IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

MEMORANDUM OPINION AND ORDER

In this patent infringement action, plaintiff Kaneka Corporation ("Kaneka") asserts claims 5 and 15 of U.S. Patent No. 7,829,080 ("the '080 patent") against defendants Designs for Health, Inc. ("DFH") and American River Nutrition LLC ("ARN"). Kaneka is a Japanese firm that manufactures and sells ingredients for nutritional supplements, including compositions that contain reduced coenzyme Q_{10}. Defendant ARN produces a trademarked formulation of reduced coenzyme Q_{10} known as DuoQuinol. Defendant DFH manufactures, distributes, and sells nutritional supplements in softgel form that contain DuoQuinol.

In the first phase of this action, the court held a bench trial in late May and early June of 2024. I found that the defendants' original products (i.e., the CoQnol-100, CoQnol-200, Q10.1-100, and Q10.1-200 products sold prior to their reformulation in 2023) infringed claims 5 and 15 of the '080 patent, and I rejected the defendants' claims of invalidity. Dkt. No. 249. The action proceeded to the second phase of the case to determine whether the defendants' products that were reformulated in 2023 also infringe the asserted claims of Kaneka's '080 patent and what damages Kaneka is entitled to for the defendants' infringement.

On March 15, 2025, less than three months before the dates set for the second bench trial, Kaneka filed a motion for a "permanent injunction restraining and permanently enjoining Defendants . . . from engaging in the manufacture, sale, offer for sale, or importing into the United States any products that infringe the '080 Patent, including the Accused Products and the Alleged Reformulations." Dkt. No. 268 at 15–16. However, during a conference with the court held on March 19, 2025, Kaneka agreed that it was seeking a preliminary injunction, since the court had not yet adjudicated liability for the reformulated products. Dkt. No. 312-2 at 14:17–24. Based on the parties' proposals, I revised the scheduling order so that the hearing on Kaneka's motion for a preliminary injunction would be conducted at the same time as the second bench trial. *See* Dkt. Nos. 276, 277, 281. The goal of combining the two events was to avoid delaying the trial on the merits (which would address issues beyond whether the reformulated products were infringing), while providing Kaneka with an opportunity to be heard on its motion for a preliminary injunction regarding the reformulated products.

The second bench trial and the hearing on the motion for a preliminary injunction were held during the week of July 21, 2025. The motion for a preliminary injunction was fully briefed prior to trial.[1] *See* Dkt. Nos. 268, 334, 352, 374. In addition to the parties' briefing and evidence submitted with that briefing, I have considered the evidence introduced at trial regarding the

[1] Even after restyling its motion as a motion for a preliminary injunction, Kaneka has requested the "entry of a preliminary injunction restraining and *permanently enjoining* Defendants . . . from engaging in the manufacture, sale, offer for sale, or importing into the United States any products that infringe the '080 Patent, including the Accused Products and the Alleged Reformulations." Dkt. No. 334 at 11 (emphasis added). The motion for a permanent injunction is premature at this stage. Such a motion will be considered after the court issues its findings of fact and conclusions of law on the defendants' liability for the reformulated products and the amount of damages to which Kaneka is entitled.

reformulated products in assessing the motion for a preliminary injunction. For the reasons explained below, the motion is denied.

I. Background

Kaneka is the owner of the '080 patent, titled "Stabilization Method of Reduced Coenzyme Q_{10}." PTX 1. Coenzyme Q_{10} ("CoQ_{10}") can exist in two states: an oxidized state and a reduced state. Oxidized CoQ_{10} is known as "ubiquinone," and reduced CoQ_{10} is known as "ubiquinol." As a method of stabilizing ubiquinol and preventing its oxidation into ubiquinone, the '080 patent teaches a composition of ubiquinol that also contains reduced Coenzyme Q_9 ("CoQ_9") and/or reduced Coenzyme Q_{11} ("CoQ_{11}"), and a method of producing such a composition. *See id*. at col. 2, ll. 36–41.

Claims 5 and 15 of '080 patent are the asserted claims in this case. Claim 5 recites as follows:

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

Id. at col. 16, ll. 55–65.

Claim 15 recites as follows:

> A method for producing a reduced coenzyme Q_{10}-containing composition, which method comprises
>
> > providing a composition comprising oxidized coenzyme Q_{10} with one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11}, and then

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

Id. at col. 18, ll. 4–21.

The ratio of reduced CoQ_{10} (ubiquinol) relative to the total amount of CoQ_{10} (the sum of ubiquinol and ubiquinol) is referred to as the "QH ratio." The focus of Kaneka's motion for a preliminary injunction is the limitation in both claims 5 and 15 of the '080 patent that the QH ratio be not less than 90 weight percent ("the QH limitation"). The defendants dispute whether their reformulated products that Kaneka specifically accuses of infringement—CoQnol 100 and CoQnol 200—meet the QH limitation. The defendants do not dispute that their reformulated products meet every other limitation of claims 5 and 15. *See* Dkt. No. 352 at 6–9.

The defendants' trademarked ubiquinol composition, DuoQuinol, is made with geranylgeraniol ("GG"), ascorbyl palmitate ("AP"), and ubiquinone. GG is the solvent that dissolves the ubiquinone, and AP is a reducing agent that converts the ubiquinone into ubiquinol. *See* TD2 at 404:14–405:1.[2]

The defendants' original products contained DuoQuinol that was made with a 4 to 2 to 4 ratio of GG to AP to ubiquinone. TD2 at 315:13–16. After a discussion about reformulating their products in June 2023, *see* PTX 268, the defendants experimented with altering the ratio of GG to

[2] TD1 through TD4 refers to the trial transcript for the first through fourth day of the trial. Dkt. Nos. 409–12.

AP to ubiquinone to ensure that the conversion of ubiquinone into ubiquinol would stop before the QH ratio reached 90 percent, *see* PTX 269. The defendants experimented with six different ratios and ultimately settled on the ratio of 4 to 1.5 to 4 of GG to AP to ubiquinone for their reformulated version of DuoQuinol. *See* PTX 270, DTX 489.

