combined petition for panel rehearing and rehearing en banc. A response was invited by the court and filed by Appellees Pacific Rainbow International Inc. and Xiamen Kingdomway Group Company. The petition was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on August 19, 2019.

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* Circuit Judge Bryson participated only in the decision on the petition for panel rehearing.

Appendix F

For the Court

August 12, 2019
Date

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