The defendants' products contain different amounts of the DuoQuinol formulation depending on the label. CoQnol 100 contains the amount of the formulation needed to fulfill the labeled claim of 100 milligrams of ubiquinol per softgel, and CoQnol 200 contains the amount of the formulation needed to fulfill the labeled claim of 200 milligrams of ubiquinol per softgel. TD2 at 309:12–23; *see also* DTX 491. The composition of the DuoQuinol formulation that is used in the softgels, however, is the same for CoQnol 100 and CoQnol 200 products. *See* TD2 at 309:12–23.

The defendants' manufacturing process has four stages. The first stage, making DuoQuinol, entails blending GG, AP, and ubiquinone in a reaction tank at 55 degrees Celsius (131 degrees Fahrenheit) for 5.5 days. DTX 489 at 3. The reduction of ubiquinone begins in that reaction tank. In the second stage of the manufacturing process, the defendants mix MCT [medium-chain tryglycerides] oil with Quillaja extract in a separate tank. *Id*. at 6. The MCT/Quillaja blend is then added to the reaction tank containing DuoQuinol. *Id*. More GG is added to that tank, which is then flushed with argon gas. *Id*. The resulting blend, referred to as the CoQnol blend, is held for no more than two days at 35 to 42 degrees Celsius (95 to 107.6 degrees Fahrenheit). *Id*. In the third stage, the CoQnol blend is encapsulated in softgels, which are then held in storage in preparation for bottling. *See* TD3 at 746:21–747:2. In the fourth stage, the softgels are bottled and labeled with an expiration date. There is, however, some variation in how long the softgels are held in storage before bottling. *See id*. at 749:12–25; *id*. at 754:9–755:25.

A key trial exhibit that both parties relied on is a spreadsheet that contains QH ratio measurements that the defendants made of certain softgel lots and the DuoQuinol lots that went into making those softgel lots. *See* PTX 326 and DTX 356 (same spreadsheet).[3] The date on the far lefthand column of PTX 326 is the scheduled date of bottling the softgels, which is not necessarily the date on which the softgels were actually bottled. *See* TD3 at 751:3–25. The date on the second to the far righthand column of PTX 326 is the date on which the defendants measured the QH ratio of the softgel lot (recorded in the third column from the far right), which was shortly before the softgels were bottled. *See id*. at 753:6–12. The "manufacturing date" that the parties referred to at trial is not necessarily either of those dates in PTX 326, because the "manufacturing date" means the date on which the softgels were actually bottled. *See id*. at 752:4–22.

In addition to containing the QH ratios of the softgel lots prior to bottling, PTX 326 also records the QH ratios of the DuoQuinol lots that went into making the softgel lots, the measurements for which were necessarily made earlier than the measurements of the QH ratios of the softgel lots. Kaneka relies on the QH ratios of the softgel lots in PTX 326 as the "starting" QH ratios of those lots for purposes of its infringement analysis.

The defendants first released their reformulated products for sale on October 10, 2023. TD2 at 344:2–7. Until December 2024, the reformulated products were sold with a designated shelf life of 36 months. At that point, the defendants revised the shelf life of the products to 18 months. *Id*. at 317:4–16. The shelf life designated for all of the defendants' products manufactured since that time has been 18 months. *Id*. at 316:21–22.

[3] The spreadsheet that was admitted as PTX 326 and DTX 356 was also Exhibit C to the declaration in opposition to the motion for a preliminary injunction filed by the defendants' expert witness, Dr. Umesh Banakar. Dkt. No. 354-1, Exh. C.

II. Legal Standard

A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Nat. Res. Defense Council, Inc.*, 555 U.S. 7, 22 (2008); *Insulet Corp. v. EOFlow, Co.*, 104 F.4th 873, 878 (Fed. Cir. 2024); *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361, 1366 (Fed. Cir. 2013). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter*, 555 U.S. at 20.

The standard for determining the likelihood of success in establishing infringement is governed by Federal Circuit law, while the other factors are governed by the law of the regional circuit. *ABC Corp. I v. P'ship & Unincorporated Ass'ns Identified on Schedule "A"*, 52 F.4th 934, 941 (Fed. Cir. 2022). "[A]ny one factor may give a district court enough reason to exercise its sound discretion by denying an injunction." *Del. State Sportsmen's Ass'n v. Del. Dep't of Safety & Homeland Sec.*, 108 F.4th 194, 203 (3d Cir. 2024). "When one factor is dispositive, a district court need not consider the others." *Id*. (cleaned up).

"To prove a likelihood of success on the merits, a patentee must prove that success in establishing infringement is more likely than not." *Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1166 (Fed. Cir. 2014) (cleaned up). However, "[a]n accused infringer can defeat a showing of likelihood of success on the merits by demonstrating a substantial question of validity or infringement." *Id.* at 1165; *see also ABC Corp.*, 52 F.4th at 942; *Tinnus Enters., LLC v.*

Telebrands Corp., 846 F.3d 1190, 1202 (Fed. Cir. 2017); *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350–51 (Fed. Cir. 2001).[4]

III. Discussion

Kaneka tested multiple lots of the reformulated CoQnol 100 and CoQnol 200 softgels at the Triclinic Labs in Indiana ("Triclinic testing"). The Triclinic testing was performed under the direction of Kaneka's expert witness, Dr. Allan Myerson, between March and May 2025.[5] *See* PTX 159 and PTX 225. In addition to the Triclinic testing, Kaneka relies on the stability testing that the defendants conducted on a particular lot of CoQnol 100 softgels known as Lot 35550. *See* PTX 226 ("Stability Testing Spreadsheet"). Kaneka also relies on the QH ratios the defendants measured prior to bottling the softgels, recorded in PTX 326. For the reasons explained below, I

[4] Kaneka suggests that whenever there is a redesign, the defendants bear the burden of showing "very persuasive" evidence that "further infringement will not take place." Dkt. No. 268 at 12 (quoting *Qorvo, Inc. v. Akoustis Techs., Inc.*, No. 1:21-cv-1417, 2024 WL 5336415, at *5 (D. Del. Oct. 11, 2024)). The case law that Kaneka cites, however, is inapplicable to the facts of this case. In *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, the Federal Circuit held, in the context of a motion for a permanent injunction, that "[t]he fact that the defendant has stopped infringing is generally not a reason for denying an injunction against future infringement unless the evidence is very persuasive that further infringement will not take place." 842 F.2d 1275, 1281–82 (Fed. Cir. 1988). District courts have since cited *W.L. Gore* to reject an alleged redesign as a valid reason to deny a permanent injunction after finding that an existing product was infringing. *See Qorvo*, 2024 WL 5336415, at *5; *GeigTech E. Bay LLC v. Lutron Elecs. Co.*, No. 18 Civ. 5290, 2024 WL 3595413, at *26 (S.D.N.Y. July 30, 2024); *SIMO Holdings Inc. v. Hong Kong uCloudlink Network Tech. Ltd.*, 396 F. Supp. 3d 323, 346 (S.D.N.Y. 2019); *Mass Engineered Design, Inc. v. Ergotron, Inc.*, 633 F. Supp. 2d 361, 394 (E.D. Tex. 2009). Importantly, in each of those cases, neither the court nor the jury decided whether the redesign was infringing. *See, e.g., GeigTech*, 2024 WL 3595413, at *26 n.6 ("Obviously the court can take no position as to whether or not this new design infringes . . . ."). Here, Kaneka seeks a preliminary injunction specifically addressing the reformulated products, and a bench trial was held on the question whether the reformulated products are infringing. In that setting, it is Kaneka's burden to demonstrate a likelihood of success in establishing infringement of the reformulated products.

[5] Triclinic also tested the reformulated version of the defendants' Q10.1 100 product line in March 2025. *See* PTX 159. However, Kaneka has withdrawn its arguments about the Q10.1 100 product, after confirming that the defendants no longer sell that product. *See* Dkt. No. 334 at 1 n.3.

find that Kaneka has not made the "clear showing" of infringement of its patent by the reformulated CoQnol 100 and CoQnol 200 products that is necessary to justify the entry of a preliminary injunction. *See Winter*, 555 U.S. at 22.

A. Triclinic Testing

In March 2025, Triclinic tested Lot 45810 of CoQnol 100 softgels and Lot 45818 of CoQnol 200 softgels, which it stored in a controlled room temperature facility. *See* PTX 159 at 3. Triclinic tested three samples of each lot and measured the QH ratio of each sample.[6] *See id*. at 15–16.

The QH ratio did not exceed 90 percent for any sample of Lot 45810 (CoQnol 100). *See* Dkt. No. 269 at 5 (Dr. Myerson's declaration in support of Kaneka's motion for a permanent injunction). Specifically, the three samples had QH ratios of 83.7 percent, 82.9 percent, and 83.9 percent. *See* PTX 159 at 15. For each sample of Lot 45818 (CoQnol 200), however, the QH ratio exceeded 90 percent. *See id*. at 16. Specifically, the three samples from Lot 45818 had QH ratios of 94.3 percent, 93.6 percent, and 93.9 percent.[7] *See id*.

The defendants assert that Lot 45818 is not representative of the reformulated CoQnol 200 product, because "the bulk product for this lot was erroneously kept in the reactor, under pressurized and heated conditions, for more than 8 weeks due to a catastrophic equipment failure, which is much longer than the 5.5 days required for the reaction." Dkt. No. 352 at 6. Kelley Karas, Vice President at DFH and a Rule 30(b)(6) witness, testified that due to a mechanical failure in the softgel melter tank, the DuoQuinol blend in the reaction tank was erroneously kept under

[6] Because the parties make no argument regarding Triclinic's testing methodology and the accuracy of its results is not contested, an explanation of the methodology is unnecessary. The Triclinic reports contain tables of the quantities of ubiquinol and ubiquinone found in each sample (in mg per capsule), from which the QH ratio can be calculated. *See* PTX 159 and PTX 225.

[7] These ratios were calculated based on the values reported in PTX 159.

reaction conditions long after the end of the 5.5-day period specified in the defendants' protocol. *See* TD2 at 367:2–25. The deviation from protocol occurred in December 2024, and in March 2025, a DFH employee was disciplined for not recognizing the deviation, but instead releasing the lot for sale. *See* DTX 455 at 2 ("Employee did not realize when compiling the results that the ratio changed drastically between reaction of DuoQuinol @ 5.5 days and post soft-gel encapsulation. The change occurred due to a catastrophic equipment failure in gel-making, which led to a process deviation allowing the ubiquinol reaction to extend >8 weeks in vessel vs the intended reaction timeframe."). Kaneka has not presented any evidence to suggest that the equipment failure did not occur as Ms. Karas recounted. I therefore credit the defendants' account of the equipment failure that affected Lot 45818.

The defendants' assertion that Lot 45818 is not representative of the reformulated CoQnol 200 product is supported by the QH ratio measurements of other softgel lots recorded in PTX 326. Lot 45818 is the only softgel lot with a QH ratio higher than 90 percent in PTX 326, whether for CoQnol 100 or CoQnol 200. Eleven other lots of CoQnol 200 softgels had QH ratios below 90 percent, the highest of those ratios being 84.96 percent. *See* PTX 326.

Moreover, Kaneka's own testing of additional lots in April and May of 2025 confirms that Lot 45818 is not representative. In April and May 2025, Triclinic tested three additional lots of CoQnol 200, using three samples of each lot: Lot 45858, Lot 35951, and Lot 36163. PTX 225 at 4. Triclinic did not find a QH ratio above 90 percent for any of those lots. *See* PTX 225 at 15–17 (Triclinic test results); Dkt. No. 335 at 3 (Dr. Myerson's calculation of CoQnol 200 QH ratios in the range of 84.5 percent to 86.44 percent).

In addition to further testing of the CoQnol 200 products, Triclinic tested four additional lots of CoQnol 100 in April and May 2025: Lot 35950, Lot 43574, Lot 43573, and Lot 35550.

PTX 225 at 4. Triclinic tested three samples of each lot and did not find a QH ratio above 90 percent for any of those lots. *See id*. at 11–14, 18, 20, 23–25 (Triclinic test results); Dkt. No. 335 at 3 (Dr. Myerson's calculation of CoQnol 100 QH ratios in the range of 82.2 percent to 85.93 percent).

In sum, the only lot that Triclinic found to have a QH ratio higher than 90 percent was Lot 45818, which, for the reasons explained above, was not representative of the reformulated CoQnol 200 product due to the equipment failure that kept the DuoQuinol under reaction conditions for longer than was intended.

B. The Defendants' Stability Testing of Lot 35550

From October 2023 to April 2025, the defendants conducted a stability test of Lot 35550 softgels. *See* PTX 226. The defendants' Stability Testing Spreadsheet states that Lot 35550 softgels are CoQnol 100 softgels with a "manufacturing date" of October 1, 2023, and a QH ratio of 77.1 percent as of that date. *See id*. According to PTX 326, the defendants also measured the QH ratio of Lot 35550 on September 15, 2023, which on that date was 77.14 percent. And the DuoQuinol lot that went into Lot 35550 (DuoQuinol Lot 35544) had a QH ratio of 78.68 percent on September 1, 2023. *See* PTX 326.

According to Dr. Myerson, "[s]tability studies are done in the pharmaceutical industry and the nutraceutical industry to determine how a product will change with time . . . [and] whether it withstands specifications in time." TD2 at 433:15–19. The product being tested is kept in its final container in an environmental chamber, and samples (in this case, different softgels) are pulled from the environmental chamber at specific intervals to measure the composition of the active ingredient in the product. *See id*. at 433:20–434:9. Ms. Karas testified that the defendants perform

stability tests to examine whether DuoQuinol "remain[s] stable outside of the reaction vessel," such that "the ubiquinol doesn't turn back into ubiquinone." *See id*. at 382:7–21.

The defendants conducted the stability test of Lot 35550 under "ambient" conditions as well as "accelerated" conditions, measuring the QH ratios on a weekly basis.[8] *See* PTX 226. The weeks were counted from when the samples of Lot 35550 entered each environmental chamber: October 13, 2023, for the ambient testing, and October 9, 2023, for the accelerated testing. *See id*. By that count, the ambient testing was conducted over a span of 18 months (from October 13, 2023, to April 23, 2025) and the accelerated testing was conducted over a span of 36 weeks (October 9, 2023, to June 20, 2024). *See id*.[9]

Ambient conditions refer to a temperature and humidity level similar to the conditions of a storage warehouse, at less than about 80 degrees Fahrenheit and less than about 60 percent humidity. *See* TD2 at 357:9–358:18. Accelerated conditions are abnormal conditions intended to stress the product by exposing them to temperatures and humidity at which they would not normally be stored. *See id*. at 359:16–24. In this case, the accelerated conditions consisted of storing the products at a temperature of 96 degrees Fahrenheit and a relative humidity of 80 to 85 percent. *See id*. at 361:12–20. Ms. Karas testified that the defendants performed accelerated testing to examine whether "the material would degrade under stress conditions . . . [and] fall below its intended label claim." *Id*. at 325:3–14. For the rows recording the results of the

[8] It appears the ambient testing was done on a weekly basis until August 12, 2024 (i.e., for 43 weeks), after which the defendants measured the QH ratios on two more dates: January 23, 2025, and April 23, 2025. *See* PTX 226. The January 23, 2025, date was marked as the "15 months" data point, and the April 23, 2025, date was marked as the "18 months" data point. *See id*.

[9] Since the QH ratio of Lot 35550 was also measured on September 15, 2023, and on October 1, 2023, the record contains QH ratio measurements for a period longer than one that begins on either October 9, 2025, or October 13, 2025. Nevertheless, for the sake of simplicity, I will use the numbered weeks and months that the defendants have used.

accelerated testing, the defendants' table states that "1 week = 1 month RT." *See* PTX 226. Ms. Karas testified that RT stands for "real time." TD2 at 360:1–7. She also explained that in an "accelerated stability chamber, one week is indicative of one month['s] performance." *Id*.

The QH ratio of Lot 35550 did not exceed 90 percent at any point in 18 months of testing under ambient conditions. *See* PTX 226. The highest QH ratio under ambient testing was 87.7 percent, measured at 18 months. *Id*. However, under accelerated conditions, the QH ratio exceeded 90 percent after 10 weeks (90.1 percent), then dropped below 90 percent until week 15, at which point it remained above 90 percent until week 36.[10] *Id*. From 15 to 36 weeks, the QH ratio generally increased, although the testing showed a drop in the QH ratio of about 7 percentage points between weeks 33 and 34. *Id*. The highest QH ratio under the accelerated testing regimen was 98.5 percent, measured in week 35. *Id*.

Kaneka relies on the accelerated testing results as evidence that the "Alleged Reformulations infringe the 90% QH Ratio limitation after ten months, and consistently stay[] above 90% after fifteen months." Dkt. No. 334 at 3. That is, Kaneka relies on accelerated testing for its prediction of ambient conditions, based on the assumption that a week under accelerated conditions is equivalent to a month under ambient conditions. Kaneka does not dispute that the defendants' products are intended to be stored under ambient conditions.

Kaneka has not shown that testing under accelerated conditions accurately predicts results under ambient conditions, at least with respect to results as far out as 18 months or longer. At trial, Dr. Myerson pointed out the close alignment between the QH ratio for 5 weeks of accelerated testing (83.2 percent) and for 5 months of ambient testing (83.5 percent). *See* TD2 at 445:4–19;

[10] On some weeks, the defendants measured the QH ratio twice, marking the second entry as "reprep." *See* PTX 226. In those instances, I have considered the QH ratio of the reprep entry.

PTX 226. However, Dr. Myerson failed to acknowledge the discrepancy between later weeks of accelerated testing and the corresponding later months of ambient testing. Unlike the QH ratio for accelerated testing at 10 weeks, the ambient testing at 10 months did not exceed a QH ratio of 90 percent. *See* PTX 226 (90.1 percent at 10 weeks of accelerated testing and 85.8 percent at 10 months of ambient testing). And unlike the QH ratio for accelerated testing at 18 weeks, the ambient testing at 18 months did not exceed a QH ratio of 90 percent. *See id*. (92.8 percent at 18 weeks of accelerated testing and 87.7 percent at 18 months of ambient testing).

The unreliability of the accelerated testing as a basis for estimating the QH ratios of the defendants' products after 18 months under ambient conditions is underscored by Triclinic's testing of Lot 35550. Triclinic tested Lot 35550 in April and May 2025, at about the same time that the defendants measured the QH ratio after 18 months of ambient stability testing. *See* PTX 226. Like the defendants' ambient testing at 18 months, Triclinic did not find QH ratios over 90 percent for any of the samples of Lot 35550. *See* PTX 225 at 14, 25; Dkt. No. 335 at 3 (QH ratios of 85.6 percent, 85.93 percent, and 85.2 percent calculated by Dr. Myerson).

Dr. Myerson acknowledged that the relationship between ambient testing and accelerated testing varies depending on the product being tested. TD2 at 435:7–21. According to Dr. Myerson, "[s]ome products are very temperature-sensitive." *Id*. There was no evidence presented at trial regarding the particular temperature sensitivity of the defendants' products, i.e., the difference that heat might make with respect to the relationship between ambient testing and accelerated testing for the defendants' products. That the defendants believed that one week of accelerated testing was generally indicative of performance after one month at ambient conditions does not by itself establish such a correlation for the defendants' products, particularly toward the end of the testing period.

Because the QH ratio of Lot 35550 exceeded 90 percent only under accelerated conditions in the defendants' stability testing, and because the accelerated testing did not serve as a reliable proxy for long-term changes in the composition of the accused products under ambient conditions, I conclude that the results of the accelerated testing failed to show that the QH ratio of Lot 35550 would exceed 90 percent under ambient conditions within either the 18-month or 36-month timeframe.

C. Dr. Myerson's Prediction of Infringement

As shown above, none of the softgel lots that were tested (apart from Lot 45818, which I discount as unrepresentative) reached a QH ratio of 90 percent when stored under ambient conditions. That was true even of the two lots for which the record contains QH ratios spanning more than 18 months: Lot 35550 and Lot 35950. Lot 35550 started at 77.14 percent on September 15, 2023, *see* PTX 326, and reached only 87.7 percent on April 23, 2025, according to the defendants' stability testing, *see* PTX 226. And when Triclinic independently tested Lot 35550 in April and May of 2025, the QH ratio did not even reach 86 percent within 18 months (85.6 percent on April 11, 2025; 85.93 percent on April 16, 2025; and 85.2 percent on May 2, 2025). *See* Dkt. No. 335 at 3. Lot 35950 started at 80.06 percent on October 13, 2023, *see* PTX 326, and reached only 85.8 percent on May 2, 2025, according to the Triclinic testing, *see* Dkt. No. 335 at 3.

Notwithstanding the absence of any reformulated softgel lot that reached 90 percent in 18 months after the initial measurement, Dr. Myerson asserted that the defendants' reformulated products will infringe within 18 months of the manufacturing date (or 36 months in the alternative), so long as they start out with a sufficiently high QH ratio. In making that assertion, Dr. Myerson first chose to rely on the rate of reduction that he calculated for Lot 35550, a lot that showed a greater increase in the QH ratio (i.e., a higher rate of reduction) in 18 months than Lot 35950. He

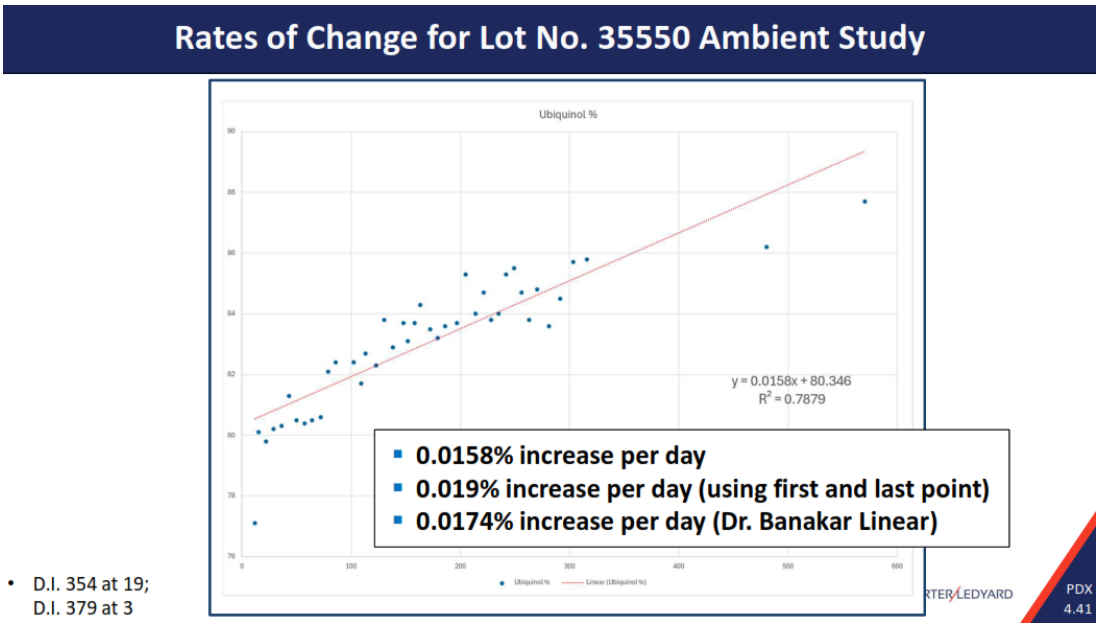
also chose to use the defendants' ambient testing data for Lot 35550, rather than the Triclinic testing data for Lot 35550, which showed a lower QH ratio in 18 months than the defendants' testing showed.

Then, using the rate of reduction for Lot 35550 based on the defendants' ambient stability testing, Dr. Myerson calculated what the starting QH ratio would have to be to reach 90 percent at either 18 or 36 months after the manufacturing date. Dr. Myerson assumed from the rate of reduction for Lot 35550 that any other lot of the reformulated products would reduce at the same rate, and thus reach 90 percent in 18 months, so long as it started out at a higher QH ratio than Lot 35550 on the manufacturing date.

At trial, Dr. Myerson conceded that the rates of reduction were different for each of the lots that Triclinic tested. TD2 at 454:1–13. He testified that he chose to calculate the rate of reduction based only on Lot 35550 because "it had the most data" and "went for the longest amount of time." *Id*. at 454:14–19. However, the QH ratio of Lot 35950 was tested across roughly the same time span as Lot 35550. And as will be explained below, Dr. Myerson disregarded most of the data points for Lot 35550, despite recognizing that Lot 35550 "had the most data." Thus, Dr. Myerson provided an insufficient justification for ignoring the lower rate of reduction for Lot 35950, and his exclusive reliance on the data for Lot 35550, based only the defendants' ambient testing data, cannot be regarded as representative of the defendants' reformulated products.

The problems with extrapolating from the data for Lot 35550 emerge more clearly in the details of Dr. Myerson's infringement analysis. The first step of that analysis involved calculating the rate of reduction for Lot 35550, which he did in two ways. First, he performed a least-squares analysis on all data points for the ambient stability testing of Lot 35550 and derived a slope that indicated a 0.0158 percent increase in the QH ratio per day. *See* TD2 at 450:5–14. However, he

acknowledged that the data was "very scattered" and that "the correlation is only 0.7870 for the least square[s] analysis." *Id*. at 450:17–19; *see also id*. at 453:15–23 (agreeing that the least squares line he obtained was "not one that you would have as much confidence in . . . as you would if the data were much less scattered"). Dr. Myerson used the graph below at trial as a demonstrative of the least squares line he developed using 42 data points. *See* PDX 4.41.



As a second method, Dr. Myerson "just took the first point and the last point [among all the data points in the ambient stability testing] and drew a straight line between them and calculated the slope." *Id*. at 450:20–23. The slope of the line he drew between the first and the last data points indicated a 0.019 percent increase in the QH ratio per day. *Id*. Dr. Myerson referred to the first method as his "linear regression" analysis and the second as his "first and last point" analysis.[11] *See id*. at 462:5–25.

[11] Dr. Myerson testified that when he drew a straight line between the first and last points, "it turns out that the first two points and the last two points are a perfect straight line." TD2 at 450:24–451:1. It is unclear what he meant by that statement, i.e., whether he meant that his straight line analysis was based on four data points, as opposed to just two. Nevertheless, the court adopts Dr. Myerson's own description of his analysis as the "first and last point" analysis.

The particular value of the slope made a difference in the next step of Dr. Myerson's infringement analysis. Assuming a constant rate of increase in the QH ratio over time, a slope of 0.0158 percent (the linear regression slope) means that any given lot would reach a QH ratio of 90 percent in 18 months if the QH ratio on the manufacturing date were 81.25 percent or higher, and would reach a QH ratio of 90 percent in 36 months if the QH ratio on the manufacturing date were 72.7 percent or higher. *See* TD2 at 462:3–21. A slope of 0.019 percent (the first and last point slope), on the other hand, means that any given lot would reach a QH ratio of 90 percent in 18 months if the QH ratio on the manufacturing date were at least 79.6 percent, and would reach a QH ratio of 90 percent in 36 months if the QH ratio on the manufacturing date were at least 69.19 percent. *See id*. at 462:22–463:4. Dr. Myerson calculated the required QH ratios on the manufacturing date by multiplying the applicable slope by 575.5 days (18 months) and 1,095 days (36 months), and subtracting that product from 90 percent. *See id*. at 462:3–463:25.

Dr. Myerson then applied those predictions to the starting ratios of the lots listed in PTX 326. Dr. Myerson testified that all of the CoQnol 100 and CoQnol 200 lots listed would infringe within 36 months, based on both his linear regression analysis and his first-and-last-point analysis. *See* TD2 at 464:2–466:7. In other words, those lots would infringe because they had sufficiently high starting QH ratios. For the 18-month timeframe, Dr. Myerson testified that 5 lots of CoQnol 200 would infringe based on his linear regression analysis, and 7 lots would infringe based on his first-and-last-point analysis. *See id*. Similarly, Dr. Myerson testified that 5 lots of CoQnol 100 would infringe based on his linear regression analysis, and 10 lots would infringe based on his first-and-last-point analysis. *See id*.

As explained above, the foremost problem with those projections is that there is no indication in the record that the rate of reduction calculated based on Lot 35550 can be applied to

all the other lots. In fact, mixing the rate of reduction based on Lot 35550 with a starting QH ratio of a different lot creates contradictions, such as in the case of Lot 35950. According to Dr. Myerson's first-and-last-point prediction, Lot 35950 is supposed to infringe in 18 months because it started out with a QH ratio of at least 79.6 percent. *See* PTX 326. But because Lot 35950 actually had a lower rate of reduction than Lot 35550, the QH ratio of Lot 35950 did not reach 90 percent when Kaneka tested that lot 18 months after the initial measurement of 79.6 percent. *See* Dkt. No. 335 at 3. Combining the higher rate of reduction of Lot 35550 with the higher starting QH ratio of Lot 35950 results in a prediction that does not accord with the actual data, as confirmed by Kaneka's own testing.

In addition, the rate of reduction that Dr. Myerson calculated for Lot 35550 is methodologically suspect. The defendants' expert witness, Dr. Umesh Banakar, took an approach to statistical modeling different from that of Dr. Myerson. First, Dr. Banakar rejected the linear model for the ambient stability testing of Lot 35550, because he regarded the correlation coefficient for that model as being insufficiently high.[12] *See* TD3 at 885:14–886:10. Dr. Banakar also stated in his declaration in opposition to Kaneka's motion for a preliminary injunction that a linear model is inappropriate because the model "doesn't take into account the slowing rate of the reaction[,] which would be expected as the AP is consumed in the reduction." Dkt. No. 354 at 20.

Dr. Banakar then performed a logarithmic regression analysis on the same data. *See* TD3 at 887:4–23. He also rejected the logarithmic model, however, because he regarded that model as showing results that were inconsistent with the underlying chemistry of the reactions in the composition. *See* TD4 at 955:1–5; Dkt. No. 354 at 21 (explaining that "neither the ascorbyl

[12] Dr. Banakar performed his own linear regression analysis, although he chose not to rely on it.

palmitate nor the [ubiquinol] will be stable" for the period of time indicated by the logarithmic model). Finally, Dr. Banakar performed a polynomial regression analysis, which indicated that the QH ratio would reach a maximum value of 86.6 percent in 497 days. *See* TD3 at 895:1–25. The defendants rely on Dr. Banakar's polynomial model to argue that the reformulated products, when stored at ambient temperatures and humidity, would never reach the 90 percent QH ratio necessary to establish infringement. *See* Dkt. No. 352 at 8.

Dr. Myerson regarded both the logarithmic and polynomial models as inappropriate as applied to this case. *See* TD2 at 455:16–457:23. Regarding the polynomial model in particular, Dr. Myerson testified that there was no basis for predicting that "the QH ratio will reach a maximum and then start going down," as Dr. Banakar predicted. *See id*. at 457:7–13. According to Dr. Myerson, the only two acceptable methods of calculating the rate of reduction were through linear regression analysis or the first-and-last-point analysis. *See id*. at 458:2–4.

Dr. Myerson made clear, however, that he believed his first-and-last-point analysis was more reliable than his linear regression analysis. During his cross-examination, Dr. Myerson admitted that in his expert report he decided not to rely his linear regression analysis to support his infringement opinions, because he concluded that the fit of the least squares line "wasn't very good" and that using the first and last points "seemed to be a better way to do the analysis" by "eliminat[ing] all the scatter." *See* TD2 at 490:10–21. The slope of the first-and-last-point analysis is also the only slope that he used in his declaration in support of Kaneka's motion for a preliminary injunction. *See* Dkt. No. 335 at 4.

Dr. Myerson did not establish the reliability of his first-and-last-point analysis as a form of statistical modeling. The defendants introduced statistical literature at trial stating that "[t]he greater the number of data points along with the greater extent of concentration change, the more

statistically valid the mathematical modeling becomes." DTX 479 at 468. Citing the literature, Dr. Banakar testified that it was desirable to have at least 10 data points and that shelf-life predictions were more error prone with fewer than 8 data points. *See* TD4 at 913:2–16; DTX 479 at 468 ("[T]ypically 10 data points are equally effective with only a slight increase in the confidence limits as compared to 13 data points. Once the number of data points is reduced below 8, the confidence limits become significantly larger and shelf-life predictions become increasingly error prone."). Dr. Myerson did not cite any authority to support the reliability of using only two data points to predict the QH ratio of a product during its shelf life.

Dr. Myerson's reliance on two data points is especially problematic since he ignored the rest of the data in choosing to rely on those two points. On this issue, I credit the testimony of Dr. Banakar, who explained that the first requirement of any sort of statistical modeling is to "use all data available," TD3 at 863:3–12, and that "picking and choosing" two points out of the entire data set "is against the principles and practices" of statistical analysis, TD4 at 943:8–16. When asked why there was "any magic to taking the first and the last points as opposed to say the fifth and the fifth from the last," Dr. Myerson responded that "[t]he first point and last point are over a longer period of time." *See* TD2 at 451:8–22. But if the aim is to observe what happens over a longer period of time, it does not make sense to do so while ignoring what happens in the course of that time period. As Dr. Banakar testified, the slope changes depending on the number of data points that are considered, which would affect Dr. Myerson's prediction of how many days it would take for the QH ratio to exceed 90 percent. *See* TD3 at 898:2–23 ("So for every change, I will get a different prediction of how many days it will take to exceed 90 percent. So if I can keep two points, it will get [to 90 percent] early. If I take any two additional points, it will take a long

time."). Moreover, Dr. Myerson's decision to use only two data points is difficult to reconcile with his reliance on Lot 35550 as the lot that "had the most data." *See* TD2 at 454:14–18.

Kaneka gets no closer to meeting its preliminary injunction burden by relying on Dr. Myerson's linear regression analysis. First, Kaneka has not established that the rate of reduction for Lot 35550 remains steady over time and that it is therefore appropriate to use a linear model that assumes a constant rate of reduction, whether within the 18-month period or beyond. When asked about Dr. Banakar's opinion that the process of reducing ubiquinone was slowing down over time, Dr. Myerson responded that Dr. Banakar was "demonstrably incorrect, because if you look at the last two points, the rates of change hasn't slowed down at all." TD2 at 458:5–12. But Dr. Myerson's testimony on that issue is unconvincing. Calculating the rate of reduction at different intervals and comparing those rates makes clear that the rate of reduction in the last three months was not as high as the rate of reduction between some of the earlier months.

The final two QH ratios in the ambient stability testing were 86.2 percent (15 months) and 87.7 percent (18 months), a difference of 1.5 percent over 3 months. *See* PTX 226. Earlier in the testing, the difference between tests conducted after 3 days (80.1 percent) and after 3 months (81.7 percent) was 1.6 percent. *See id*. Between 1 month (81.3 percent) and 4 months (82.9 percent), the difference was also 1.6 percent. *See id*. However, between 2 months (80.6 percent) and 5 months (83.5 percent), the difference was 2.9 percent, and between 3 months (81.7 percent) and 6 months (85.3 percent), the difference was 3.6 percent. *See id*. Those increases in the QH ratio are about twice the increase between 15 and 18 months.

In addition to there being insufficient evidence to support Kaneka's theory that the rate of reduction remains constant across 18 or 36 months, Kaneka has offered no more than speculation about the nature of the chemical process that results in the reduction of ubiquinone during that

timeframe. It is undisputed that if AP were the only reducing agent in the defendants' reformulated products, the maximum QH ratio that those products could achieve would be 78.3 percent, because the total quantity of AP that goes into the DuoQuinol formula would have been used up by that point and no further reduction caused by AP as the reducing agent would be possible. TD2 at 412:14–20 (Dr. Myerson's testimony that 78.3 percent would be the maximum QH ratio if AP were the only reducing agent); TD4 at 921:21–25 (same testimony by Dr. Banakar). However, all the testing in the record—Triclinic's testing, the defendants' stability testing of Lot 35550, and PTX 326—shows QH ratios above 78.3 percent. And it remains a mystery why and how the QH ratio has exceeded the maximum that is possible if AP were the only reducing agent.

Dr. Myerson's explanation at trial was that "something else is acting as the reducing agent."[13] TD2 at 412:17–20. His testimony about the identity of that reducing agent, however, was entirely speculative. Dr. Myerson merely hypothesized that the additional reduction was "likely due to the GG or something that the GG decomposes to." *Id*. at 414:10–12. When he was asked again about GG, he answered, "The GG itself is acting as a reducing agent, or the GG is reacting to form something else, which is acting as a reducing agent. We just don't know because we haven't really – that hasn't been studied in any level of detail." *Id*. at 416:23–417:3. He also underscored the extent of his speculation by stating, "I'm not even sure exactly what the chemistry is of this continued reduction, because as we said, these ascorbyl palmitates [AP] are all gone. I'm not even sure what the actual mechanism of a second reduction is in terms of reducing agents."

[13] It is also possible for the QH ratio to increase based on the degradation of ubiquinone: With less ubiquinone, the denominator for the QH ratio becomes smaller, resulting in a larger QH ratio. Dr. Myerson, however, testified that the total amount of CoQ_{10} would decrease if ubiquinone were degrading without being reduced. *See* TD2 at 446:5–8. Although there is variation in the total of amount of CoQ_{10} in the ambient testing of Lot 35550, there is no discernible trend in the direction of a decrease in the total amount of CoQ_{10} in the composition. *See* PTX 226.

Id. at 456:11–15. Dr. Banakar, on the other hand, testified that GG cannot act as a reducing agent. *See* TD4 at 924:24–925:2. Given the fundamental lack of clarity regarding the chemistry resulting in the amount of reduction of ubiquinone leading to a QH ratio in excess of 78.3 percent, there is insufficient support for a linear regression analysis that assumes a constant rate of reduction.

In sum, Kaneka has not met its burden to show that it is entitled to a preliminary injunction. First, the only lot that Triclinic found to have a QH ratio higher than 90 percent was Lot 45818, which was not representative of the reformulated CoQnol 200 product. Every other lot tested by Triclinic had a QH ratio below 90 percent. Second, the QH ratio of Lot 35550 exceeded 90 percent only under accelerated conditions in the defendants' stability testing, which does not reliably establish that the QH ratio of the same lot would exceed 90 percent under ambient conditions. Third, Dr. Myerson's infringement analysis that applied the rate of reduction of Lot 35550 (whether calculated through first-and-last-point analysis or linear regression analysis) to other lots and projected a constant rate of reduction over either 18 or 36 months was unreliable.

IV. Conclusion

The findings made above, as part of the court's ruling on the motion for a preliminary injunction, are not binding with regard to further proceedings in this case, including the parties' submission of proposed findings of fact and conclusions of law, and with regard to the court's findings and conclusions on the ultimate merits of the issues in this case. *See Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981). Nevertheless, for purposes of the present motion for a preliminary injunction, I find that the defendants have raised a substantial question as to infringement by the reformulated CoQnol 100 and CoQnol 200 products, and that Kaneka has not made a clear showing that it is entitled to preliminary injunctive relief. Accordingly, Kaneka's motion for a preliminary injunction is denied.

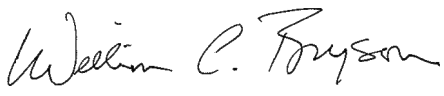
* * * * *

As per the scheduling arrangements made with counsel at the conclusion of the trial, the parties will file simultaneous Proposed Findings of Fact and Conclusions of Law with respect to the liability issues tried in the second phase of this case plus the issues of damages and other remedies as appropriate in light of the court's rulings on liability. The parties' simultaneous opening briefs of no more than 40 pages will be due for filing within 30 days of the date of this order. Simultaneous response briefs of no more than 20 pages will be due for filing within 14 days of the filing of the opening briefs.

The briefs that the parties have submitted regarding the motion for a preliminary injunction were all filed under seal. For that reason, I have filed this opinion under seal. Within ten business days of the issuance of this order, the parties are directed to advise the court by letter whether any portions of this order should remain under seal, and if so which portions. Any request that portions of the order remain under seal must be supported by a particularized showing of need to limit public access to those portions of the order.

IT IS SO ORDERED.

SIGNED this 26th day of August, 2025



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE