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.	§	

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Plaintiff Kaneka Corporation ("Kaneka") is a Japanese firm that manufactures and sells ingredients for nutritional supplements, including compositions that contain reduced coenzyme Q_{10}, an antioxidant. Kaneka owns U.S. Patent No. 7,829,080 ("the '080 patent"), which is titled "Stabilization Method of Reduced Coenzyme Q_{10}." Kaneka has asserted the '080 patent against defendants Designs for Health, Inc., ("DFH") and American River Nutrition LLC ("ARN"). Defendant ARN produces DuoQuinol, a trademarked formulation containing reduced coenzyme Q_{10}. Defendant DFH, which is affiliated with ARN, manufactures, distributes, and sells nutritional supplements that contain DuoQuinol in softgel form.

BACKGROUND

I. The Products

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. Kaneka's '080 patent claims both a ubiquinol composition and a method of stabilizing ubiquinol and preventing its oxidation into ubiquinone. The claimed ubiquinol composition also contains the

related compounds reduced Coenzyme Q_9 ("CoQ_9") and/or reduced Coenzyme Q_{11} ("CoQ_{11}"). *See* '080 patent, col. 2, ll. 36–41.

Claims 5 and 15 of '080 patent are asserted 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 ubiquinone) is referred to as the "QH ratio." At issue in this case is the limitation

in both claims 5 and 15 of the '080 patent requiring the QH ratio to be at least 90 percent by weight ("the QH limitation"). In the proceeding at issue in this stage of the litigation between Kaneka and the defendants, the defendants dispute whether certain products that Kaneka accuses of infringement—the defendants' reformulated CoQnol 100 and CoQnol 200 products—satisfy the QH limitation. The defendants do not dispute that their reformulated products satisfy every other limitation of claims 5 and 15. *See* D.I. 352 at 6–9.

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

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 used in the softgels, however, is the same for both the CoQnol 100 and CoQnol 200 products. *See* TD2 at 309:12–23.

The defendants' original products contained DuoQuinol that was made with a 4:2:4 ratio of GG to AP to ubiquinone. TD2 at 315:13–16. Those products were the subject of the first trial in this case, which resulted in a finding that the defendants' original products infringed the asserted claims of the '080 patent. That finding was based in large part on evidence that the defendants' original products had a QH ratio of more than 90 percent within the products' shelf life.

In June 2023, prior to the first trial, the defendants considered reformulating their products, *see* PTX 268, and they subsequently experimented with altering the ratio of GG to AP to ubiquinone, with the objective of ensuring 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 of components and ultimately settled on the ratio of 4:1.5:4 of GG to AP to ubiquinone for their reformulated version of DuoQuinol. *See* PTX 270, DTX 489. In October 2023, the defendants substituted the reformulated products for the original products in the market and stopped selling the original products.

II. The Proceedings

To date, this case has proceeded in two phases. In the first phase ("Phase 1"), Kaneka accused the defendants' original products, known as CoQnol-100, CoQnol-200, Q10.1-100, and Q10.1-200, of infringing claims 5 and 15 of Kaneka's '080 patent. I held a bench trial in late May and early June of 2024 to address Kaneka's infringement claims directed at those products. Following that trial, I found that the defendants' original products infringed the asserted claims, and I rejected the defendants' claims that the asserted claims were invalid. Dkt. No. 249.

Following the Phase 1 trial, Kaneka sought relief with respect to the defendants' reformulated products. Accordingly, I scheduled a second trial ("the Phase 2 trial") to determine whether the defendants' reformulated products infringed Kaneka's '080 patent and to determine what damages Kaneka was entitled to for the defendants' infringement with respect to the original products.

Three months before the Phase 2 trial was scheduled to begin, Kaneka filed a motion seeking an injunction directed at the defendants' reformulated products. D.I. 267. Because Kaneka was seeking preliminary injunctive relief with respect to the reformulated products, which

had not yet been found to infringe, I revised the scheduling order with the parties' consent so that the hearing on the motion for a preliminary injunction would be held together with the second bench trial on the merits with respect to the reformulated products. D.I. 281; *see also* D.I. 306.

The Phase 2 trial was held from July 21 through July 24, 2025.[1] On August 26, 2025, I entered an order denying Kaneka's motion for a preliminary injunction based on my findings that the defendants had failed to make a convincing showing at trial that the manufacture and sale of their reformulated products infringed the '080 patent, and that Kaneka did not otherwise show that it was entitled to preliminary injunctive relief. D.I. 413.

After the record was closed following the Phase 2 trial, the parties filed proposed findings of fact and conclusions of law on the merits of the infringement claims. In addition, Kaneka filed three motions seeking post-trial relief based on evidence that Kaneka had not introduced at trial. *See* D.I. 424, 430, and 4413. Those motions asked the court (1) to reopen the record to admit the results from testing conducted after the conclusion of the Phase 2 trial; (2) to take judicial notice of four documents (two published patents, a "white paper" posted on defendant ARN's website, and a journal article) to support a theory of infringement that was not squarely presented during the Phase 2 trial; and (3) to enter judgment on partial findings pursuant to Federal Rule of Civil Procedure 52(c). In response, the defendants filed a motion to strike Kaneka's new documents and portions of Kaneka's proposed findings of fact and conclusions of law on the ground that Kaneka's submissions were based in large part on evidence that was the subject of Kaneka's post-

[1] Transcripts of the four days of the proceedings in the second trial (TD1–TD4) are docketed at D.I. 409 through 412. Redacted versions of these transcripts are docketed at D.I. 459 through 462. The transcripts of the four days of proceedings in the first trial are docketed at D.I. 235 through 238.

trial motions but was not admitted at trial. D.I. 433. I held a hearing on January 15, 2026, to address those motions as well as the parties' proposed findings of fact and conclusions of law.

DISCUSSION

Before discussing the merits of Kaneka's claims of infringement and damages that were the subjects of the Phase 2 trial, I will address the post-trial motions filed by Kaneka and the responsive motion filed by the defendants.

I. Post-Trial Motions

Kaneka's post-trial motions share a common theme: They ask the court to consider new evidence, some of which was available prior to trial and some of which was not. With respect to the evidence that was unavailable at the time of trial, Kaneka asks the court to reopen the record to admit that evidence. With respect to the evidence that was available prior to trial but was not offered into evidence, Kaneka asks the court to take judicial notice of that evidence and consider it in connection with Kaneka's new arguments on infringement.

The volume of evidence Kaneka urges the court to consider is substantial and reflects a significant change in the focus of Kaneka's infringement case. In effect, without suggesting that there was any error in the manner in which the case was tried, Kaneka is asking for a do-over. Kaneka has put forth no justification for such a dramatic departure from regular order, and for the reasons set forth in detail below, I will deny Kaneka's various motions directed to that end.

A. Kaneka's Motion to Reopen the Record

Kaneka first seeks to reopen the record to introduce test results that it contends were unavailable at the time of the Phase 2 trial. The defendants respond that Kaneka's motion to reopen the record seeks to present new evidence that reactions in the defendants' reformulated products have caused the QH ratio in those products to exceed 90 percent prior to the end of the products'

designated shelf life and a new theory as to why that is so. D.I. 425 at 6 ("Kaneka's request is not limited to merely admitting 'supplemental' testing results, it also presents new arguments.").

According to Kaneka, the results from the post-trial testing—what Kaneka refers to as the "Supplemental Tests"—show that the reformulated products at issue in the Phase 2 trial will exceed a QH ratio of 90 percent within their shelf life and thus will satisfy the QH limitation in the asserted claims of the '080 patent. Kaneka asserts that the new test results were not previously available because the time required for the QH ratio in those products to exceed 90 percent had not elapsed when the trial occurred, and that it is now "in the interest of equity and preservation of a complete record" for the court to reopen the record to admit them. D.I. 425 at 2–4. Kaneka contends that if the Phase 2 trial "had been held just a few months later, the products would have had sufficient time to reduce, and . . . reach the 90% QH Ratio." *Id.*

The defendants, on the other hand, point out that Kaneka had urged the court to move forward with the Phase 2 trial, and they argue that Kaneka "should not be permitted to cure its failure to show infringement at trial at this late stage in the case." D.I. 448 at 1. The defendants point out that the new test results that Kaneka seeks to add to the trial record "were not the subject of fact or expert discovery" and were not subject to cross-examination at trial. *Id.* In the defendants' view, Kaneka's motion is "completely improper, unfair, and prejudices Defendants." *Id.*

The decision to reopen the record "to submit additional proof is addressed to [the court's] sound discretion," *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 401 U.S. 321, 331 (1971), although the court "must avoid perpetrating any type of injustice in so doing." *Gibson v. Mayor & Council of City of Wilmington*, 355 F.3d 215, 229 (3d Cir. 2004) (citation omitted). The Third Circuit has outlined several factors that must be considered in deciding whether such an injustice will occur.

Those factors are (1) "the burden that will be placed on the parties and their witnesses"; (2) "the undue prejudice that may result from admitting or not admitting the new evidence"; and (3) "considerations of judicial economy." *Id.* (citing *Rochez Bros., Inc. v. Rhoades*, 527 F.2d 891, 894 n.6 (3d Cir. 1975)).

1. The Burden on the Parties and their Witnesses

The first factor to consider is the burden that would be imposed on the parties and their witnesses if the record were reopened at this point to allow Kaneka to introduce additional evidence. Kaneka contends that the burden on the parties and witnesses would be minimal, since the motion was filed concurrently with the parties' proposed findings of fact and conclusions of law, only about two months after the trial. From Kaneka's perspective, the issue of whether the QH ratio will reach 90 percent has already been explored at trial by the parties, and the new test results would simply supplement the test results presented at trial with additional results of testing conducted at the same Triclinic facility that was responsible for the test results that are already in evidence. D.I. 425 at 10.

The defendants take issue with that characterization of the new evidence Kaneka seeks to introduce. They argue that only some of the test results that Kaneka now seeks to admit are from testing conducted at the Triclinic facility and that those results were obtained by a different testing protocol from the one used in prior Triclinic testing), while other test results were produced by Kaneka's in-house Quality Assurance Team (QAT) using an undisclosed procedure. The defendants further contend that Kaneka is seeking to present new evidence in support of arguments that go beyond the testimony of Kaneka's expert. D.I. 448 at 4–6. As for the test results themselves, the defendants argue that differences in the "sample preparation procedure" and the lack of triplicate runs in testing means that the results Kaneka seeks to admit raise questions

requiring additional fact and expert discovery. *Id.* at 5. Such measures, the defendants contend, would impose a significant burden on the parties and their witnesses.

The defendants' argument is a compelling one. Cases in which courts have allowed the record of a trial to be reopened mainly involve measures designed to cure a technical error, such as the failure to admit evidence of an undisputed fact that a party neglected to offer at trial. *See, e.g., United States v. Trant*, 924 F.3d 83 (3d Cir. 2019) (allowing reopening of the evidence to permit the prosecution to admit parties' stipulation that the defendant had a prior felony conviction); *United States v. Leslie*, 103 F.3d 1093, 1104 (2d Cir. 1997) ("Generally a district court will allow reopening to establish venue, identify the defendant, or attend to other technical matters.") (citing cases); *Am. Trucking Ass'ns, Inc. v. Alviti*, 630 F. Supp. 3d 357, 372–73 (D.R.I. 2022) (allowing reopening to admit evidence establishing plaintiffs' standing, which the defendants had not previously challenged).

Reopening the record for such purposes is different *toto caelo* from allowing reopening to introduce substantial new evidence or new theories of recovery never offered at trial. *See Sunoco Partners & Mktg. Terminals L.P. v. Powder Spring Logistics, Inc.*, No. 17-1390, D.I. 848 at 2 (D. Del. Aug. 16, 2022) (A request for proposed findings of fact "was not an invitation for Defendants to submit new evidence. It is entirely too late for Defendants to introduce new evidence to the record."); *TruePosition Inc. v. Andrew Corp.*, No. 05-747, 2008 WL 205305, at *2 (D. Del. Jan. 23, 2008) ("the time for gathering and presenting rebuttal evidence . . . has come and gone. . . . This evidence postdates the jury's verdict and, because it was not part of 'the factual record created at trial,' was not permissibly included in defendant's post-trial briefing."); *Late v. United States*, No. 0756, 2016 WL 8787120, at *2 n.1 (M.D. Pa. Nov. 10, 2016) (denying motion to reopen the record after a bench trial, noting that the party seeking reopening did not "simply fail to move for

the admission of evidence it presented at trial, but, rather is attempting to add evidence not available during trial to the record after the trial has ended.").

Kaneka seeks to add a substantial volume of new information that was not previously disclosed to the defendants and that the defendants have not had the opportunity to challenge or rebut. There is no justification for allowing Kaneka to take this second bite at the apple. The Phase 2 trial in the case has already occurred. Discovery was completed, the experts prepared reports, were deposed, and testified. There was no suggestion from Kaneka, either before or at the time of trial, that there was other evidence, either in existence or expected to be developed, that Kaneka wished to introduce. If the record were reopened to admit Kaneka's new evidence, the defendants would have to be given an opportunity to respond to the new evidence, likely including their own further testing and challenges to Kaneka's new theory to explain the continuing reduction in the accused products. Requiring the experts to examine the new data, prepare new reports, and testify again would impose a substantial burden on the parties and the witnesses. In effect, Kaneka's request to reopen the record would lead to what would, in all likelihood, amount to a new trial on infringement. The burden on the parties and their witnesses weighs strongly against granting Kaneka's motion.

2. Undue Prejudice

The second factor I must consider is the prejudice that would result from reopening or not reopening the record following the close of the evidence. Kaneka argues that a decision by the court not to reopen the record would result in extreme prejudice to it and a windfall for defendants. According to Kaneka, that is because the new test results directly relate to the primary issue in the case, the new data is not cumulative, and it is potentially outcome determinative. Kaneka notes that during trial the defendants did not raise any concerns about the testing method, which Kaneka

alleges is the same method that was used to generate the new test data. D.I. 425 at 10–11. Therefore, Kaneka contends, the defendants have failed to raise a convincing challenge to the testing protocol used to develop the new testing results.

For their part, the defendants point to some of the same concerns that apply to the burden on the parties and the witnesses: a further delay in the court's decision if the motion to reopen is granted and the need for new discovery, new expert reports, new testimony from both parties, and a new opportunity for cross-examination, entailing a substantial commitment of time and resources devoted to new pretrial and trial proceedings. D.I. 448 at 7–8.

Both sides point to *Wirtgen America., Inc. v. Caterpillar, Inc.*, No. 17-770, 2024 WL 3858847, at *1 (D. Del. Aug. 19, 2024), in support of their respective positions on the reopening issue. In *Wirtgen*, the court denied the defendant's motion to reopen the record and admit new evidence related to equitable defenses, an issue that remained open for the judge to decide after the jury returned a verdict of patent infringement for the plaintiff. Kaneka argues that unlike in *Wirtgen*, Kaneka's request for injunctive relief would not delay the case; in addition, Kaneka argues that it "had no prior opportunity to submit this evidence." D.I. 425 at 12.

The defendants respond that Kaneka is in the same posture as the defendants in *Wirtgen*: Kaneka is attempting to "jam additional evidence" into the record without giving opposing counsel the chance to address it; Kaneka failed to previously notify the court or defendants of the new evidence; and allowing the evidence into the record would either severely prejudice the defendants (if they were not given a full opportunity to contest the evidence) or result in substantial delay (if they were). D.I. 448 at 8 (quoting *Wirtgen*, 2024 WL 3858847, at *2).

Although the facts of *Wirtgen* differ from the facts of this case, the principles the court applied in that case are applicable here. As with the defendant's attempt to reopen the record in

Wirtgen, Kaneka could have arranged to present the new evidence at trial. Kaneka responds that it did not have an opportunity to test the reformulated products at the end of their shelf life because Kaneka did not become aware that the defendants had reformulated their products until April 2024.

There are several answers to that argument. First, Kaneka could have requested a postponement of the trial until such time as those reformulated products had reached the end of their shelf life or, in the alternative, until such earlier time as testing established that the products had a QH ratio higher than 90 percent. To the extent that Kaneka could obtain samples of the defendants' reformulated products that were marketed shortly after the reformulation was effected in October 2023, the shelf life of those products, which the defendants shortened to 18 months in January 2025, would have run by the time of the trial July 2025 trial. Instead, Kaneka sought to prove infringement not through direct evidence that the reformulated products had a QH ratio of more than 90 percent, but rather by using indirect methods of proof such as testing under accelerated conditions or extrapolating from test data showing products with QH ratios of less than 90 percent and predicting that the QH ratios in those products would rise to more than 90 percent before the expiration of the products' shelf life.

Rather than elect that more conservative course, Kaneka insisted on having a trial on the merits of the infringement issue as to the reformulated products as early as the summer of 2025. Although Kaneka hints in its briefing that it was forced to go to trial in Phase 2 of this case before it was ready, that is not the case, as is shown by the record of the positions taken by the parties prior to the Phase 2 trial.

An additional factor that bears on whether to reopen the record is whether Kaneka has offered a persuasive justification for its failure to introduce the new evidence earlier, so that the new evidence could be considered along with the rest of the evidence that was introduced at trial.

Kaneka argues that it could not have offered the new evidence in question earlier, because the evidence did not exist at that time. *See* D.I. 425 at 14 ("There was nothing [Kaneka] could have done, no additional diligence or investigation it could have conducted, that would have revealed this evidence earlier."). That argument is not convincing. Kaneka arranged for the testing in dispute shortly after the Phase 2 trial. The Phase 2 trial ended on July 24, 2025, and I issued my order denying a preliminary injunction on August 26, 2025. According to Kaneka's records, Kaneka shipped additional bottles of the defendants' reformulated product to Triclinic and Kaneka's laboratories for testing shortly thereafter, on August 27, September 6, and September 15 of 2025. D.I. 426 at ¶¶ 5, 8, 10. Kaneka has not explained why it could not have submitted those same products for testing a few weeks earlier, prior to the Phase 2 trial in July 2025.

To the extent Kaneka relies on the fact that the shelf life of the reformulated products (initially 36 months, but after December 2024, 18 months) had not expired by the time of the trial in July 2025, and thus testing those products at the end of their shelf lives prior to the trial would not have been possible before the trial, that was an issue Kaneka could have avoided by agreeing to postpone the Phase 2 trial until all the relevant testing could be completed.[2] In fact, prior to the July 2025 trial the court offered the parties the opportunity to postpone the trial, but Kaneka resisted any delay in the trial.

[2] Kaneka asserts that it was not until April 2024 that it learned the defendants had reformulated their products beginning in October 2023. If Kaneka had begun testing the reformulated products in April 2024, it could have determined by April 2025 whether products made in October 2023 infringed after 18 months, the shelf life that the defendants adopted for all their products sold after January 2025. If, as Kaneka asserts, it could prove that all of the defendants' reformulated products infringed within 18 months of their manufacture, it would not have been necessary for the defendants to wait 36 months to be able to prove infringement as to all of the reformulated products, including the products that were assigned a 36-month shelf life prior to December 2024.

A close examination of the record makes it clear that Kaneka was not forced to go to trial before it was ready; quite the opposite. Following the court's entry of findings of fact and conclusions of law in the Phase 1 trial on December 20, 2024, the court asked the parties to agree on a schedule for the Phase 2 proceedings. The Phase 2 trial was intended to assess damages for the defendants' original products that were found to infringe in the Phase 1 portion of the case and to determine liability and damages, if any, for the reformulated product that the defendants began selling in October 2023. On December 30, 2024, the parties agreed on a schedule leading to the Phase 2 trial on June 9 and 10, 2025. D.I. 251. The court adopted that agreed-upon proposed schedule without change. D.I. 251.

On March 15, 2025, Kaneka moved for an injunction in the case, which the court treated as a motion for a preliminary injunction, as it was directed at enjoining the sales of the defendants' reformulated products, which had not yet been found to be infringing. D.I. 267. Two days later, the defendants wrote to the court seeking a status conference to discuss the need to modify the scheduling order, including the June 2025 trial date. D.I. 271. The defendants complained that in light of what they characterized as the "expanded scope of [Kaneka's] newly disclosed infringement allegations," additional time would be required to address those allegations. *Id.* at 1. Kaneka replied the next day, objecting to any postponement of the trial and contending that the defendants' "delay tactics compound the harm to Kaneka, which continues to suffer from Defendants' infringement." D.I. 273, at 2.

At the parties' request, the court held a status conference on March 19, 2025, at which the parties discussed scheduling and in particular the date for the Phase 2 trial. At that status conference, the defendants sought to postpone the trial, but Kaneka's counsel objected, stating that "Kaneka's position is clear that we don't want any further delay. We want to move forward," D.I.

289 at 54:10–11; *id*. at 44:22–45:2 (we "want to move forward with the damages portion of the trial" in June). The court proposed combining the preliminary injunction hearing with the trial on the merits as to the reformulated products, both to be conducted on June 9–10, 2025. Kaneka and the defendants both agreed with that proposal, subject to some changes in the timing of certain pretrial events. *See* D.I. 276, 277.

At a further conference on March 27, 2025, the parties again discussed the issue of timing. D.I. 472. After discussion, the court concluded that it would be necessary to delay the trial somewhat—until July or August of 2025, as the defendants had requested. Kaneka agreed to a brief postponement, but stated:

> [O]bviously, we're interested in pushing this forward. We thought that the schedule that Your Honor had put in place back when the case was bifurcated covered all of this. But I understand that the defendants are raising issues in their letters that may support additional time.
>
> But we don't obviously, and I said this on our last call want this to be delayed several months. To the extent we can complete the damages portion of the trial on the initial product and the preliminary injunction hearing on the same day in June, we would be in favor of that with the hope that we could schedule liability for the reformulated products soon thereafter to the extent Your Honor has time for us.

Id. at 10:17–11:8.

The pretrial events make it clear that Kaneka never suggested that it needed a postponement of the trial to enable it to conduct further testing of the accused products. Kaneka's position now is that the testing evidence it developed within a month after the trial would have greatly strengthened its infringement case, but that it was not able to conduct that testing prior to trial. Before the trial, however, Kaneka pressed to go forward with the trial in June or July 2025. Having chosen to urge an early trial, Kaneka took the risk that the evidence it introduced at trial would not be strong enough to justify a preliminary injunction or for Kaneka to prevail on the merits of its infringement claims. That concern was no doubt heightened in August 2025, when the court filed

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its order denying Kaneka's request for a preliminary injunction on its Phase 2 infringement claims. At that point, rather than attempting to support its claims of infringement based on the record made at trial, Kaneka decided to try to buttress its evidence by introducing new evidence that was not before the court during the trial.

Kaneka's effort to repair an insufficient case after the fact will not work. "[A] party cannot request relief from the court for its own errors in judgment, when the strategy of litigation was based on conscious and informed choices." *Bell Tel. Lab'ys, Inc. v. Hughes Aircraft Co.*, 73 F.R.D. 16, 23 (D. Del. 1976). As with a waived argument or defense, a party's litigation decisions may be consequential, but they are not excusable errors that can be repaired after the trial has ended.

If I were to grant Kaneka's motion to reopen the record without giving the defendants the opportunity to properly challenge the new test results, I would be gravely prejudicing the defendants. In their post-trial briefing, the defendants point to a number of questions about Kaneka's new test results and argue that they should be "entitled to challenge [that evidence] before the results are accepted, as the trial record is devoid of any witness testimony establishing the reliability of Kaneka's new testing." D.I. 448 at 10. Not allowing the defendants the opportunity to challenge the new test results would be unfair, just as the lack of cross-examination of the two expert witness declarations submitted after the close of evidence in *Wirtgen* was unfair. *See Wirtgen*, 2024 WL 3858847, at *2; *see also Mars, Inc. v. Coin Acceptors, Inc.*, No. 90-49, 2004 WL 4999044, at *2 (D. Del. Aug. 12, 2004) ("[T]he unfairness to Mars which would result from the Court considering this new evidence is obvious; Mars has had no opportunity to cross-examine the witnesses on the new evidence, and the Court is not willing to set up some deposition or reopening-the-trial procedure to provide such an opportunity, particularly when Coinco could have presented such evidence at trial.").

Because I regard the problem that Kaneka faced at trial to be the result of Kaneka's insisting on going to trial before it had the testing data that it now regards as important to proving its case, and because of the burden on the defendants that would result from reopening the case to allow Kaneka to introduce the evidence that Kaneka developed after the trial, I regard this factor as weighing strongly against reopening the record at this point.

3. Judicial Economy

The third factor bearing on whether to reopen the evidence is judicial economy. According to Kaneka, it would be most efficient to reopen the record and resolve this case using the new test results, because it "would be significantly less onerous at this juncture than at any later date." D.I. 425 at 12. In particular, Kaneka asserts that admitting the new evidence would avoid the "burdens and expenses" of another lawsuit at which the new evidence would be introduced. *Id.* at 13.

The defendants respond that it is not more efficient to reopen the record, given that Kaneka is responsible for the additional burden on the court because of its failure to notify the court and the defendants of its additional testing prior to trial or to request postponement of the trial until the new round of testing had been completed. With respect to Kaneka's argument that reopening the record to admit Kaneka's new evidence would avoid the need for a whole new trial at which that evidence would be offered, the defendants argue that collateral estoppel will prevent Kaneka from bringing any duplicative claims in future litigation. D.I. 448 at 8.

The inefficiencies resulting from reopening the evidence in this case are plain: I would have to provide the defendants with the opportunity to mount a full challenge to the new evidence, which would likely include additional fact discovery, new expert witness declarations and expert discovery, and further presentation of live testimony and cross-examination, all of which would

further prolong this case. In effect, I would need to conduct a third set of pretrial proceedings and a third trial in this case, which is already more than five years old.

On the other hand, the possible inefficiencies flowing from denial of the request to reopen the record are speculative. It is by no means certain that Kaneka would file a further infringement action in the event that the defendants continue to sell their reformulated product. In light of the new evidence, the defendants might further modify their products, or the parties could resolve their differences, which would avoid the burden and expense of further litigation. As for the defendants' contention that collateral estoppel would bar any future litigation over the defendants' DuoQuinol products, that argument is, again, speculative. Thus, reopening the record ensures that burdensome further proceedings will be required. Declining Kaneka's request to reopen the record raises the possibility of further proceedings of undetermined complexity. On balance, the judicial economy factor weighs in favor of denying Kaneka's motion to reopen.

Considering the three factors discussed above, I am persuaded that I should not reopen the record at this point in the litigation to admit the evidence with which Kaneka seeks to supplement its case. To do so would invite substantial additional proceedings in what would amount to a do-over for Kaneka in a case that has already proceeded through two trials. On balance, I find that reopening the record would not be consistent with the Third Circuit's directive that in deciding whether to reopen the record following a trial, the court "must avoid perpetrating any type of injustice in so doing." *Gibson*, 355 F.3d at 229.

Kaneka's motion to reopen the record is denied.

B. Kaneka's Motion for Judicial Notice

After the defendants filed a motion to strike portions of Kaneka's proposed findings of fact and conclusions of law, Kaneka filed a cross-motion for the court to take judicial notice of four

publicly available documents relating to GG, a component found in the defendants' products. D.I. 441 & 442. The four documents are: (1) U.S. Patent No. 7,989,006; (2) U.S. Patent No. 9,949,938; (3) *Geranylgeraniol (GG): An Extensive Overview*, a white paper on ARN's website discussing a product manufactured by ARN, which the white paper refers to as "GG-Gold"; and (4) *Evaluation of Antidiabetic and Antioxidant Potential of Methanolic Extract of Bixa Orellana Seeds,* an article by Tamanna Sharmin Tonny, et al. in the Biomedicine Pharmacology Journal. D.I. 443 at Exhs. 3–6.

I will address Kaneka's motion for judicial notice before discussing the defendants' motion to strike because Kaneka's judicial notice motion is similar in character to Kaneka's motion to reopen the record. Like the motion to reopen the record, the motion to take judicial notice of evidence that was not introduced at trial seeks to expand the record after the close of the evidence at trial, the difference being that Kaneka's motion to reopen is directed to evidence that had not been developed at the time of the trial, while the motion for judicial notice is directed to evidence that was publicly available prior to the trial. For the reasons discussed below, I find Kaneka's request to be unjustified, and I therefore decline to take judicial notice of the four documents at issue.

Rule 201 of the Federal Rules of Evidence provides that a court may judicially notice a fact that is not subject to reasonable dispute if the fact in question is "generally known within the trial court's territorial jurisdiction" or "can be accurately and readily determined from sources whose accuracy cannot be questioned." Fed. R. Evid. 201(b).

Kaneka urges this court to take judicial notice not only of the existence of the four designated documents, but also "of the truth of the matters asserted" in those documents "because they are 'not subject to reasonable dispute' and 'can be accurately and readily determined from

sources whose accuracy cannot be reasonably questioned.'" D.I. 442 at 15 (quoting Fed. R. Evid. 201(b)). According to Kaneka, the four documents are not subject to objection on hearsay grounds because they constitute statements of a party opponent (the two patents owned by ARN and the white paper on ARN's website), as public records (the two patents), or as statements in a periodical (the journal article by Tonny *et al.)*. *Id.* at 14–16 (citing Fed. R. Evid. 801(d)(2), 803(8), 803(18)). Even if those documents are not admissible for the truth of the matters asserted in them, Kaneka argues that the documents may be used to impeach the defendants' expert witness, Dr. Umesh Banakar. D.I. 442 at 17 n.15; *see* Fed. R. Evid. 806.

In support of its motion, Kaneka asserts that its proffered documents do not pertain to an entirely new theory of infringement, but relate to expert witness testimony that was presented at trial, i.e., the suggestion by Kaneka's expert, Dr. Allan Myerson, that the GG component in the accused products or a derivative of that component may have been responsible for additional reduction of the ubiquinone in the defendant's reformulated products that would render those products infringing during the products' designated shelf life. *Id.* at 18–19.

The defendants respond that "there is a reasonable dispute about whether GG . . . [or] an ingredient in GG Gold[] can act as a reducing agent in the Reformulated Products," and that it would therefore be improper for the court to take judicial notice of the four proffered documents. D.I. 447 at 4 (noting that Dr. Myerson was uncertain at trial about the cause of the continued reduction of the ubiquinone and that Dr. Banakar testified that the GG in the defendants' reformulated products was not responsible for any such reduction). The defendants assert that Kaneka is asking the court to accept not just the existence of the four disputed documents, but also Kaneka's interpretation of those documents. *Id.* at 5–6. The defendants further note that even though the four documents were in existence well before the trial, Kaneka "did not identify the

GG documents during fact discovery, expert discovery or at trial," thereby depriving the defendants of the "opportunity to respond to Kaneka's theory." *Id.* at 6. Kaneka does not dispute that the four documents for which Kaneka seeks judicial notice were all available during the pretrial period and that Kaneka did not seek to have the four documents admitted into evidence at trial.

In its discussion of Rule 201, the Advisory Committee on the Federal Rules of Evidence explained that the "usual method of establishing adjudicative facts is through the introduction of evidence, ordinarily consisting of the testimony of witnesses. If particular facts are outside the area of reasonable controversy, this process is dispensed with as unnecessary. A high degree of indisputability is the essential prerequisite." Advisory Committee Notes on the 1972 Proposed Rules of Evidence. In *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1378 (Fed. Cir. 2017), the Federal Circuit made the same point; it declined to take judicial notice of the scientific premise behind a particular antigen test, noting that doing so would "displace the required fact finding with what amounts to a rule of law." In this case, I likewise see no justification for taking judicial notice of a disputed fact question bearing on an element of Kaneka's theory of infringement that could have been presented through the usual process of admitting factual evidence at trial.

In addition, Kaneka has provided no persuasive reason why the four documents in question could not have been proffered as evidence during the Phase 2 trial. The patents for which Kaneka seeks judicial notice were issued in 2011 and 2018, more than seven years before the trial. *See* Patent No. 7,989,006 (issued Aug. 2, 2011); Patent No. 9,949,938 (issued Apr. 24, 2018). And Kaneka does not suggest that the white paper found on the defendants' website or the 2024 journal article became available only after the July 2025 trial.

Kaneka's request is similar to the unsuccessful request for judicial notice of a patent application more than two months after trial in *UCB, Inc. v. Actavis Laboratories UT, Inc.*, Civil Action No. 19-474, 2021 WL 1880993, at *18 n.13 (D. Del. Mar. 26, 2021). In denying that request, the court noted that the plaintiff "should have identified the patent application and vetted it during fact and expert discovery long ago, but they did not identify it in any pleading contention, interrogatory response or expert report . . . . Nor did they introduce it at trial." *Id.* (citation omitted). Here, the four documents for which Kaneka seeks judicial notice should have been offered into evidence at trial, not during the post-trial briefing. Moreover, to the extent Kaneka contends that the four documents have value for impeachment purposes with regard to the testimony of Dr. Banakar, the defendants' expert witness, the proper course would have been to use them at trial while cross-examining him.

Importantly, Kaneka asks the court to take judicial notice for more than just the fact of the existence of the documents. Rather, Kaneka asks that these documents be entered into evidence to support, and expand upon, a theory explaining the continued reduction and increase in the QH ratio of the reformulated products beyond that which can be attributed to the AP in those products. D.I. 428 at 5–6; *see* D.I. 442 at 16–17. That theory was advanced somewhat tentatively at trial by Dr. Myerson, who testified that the continuing reduction was "likely due to the GG or something that the GG decomposes to." D.I. 410 at 414:11–12. He testified that the GG in the reformulated products was clearly reacting because the concentration of GG in the products "is going down. So it's obviously reacting. And so I only can see two possibilities. 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. But we know that reduction is continuing, and we know that the ascorbyl palmitate is used up, and we

know the concentration of GG is going down. So my analysis would be GG or a derivative of GG is a reducing agent." *Id.* at 416:16–417:8.

Dr. Banakar disagreed with Dr. Myerson's analysis. He testified unequivocally that GG cannot act as a reducing agent. TD4 at 924:24–925:5. Kaneka now wishes to use the four documents at issue not simply to support Dr. Myerson's tentative theory regarding the role of GG in causing continuing reduction; rather, Kaneka seeks to use the documents to go well beyond Dr. Myerson's testimony and to identify tocotrienols, compounds that Kaneka asserts are contained in the GG component of the defendants' products, as powerful reducing agents that are causing continuing reduction of the ubiquinone in the defendants' products.

It may be that if the documents at issue had been introduced at trial, they would have led to the conclusion that the GG in the defendants' reformulated products caused additional reduction and that Dr. Banakar's testimony to the contrary was wrong. But that was an issue that should have been resolved through the admission of all the relevant conflicting evidence at trial, not by an end run through using judicial notice to buttress Dr. Myerson's tentative trial testimony after the trial was concluded.

In denying the plaintiff's request for judicial notice made two months after trial, the court in *UCB* emphasized that the plaintiffs did not want the court just to "take notice of the existence of the application" but also wanted the court to "rely on [the plaintiff's] characterization of specific technical disclosures to assess secondary indicia of nonobviousness." 2021 WL 1880993, at *18 n.13. Likewise, the court in *Irrevocable Trust of Antonious v. Nike, Inc.*, distinguished between taking "judicial notice of the *existence* of a publicly filed patent" and making technical arguments based on those patents, which would require reopening discovery. No. 11-CV-06327, 2016 WL 3176576, at *6 (D.N.J. June 2, 2016); *see also Whitewater W. Indus., Ltd. v. Pac. Surf Designs,*

Inc., No. 3:17-CV-01118, 2017 WL 4518526, at *2 (S.D. Cal. Oct. 10, 2017) (pointing out the difference between judicially noticing the existence of documents and judicially noticing "how to interpret those documents"). Even if I were to take judicial notice of the existence of the patents, the white paper, and the journal article, I cannot conclude that the scientific principles for which Kaneka seeks to use those documents are not subject to reasonable dispute and therefore are judicially noticeable.

While the documents proffered by Kaneka may not be subject to exclusion on hearsay grounds in light of Kaneka's arguments that they are admissible as party admissions or under the hearsay exception for periodicals,[3] the principal problem is whether the documents are subject to judicial notice at all, given that it is undisputed that the documents were available prior to the trial but were not offered in evidence at that time, with no explanation for why they were not offered at trial.

Kaneka notes (D.I. 451 at 3 n.4) that a court may take judicial notice "at any stage of the proceeding." Fed. R. Evid. 201(d). For example, the court in *Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, 694 F. Supp. 3d 511, 534 & n.9 (D. Del. 2023), took judicial notice of terminology in a patent that was not in the record but that the patents at issue could be traced to as continuations in order to better understand terms in the patents at issue. Kaneka's request for judicial notice, however, goes far beyond simply seeking to clarify the meaning of undefined terms. If granted, Kaneka's request would open the door to an argument that the defendants did not have the

[3] There are several problems with Kaneka's argument that the 2024 journal article would be admissible under Federal Rule of Evidence 803(18), the hearsay exception for statements in learned treatises, periodicals, or pamphlets. First, such statements must be "called to the attention of an expert witness on cross-examination or relied on by the expert on direct examination," which of course did not occur here. Second, the publication must be "established as a reliable authority by the expert's testimony, or by judicial notice," which also did not occur here. And third, if admitted, the statement may be read into evidence, but may not be received as an exhibit.

opportunity to confront at trial. As a matter of fairness to the defendants, granting Kaneka's request would require me to reopen discovery and reconvene the trial.

As the Fifth Circuit stated in *Colonial Leasing Co. of New England v. Logistics Control Group International*, 762 F.2d 454, 461 (5th Cir. 1985), although Rule 201(d) is "broadly and bluntly stated, the Rule is not without limits." The court in that case pointed out, for example, that "a trial court could not take judicial notice, in its written opinion, of facts supporting its jurisdiction two years after the stipulated evidence was concluded." *Id.* A court's power to take judicial notice after the fact, the court explained, "is limited by 'the requirement of fairness.'" *Id.* (citing Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 5110).

The court in *Knop v. Johnson*, 667 F. Supp. 467, 485 (W.D. Mich. 1987), made the same point, noting that despite the broad language of Rule 201(d), it is "not as broad as it appears to be." As the court explained, "judicial notice is an alternative means of proof that is subject, like all other offers of evidence, to rule 403 and 611(a)," which allows a court to "exercise reasonable control over the mode and order of examining witnesses and presenting evidence." The court in that case denied the request for judicial notice based on the untimeliness of the request. The same result is justified here.

A further problem with Kaneka's request that the court take judicial notice of the four new documents is that even if Kaneka is correct that tocotrienols can be converted from GG, and that tocotrienols have the capacity to reduce ubiquinone, the evidence is silent as to the conditions under which GG converts into tocotrienols and how much reducing capacity any tocotrienols converted from the GG in the defendants' reformulated products would have.[4] For that reason,

[4] Further uncertainty is added by Kaneka's distinction between the "GG Gold" referred to in the ARN white paper and the GG referred to by Dr. Banakar in his testimony. Kaneka suggests that Dr. Banakar's testimony that GG cannot serve as a reducing agent is suspect because he

even if some further reduction of ubiquinone could be attributable to the conversion of GG into tocotrienols, it would be impossible to determine without additional evidence how much further reduction would occur, and thus whether the further reduction could confidently be predicted to go beyond the 90 percent QH ratio specified in the asserted claims of the '080 patent. The evidence for which Kaneka asks the court to take judicial notice would therefore be only the beginning of a new proceeding exploring the chemistry of GG, the conditions under which GG converts to tocotrienols, and the amount of reduction that would result from the concentration of GG in the accused products. Because all four of the contested documents were publicly available prior to the trial, Kaneka could have explored those issues in discovery, in its expert reports, and at trial, but it did not. Post-trial proceedings are not the time to propose a new theory of infringement.

Justice Cardozo's statement addressing the use of judicial notice for valuations of land, buildings, and equipment from almost ninety years ago continues to ring true here. "[T]o press the doctrine of judicial notice to the extent attempted in this case and to do that retroactively after the case had been submitted, would be to turn the doctrine into a pretext for dispensing with a trial." *Ohio Bell Tel. Co. v. Pub. Utilities Comm'n of Ohio*, 301 U.S. 292, 302 (1937).

Kaneka's motion to take judicial notice of the four documents Kaneka has proffered in its post-trial motion is denied.

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testified about GG, not GG Gold. It is unclear even now whether there is a distinction between the "GG" referred to in the '080 patent and the "GG Gold 75 Oil" used in the defendants' products (*see* DTX 489 at 2). In any event, that question was not addressed at trial, and the possible distinction to the two was not called to Dr. Banakar's attention on cross-examination. For that reason, he can hardly be faulted for having testified about his understanding of the characteristics of GG generally, and not about the possibility that the characteristics of "GG Gold" differ from those of GG.

C. Kaneka's Motion for Judgment on Partial Findings of Infringement

On the same day that Kaneka filed its proposed findings of fact and conclusions of law along with its motion to reopen the record, Kaneka filed a motion for judgment on partial findings of patent infringement pursuant to Federal Rule of Civil Procedure 52(c). D.I. 430. The defendants opposed the motion. D.I. 450. Kaneka's motion for judgment on partial findings relies on the testing Kaneka arranged to be conducted after the trial. For many of the same reasons that I have denied Kaneka's motions to reopen the record and to take judicial notice of newly presented documents, I deny Kaneka's motion for judgment on partial findings of patent infringement.

Rule 52(c) provides that in a bench trial a "court may enter judgment against [a] party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue" after the "party has been fully heard on that issue . . . and the court finds against the party." Fed. R. Civ. P. 52(c). Rule 52(c) allows the district court to "resolve disputed factual questions." *Rego v. ARC Water Treatment Co. of Pa.*, 181 F.3d 396, 400 (3d Cir. 1999). Under Rule 52(c), the court does not "consider the evidence in the light most favorable to the nonmoving party," but instead "weighs the evidence and assesses the credibility of witnesses to determine whether or not the plaintiff has demonstrated a factual and legal right to relief" sufficient to meet the applicable burden of persuasion. *United Techs. Corp. v. Chromalloy Gas Turbine Corp.*, 105 F. Supp. 2d 346, 355–56 (D. Del. 2000), *aff'd*, 30 F. App'x 980 (Fed. Cir. 2002) (citations omitted).

Kaneka argues that the "evidence presented at trial, and tests conducted post-trial, conclusively demonstrate that the Reformulated Products are infringing" claims 5 and 15 of the '080 patent. D.I. 430 at 1. Kaneka points to samples from the defendants' product lots 45810, 45818, 53504, and 53510 and alleges that "all have a QH Ratio of over 90%" as viewed in light of

the post-trial testing. *Id.* at 2 & n.2. According to Kaneka, the different rates of reduction can be explained by variation in the defendants' manufacturing process. *Id.* at 4. Kaneka also introduces the theory that tocotrienols in the GG component of the reformulated products "act as a secondary reducing agent," further reducing the ubiquinone and increasing the QH ratio beyond the maximum ratio of 78.3 percent attributable to the amount of AP in the reformulated products. *Id.* at 4–6. Additionally, Kaneka contends that the contrary opinions of the defendants' expert, Dr. Banakar, "should be rejected for being 'clearly litigation driven' and 'contrary to common sense.'" *Id.* at 6 (citation omitted).

The defendants point out that Kaneka's post-trial test results have not been admitted into evidence; they argue that those results should not be considered in the Rule 52(c) analysis, because Rule 52(c) allows the court to enter judgment based only on evidence in the record. D.I. 450 at 1. The defendants further assert that Kaneka has failed to prove that the accused reformulated products infringe, because the only lot in the record that reached a QH Ratio of 90 percent was unrepresentative due to an equipment failure, and the predictive linear models advanced by Kaneka only "showed the Reformulated Products are no longer in defendants' possession at either [shelf life] timepoint so the linear model cannot establish defendants' direct infringement." *Id.* at 3–4. The defendants contend that Kaneka's theory about tocotrienols in GG Gold acting as a reducing agent was not presented at trial and that Kaneka's theory relies on documents that were not in evidence. *Id.* at 5. Finally, the defendants assert that "Dr. Banakar relied on scientific publications to support his testimony" and that Dr. Banakar did not have an opportunity to address the new documents that Kaneka has sought to admit into evidence after the trial. *Id.* at 7.

For the same reasons that apply to Kaneka's other motions, it would be inappropriate for me to consider the new evidence that Kaneka seeks to admit post-trial in deciding Kaneka's Rule

52(c) motion for judgment on partial findings of patent infringement. If I were to admit the evidence and grant this motion, as Kaneka asks, the defendants would be deprived of an opportunity to be "fully heard on [that] issue," Fed. R. Civ. P. 52(c), which by itself would be sufficient to make granting the Rule 52(c) motion improper. Accordingly, I will analyze Kaneka's motion based only on the evidence admitted when the record was closed at the conclusion of the trial. Considering only the evidence in the record at the time of trial, I find that Kaneka has failed to satisfy its burden to justify the entry of judgment on partial findings of fact. The motion under Rule 52(c) is therefore denied.

In a footnote, Kaneka asserts that the evidence supports a finding that four of the tested lots of ubiquinol reached a QH ratio of more than 90 percent. D.I. 430 at 2 & n.2. That argument ignores the fact that for three of those lots the results relied on the testing that was conducted after the trial and not admitted into evidence. According to Kaneka, Lots 45810, 53504, and 53510 reached a QH ratio of more than 90 percent in the testing conducted by Triclinic on September 24, 2025, two months after the conclusion of the trial in July 2025. D.I. 425 at 6. Those test results were not available at the time of trial, and the defendants were not afforded an opportunity to challenge the results or cross-examine witnesses about them. As I explained in my order denying the motion for a preliminary injunction, Lot 45818 is not a representative lot. *See* D.I. 413 at 9–11. The anomaly in Lot 45818 can be explained by the extended time that lot spent under reaction conditions due to an equipment failure in the softgel melter tank. *Id.* Except for that lot, the evidence at trial does not establish infringement sufficient to justify granting a Rule 52(c) motion for judgment on partial findings.

Both parties discuss variability in the data, but the conclusions drawn by the parties about how to interpret the evidence that each softgel acts as its own "unique little reactor" point in

different directions. *Compare* D.I. 430 at 4 (differences in the results of testing different samples is "not evidence of a fluctuating rate of change, but rather evidence of the variance inherent in Defendants' manufacturing process"), *with* D.I. 450 at 4 ("applying a constant rate of change to predict QH ratios for other lots is unreliable"); *see also* D.I. 460 at 443:1.

The parties offer linear, logarithmic, and polynomial regression analyses as the basis of a predictive model for reduction and the resultant QH ratio. *See* D.I. 450 at 4–5. Modeling often involves data points or noise that does not perfectly fit the model, and in weighing the models advanced by the parties, expert witness testimony may prove helpful. For purposes of deciding this motion, however, I need not decide which predictive model I find more persuasive. I find that Kaneka, as the moving party, has not carried its burden for judgment on the findings. I will address the variability and competing models issue in further detail in my decision on the merits of the infringement claims in Part II, below.

The third issue is whether the tocotrienols found in GG can act as reducing agents. The defendants call this a "new and different theory" advanced by Kaneka, while Kaneka asserts that it is a response to the defendants' expert testimony. D.I. 430 at 6; D.I. 450 at 5. As with the additional testing results, the problem with Kaneka's current theory is that it was not advanced at trial, and the documents that Kaneka cites as evidence are not in the record. D.I. 430 at 4–6. The viability of Kaneka's theory that tocotrienols in GG could act as a reducing agent will be addressed in further detail in Part II, below. For purposes of the present motion, however, Kaneka has failed to meet its burden to justify the entry of judgment on partial findings.

The final issue raised in Kaneka's motion relates to the credibility of the defendants' expert witness, Dr. Banakar. I previously granted Kaneka's motion to strike Dr. Banakar's opening invalidity report because I ruled that it was improper to raise indefiniteness in the Phase 2 trial

proceedings. D.I. 378. Whether other portions Dr. Banakar's evidence should be rejected for being "clearly litigation driven" and "contrary to common sense," as Kaneka asserts (D.I. 430 at 6), is a question to be addressed in my decision on the merits. In so doing, I will weigh Dr. Banakar's opinions based on my assessment of his credibility in light of the evidence introduced at trial, without consideration of the new evidence that is the subject of Kaneka's post-trial motions.

Kaneka's motion for Rule 52(c) judgment on partial findings of patent infringement is denied.

D. The Defendants' Motion to Strike Kaneka's Post-Trial Brief

A week after Kaneka filed its proposed findings of fact and conclusions of law and two of its post-trial motions, the defendants moved to strike "Kaneka's new documents and all portions of Kaneka's Phase 2 Post-Trial Brief that rely upon them" as not in evidence at the time of the trial in July. D.I. 433 at 1. Kaneka opposed the defendants' motion in a combined brief that also contained Kaneka's cross-motion for judicial notice. D.I. 442. The defendants replied to Kaneka's opposition in a combined brief that included a response to Kaneka's cross-motion to take judicial notice of Kaneka's four new documents. D.I. 447.

The defendants' motion is closely tied to the disposition of Kaneka's motions to reopen the record and to take judicial notice. Because I have denied both of those motions, I will not consider those portions of Kaneka's post-trial brief that rely on the additional post-trial testing evidence or the four new documents for which Kaneka has asked the court to take judicial notice. I therefore grant the defendants' motion to the extent that I will disregard those portions of Kaneka's post-trial briefing that rely on that evidence, and I will not consider that evidence in considering the parties' arguments and rendering a judgment on the merits in this case.

II. Infringement

Following the Phase 1 trial in this case, I found that the defendants' original products infringed the '080 patent. In October 2023, the defendants changed the ratios of the components in the accused products; the new formulation has been used in all the defendants' products since that time. Those new products are referred to as the defendants' reformulated products. Whether the reformulated products infringe turns on whether they will reach a QH ratio of at least 90 percent within the shelf life of the product. Except for one anomalous lot of the reformulated products, I find that Kaneka failed to prove by a preponderance of the evidence that the defendants directly infringed the asserted claims of the '080 patent.[5] However, I find that the sale of the defendants' products from the one anomalous lot of the reformulated products, Lot 45818, directly infringed the '080 patent.

As noted in the preliminary injunction order entered on August 26, 2025, D.I. 413 at 24, the court is not bound by the findings in that order in reaching a final decision in this case. However, based on the evidence in the record at the close of the trial the plaintiff has failed to persuade me that my analysis of the infringement allegations should be substantially different from the analysis set forth in that order. For that reason, the discussion below largely tracks the analysis in my preliminary injunction order.

A. Legal Standard

"An accused product infringes a claim if it embodies each claim element or its equivalent." *TEK Glob., S.R.L. v. Sealant Sys. Int'l, Inc.*, 920 F.3d 777, 784 (Fed. Cir. 2019) (citation omitted). The plaintiff bears the burden of establishing "by a preponderance of the evidence that the accused device infringes one or more claims of the patent either literally or under the doctrine of

[5] Kaneka has alleged only direct infringement, not indirect infringement.

equivalents." *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 261 F.3d 1329, 1336 (Fed. Cir. 2001) (citation omitted).

B. Analysis

The question whether the 90 percent QH ratio claim limitation is met for the reformulated products is more complex than the infringement issue presented in Phase 1 of this case. *See* D.I. 249 at 10, 22–23. The reformulated products have a QH ratio that changes as reactions in the product continue over time. The Phase 2 infringement analysis must consider this variation in QH ratios, which is made more difficult by the limited test data available at the time of the trial and the speculative nature of the predictive modeling that the parties provided to the court.

Testing was conducted by both the plaintiff and the defendants under ambient and accelerated testing conditions. Aside from the testing under accelerated conditions, no test showed a QH ratio that met the 90 percent QH ratio limitation except for the testing of Lot 45818, which will be addressed separately. Accelerated test data provided to the court is also of limited predictive value because the results of the ambient and accelerated testing appear to diverge over time. The court is left with a predictive model that falls short of satisfying Kaneka's burden to persuade the court that the reformulated products will infringe.

Kaneka tested multiple lots of the reformulated CoQnol 100 and CoQnol 200 softgels at the Triclinic Labs in Indiana. The Triclinic testing was performed under the direction of Dr. Myerson between March and May 2025.[6] *See* PTX 159 and PTX 225. In addition to the Triclinic

[6] At trial, the parties did not make an issue of the methodology of Triclinic's testing, and the accuracy of the Triclinic test results was not contested. A detailed account of the testing protocol is thus unnecessary. The Triclinic reports contain tables setting forth the quantities of ubiquinol and ubiquinone found in each sample (in mlligrams per capsule) from which the QH ratio can be calculated. *See* PTX 159 and PTX 225. Triclinic also tested the reformulated version of the defendants' Q10.1 100 product line in March 2025. *See* PTX 159. However, Kaneka

testing, Kaneka relies on 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 based on the defendants' testing of the reformulated products prior to bottling the softgels, as recorded in PTX 326.

1. Lot 45818

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 from each lot and measured the QH ratio of each sample. *See id*. at 15–16. The QH ratio exceeded 90 percent for each sample of Lot 45818 (CoQnol 200). *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. *See id*. Lot 45818, therefore, met the QH claim limitation, and I find that the reformulated products in that lot directly infringed the '080 patent.[7]

Lot 45818, however, was an unrepresentative lot of the reformulated products. First, the defendants explained that due to a mechanical failure in the softgel melter tank, the DuoQuinol blend for Lot 45818 was erroneously kept in the reactor under pressurized and heated conditions for more than eight weeks, which was much longer than the 5.5 days prescribed by the defendants' protocol. D.I. 352 at 6; *see also* TD2 at 367:2–25 (deposition testimony of Kelley Karas, Vice President of DFH). A DFH employee was disciplined for not recognizing the deviation and releasing the lot for sale in December 2024. *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

withdrew its arguments about the Q10.1 100 product after confirming that the defendants no longer sell that product. *See* D.I. 334 at 1 n.3.

[7] At the post-trial argument on the findings of fact and conclusions of law, the defendants acknowledged that the products derived from Lot 45818 were infringing.

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 did not present evidence to persuade me that the equipment failure did not occur as Ms. Karas recounted.

Second, the QH ratio measurements for other softgel lots recorded in PTX 326 (the chart recording the defendants' testing results) indicate that the QH ratio for Lot 45818 was an anomaly. Lot 45818 is the only softgel lot listed in PTX 326 that had samples with a QH ratio higher than 90 percent for either CoQnol 100 or CoQnol 200. For CoQnol 100, the QH ratio did not exceed 90 percent for any sample of Lot 45810, the lot that was tested together with lot 45818. *See* D.I. 269 at 5 (Dr. Myerson's declaration in support of Kaneka's motion for a permanent injunction). The three samples of that lot had QH ratios of 83.7 percent, 82.9 percent, and 83.9 percent. *See* PTX 159 at 15.

Triclinic also 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 samples. *See id*. at 11–14, 18, 20, 23–25 (Triclinic test results); D.I. 335 at 3 (Dr. Myerson's calculation of CoQnol 100 QH ratios in the range of 82.2 percent to 85.93 percent).

For the CoQnol 200 softgels, 11 other lots that were tested had QH ratios below 90 percent, the highest of those ratios being 84.96 percent. *See* PTX 326. In April and May 2025, Triclinic tested three additional lots of CoQnol 200, using three samples from each of Lot 45858, Lot 35951, and Lot 36163. PTX 225 at 4. Triclinic's testing did not disclose a QH ratio above 90 percent for any of those samples. *See* PTX 225 at 15–17 (Triclinic test results); D.I. 335 at 3 (Dr. Myerson's calculation of CoQnol 200 QH ratios, which ranged from 84.5 percent to 86.44 percent).

In sum, the only lot that Triclinic found to have a QH ratio higher than 90 percent was Lot 45818.[8] The evidence of the QH ratio for Lot 45818 makes it clear that the products from Lot 45818 directly infringed the '080 patent. However, Lot 45818 was not representative of the reformulated CoQnol 200, and I find that the higher QH ratio in that lot was likely caused by the equipment failure that kept the DuoQuinol under reaction conditions for much longer than the defendants' protocol prescribed.

2. Lot 35550 Testing

In addition to the previously discussed testing, the defendants also conducted stability testing of softgels from Lot 35550 between October 2023 and April 2025. That testing was inconclusive. The defendants' stability testing included testing under both ambient and accelerated conditions. *See* PTX 226. Ambient conditions refer to a temperature and humidity level similar to the conditions of a storage warehouse, i.e., less than about 80 degrees Fahrenheit and less than about 60 percent humidity. *See* TD2 at 357:9–358:18. Accelerated conditions, on the other hand, are abnormal conditions intended to stress the product by exposing it to temperatures and humidity higher than those at which it would 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 determine whether "the material would degrade under stress conditions . . . [and] fall below its intended label claim." *Id*. at 325:3–14. The defendants' records of the results of the accelerated testing state that "1 week = 1 month RT." *See* PTX 226.

[8] Kaneka confirmed at the post-trial hearing that Lot 45818 was the only lot that had a QH ratio above 90 percent at ambient testing conditions at the time of trial. D.I. 474 at 75.

Ms. Karas testified that RT stands for "real time." TD2 at 360:1–7. She explained that in an "accelerated stability chamber, one week is indicative of one month['s] performance." *Id*.

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 the reaction vessel," such that "the ubiquinol doesn't turn back into ubiquinone." *See id*. at 382:7–21.

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* PTX 226. Before the stability testing, the defendants also measured the QH ratio of Lot 35550 as a finished product on September 15, 2023. The QH ratio of Lot 35550 on that date was 77.14. *See* PTX 326. The DuoQuinol lot from which Lot 35550 was derived (DuoQuinol Lot 35544) had a QH ratio of 78.68 percent on September 1, 2023. *See* PTX 326.

The Lot 35550 stability testing resulted in measurements of the QH ratios on a weekly basis.[9] *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

[9] 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*.

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*.[10]

Under ambient conditions, the QH ratios of samples from Lot 35550 did not exceed 90 percent at any point in 18 months of testing. *See* PTX 226. The highest QH ratio under ambient testing was 87.7 percent, which was measured at 18 months. *Id*. Under accelerated conditions, however, the QH ratio of the Lot 35550 samples exceeded 90 percent after 10 weeks (90.1 percent), then dropped below 90 percent until week 15. After that, the QH ratio rose above 90 percent and remained at that level until week 36.[11] *Id*. From 15 to 36 weeks, the QH ratio generally increased, but 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 conditions was 98.5 percent, which was measured in week 35. *Id*.

According to Kaneka, the accelerated conditions testing showed that the reformulated products will infringe after ten months under ambient conditions. D.I. 334 at 3 ("Alleged Reformulations infringe the 90 percent QH Ratio limitation after ten months, and consistently stay[] above 90% after fifteen months"). Kaneka assumes that accelerated testing can accurately predict testing results under ambient conditions and 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.

[10] Since the QH ratios for 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 beginning 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.

[11] 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.

The problem is that 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 noted the close alignment between the QH ratio for five weeks of accelerated testing (83.2 percent) and for five months of ambient testing (83.5 percent). *See* TD2 at 445:4–19; PTX 226. However, Dr. Myerson failed to acknowledge the discrepancy between the results for later weeks of accelerated testing and the results for later months of ambient testing. The QH ratio for accelerated testing at ten weeks showed a QH ratio above 90 percent while the ambient testing at ten months showed a QH ratio of less than 86 percent. *See* PTX 226 (90.1 percent at ten weeks of accelerated testing and 85.8 percent at ten months of ambient testing). And at 18 weeks, the accelerated testing QH ratio was above 90 percent, while ambient testing after 18 months remained below 88 percent. *See id*. (92.8 percent at 18 weeks of accelerated testing and 87.7 percent at 18 months of ambient testing).

Triclinic's testing of Lot 35550 provides further evidence of the unreliability of accelerated testing as a basis for estimating the QH ratios of the defendants' products after 18 months under ambient conditions. Triclinic tested Lot 35550 in April and May 2025, which was 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; D.I. 335 at 3 (QH ratios of 85.6 percent, 85.93 percent, and 85.2 percent calculated by Dr. Myerson). Triclinic's testing was much closer to the 87.7 percent QH ratio from ambient conditions than the 92.8 percent produced under accelerated conditions.

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. The defendants' belief that one week of accelerated testing was generally indicative of performance after one month at ambient conditions does not establish such a correlation for the defendants' products, especially over a substantial period of time.

None of the representative lots that were tested reached a QH ratio of 90 percent when stored under ambient conditions. That was true even for the two lots for which the record contains QH ratios spanning more than 18 months, Lot 35550 and Lot 35950. According to the defendants' stability testing, the QH ratio for Lot 35550 started at 77.14 percent on September 15, 2023, *see* PTX 326, and reached only 87.7 percent on April 23, 2025, *see* PTX 226. 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* D.I. 335 at 3. Triclinic's testing data for Lot 35950, which started at 80.06 percent on October 13, 2023, *see* PTX 326, shows that it reached only 85.8 percent on May 2, 2025, *see* D.I. 335 at 3.

Despite a substantial amount of testing across an array of lots, the QH ratio exceeded 90 percent *only* with Lot 35550, and then only when tested under accelerated conditions. The divergence between the results of accelerated and the results of ambient testing raises significant doubt as to the reliability of accelerated results in accurately predicting the QH ratio after an extended period of time. I therefore conclude that the results of the accelerated testing are not sufficient to satisfy the plaintiff's burden 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 representative of the product's shelf life.

3. Predictive Modeling

Without test data showing that the reformulated products reach a QH ratio of 90 percent, Kaneka is left with its predictive modeling theory to support its contention that the reformulated products will meet the 90 percent claim limitation within the designated shelf life of those products. I am unpersuaded that the predictive modeling theory, even in combination with the testing data that Kaneka presented, is sufficient to show that the defendants' reformulated products infringe the asserted claims. First, there is a lack of clarity regarding the science underlying the changing QH ratio, which calls into doubt the accuracy of predictive models. Second, reducing scattered test data to a single rate of change and then using that rate of change to predict whether another product will infringe is fraught with uncertainties. Third, using a predictive model to ascertain a change in QH ratios with the level of precision required is problematic. As in the case of the accelerated and ambient testing, I find that Kaneka has failed to meet its burden of proving infringement through predictive modeling.

To begin with, there was a lack of evidence at the trial about the underlying chemistry occurring within the reformulated products. Such knowledge, of course, is not required to show that a product infringes. A product need only meet the limitations of a patented claim for a finding of direct infringement, even if the inventor does not understand the science underlying the invention. *See Diamond Rubber Co. v. Consol. Rubber Tire Co.*, 220 U.S. 428, 435–36 (1911) ("It is certainly not necessary that [the inventor] understand or be able to state the scientific principles underlying his invention, and it is immaterial whether he can stand a successful examination as to the speculative ideas involved."); *Teva Pharm. Indus. Ltd. v. AstraZeneca*

Pharms. LP, 661 F.3d 1378, 1383 (Fed. Cir. 2011) (an inventor "need not understand precisely why his invention works in order to achieve an actual reduction to practice") (quoting *Parker v. Frilette*, 462 F.2d 544, 547 (C.C.P.A. 1972). However, where the product does not currently meet the limitations of an asserted claim, but it is contended that it is likely to do so at some future date, an understanding of the mechanism by which the change is believed to occur may well prove important in determining whether the plaintiff has satisfied his burden. In this case, the evidence at trial fell short of demonstrating such an understanding.

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. That is 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 the record of the defendants' testing found in PTX 326—shows that in the accused products, the QH ratios rose above 78.3 percent. But the evidence at trial did not explain why the QH ratio of the reformulated products exceeded the maximum that was possible as a result of AP as the sole reducing agent.

Kaneka's theory is that the increased QH ratio resulted from continued reduction of the ubiquinone into ubiquinol. At trial, however, Kaneka offered little more than speculation about the nature of the chemical process that results in the QH ratio exceeding 78.3 percent during the 18- or 36-month timeframes. Dr. Myerson's explanation at trial was that "something else is acting

as the reducing agent." TD2 at 412:17–20. But his testimony about the identity of that reducing agent was largely speculative.

Dr. Myerson hypothesized that the additional reduction was "likely due to the GG or something that the GG decomposes to." *Id*. at 414:10–12. As noted, when he was questioned about the role of GG in the defendants' formulation, Dr. Myerson 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. Dr. Myerson 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." *Id*. at 456:11–15. The defendants' expert, Dr. Banakar, disagreed with Kaneka's theory regarding continued reduction and testified unequivocally that GG cannot act as a reducing agent. TD4 at 924:24–925:2.

The defendants' explanation for the changing QH ratio was that it could be attributed to degradation of CoQ_{10} in the product over time. Such degradation, according to the defendants' theory, would cause the QH ratio to rise, because that degradation would result in less ubiquinone in the composition. With less ubiquinone, the denominator of the QH ratio would become smaller, resulting in a larger QH ratio. Dr. Myerson, however, testified that if degradation were occurring, the total amount of CoQ_{10} would decrease, and that was not observed. *See* TD2 at 446:5–8. Although there is variation in the total 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 over time. *See* PTX 226.

The difficulty remains that without an adequate understanding of the chemistry underlying the change in the QH ratio, it is challenging—if not impossible—to build a model with confidence that accurately captures the behavior it is intended to predict. 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, the support for any specific model, including a model assuming a constant rate of reduction, is speculative.

Despite his lack of knowledge about the underlying chemistry, 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, he assumed that the products experienced a linear rate of reduction over time.

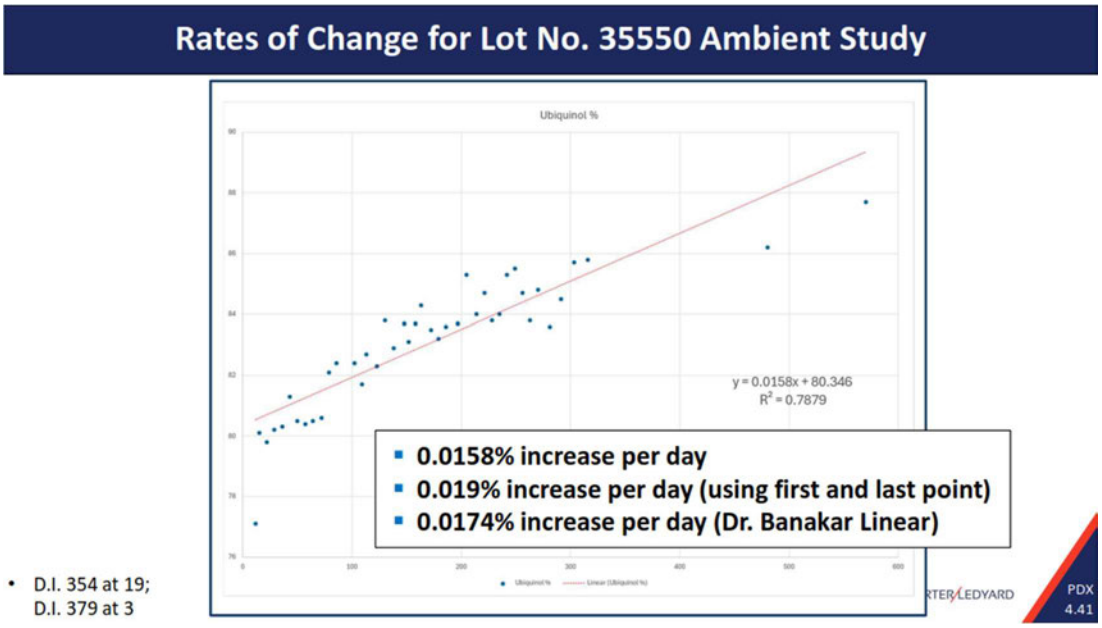
Dr. Myerson first chose to rely on the rate of reduction that he calculated for Lot 35550, a lot that showed a greater increase in the QH ratio (i.e., a higher rate of reduction) after 18 months than Lot 35950. He also chose to use the defendants' ambient testing data for Lot 35550, rather than the Triclinic testing data for Lot 35550, which showed a lower QH ratio after 18 months than the defendants' testing showed. Then, using the rate of reduction for Lot 35550, Dr. Myerson calculated the starting QH ratio that would be needed to reach 90 percent within either 18 or 36 months after the manufacturing date. In addition to assuming a linear rate of reduction, Dr. Myerson assumed the rate of reduction for Lot 35550 would be representative of any other lot. So long as it started out at a higher QH ratio than Lot 35550 on the manufacturing date, Dr. Myerson predicted that any other lot would reduce at the same rate, and therefore would reach 90 percent within 18 months.

This leads to a second problem. To assume that test data from one lot is representative of other lots further undermines confidence in the predictive model. Kaneka's position regarding variances in the data underscores this point. Kaneka argues that each softgel is undergoing continued reduction at its own rate as a result of the defendants' manufacturing process and that it is difficult to know what will happen in each softgel. At the same time, Kaneka argues that it is possible to predict whether a lot will reach a QH ratio of 90 percent at a given point based on data from a different lot. While it may be possible to overcome this inconsistency in the aggregate, Kaneka did not adequately explain why that is so in this case.

One difficulty with the use of predictive modeling in this setting is selecting which data sets to use for the predictive model. At trial, Dr. Myerson conceded that the rates of reduction were different for each of the lots Triclinic tested. TD2 at 454:1–13. Dr. Myerson 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, Dr. Myerson ignored data for Lot 35950, which was tested across roughly the same time span as Lot 35550, but had a lower measured rate of reduction than Lot 35550. Given the demonstrated variance in the reduction rates among the tested lots, Dr. Myerson's exclusive reliance on the data for Lot 35550 casts doubt on his assumption that the samples from Lot 35550 were representative of the defendants' reformulated products as a whole.

But that is only one of several difficulties with Dr. Myerson's analysis of the data. Other 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, Dr. Myerson performed a least-squares

analysis of all the data points for the ambient stability testing of Lot 35550.[12] From that analysis, he 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 of measuring the rate of change in the pace of reduction, 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" of that line. *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

[12] Least squares analysis is a statistical technique used to assess how much a set of data corresponds to a particular model. The degree of correlation between the model and the data is referred to as the correlation coefficient.

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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.[13] *See id*. at 462:5–25.

Dr. Myerson then applied those predictions to the starting ratios of the CoQnol lots listed in PTX 326. Based on both his linear regression analysis and his first-and-last-point analysis, Dr. Myerson testified that all the CoQnol 100 and CoQnol 200 lots listed would infringe within 36 months. *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 five lots of CoQnol 200 would infringe based on his linear regression analysis, and seven lots would infringe based on his first-and-last-point analysis. *See id*. Similarly, Dr. Myerson testified that five lots of CoQnol 100 would infringe based on his linear regression analysis, and ten lots would infringe based on his first-and-last-point analysis. *See id*.

There is no basis in the record from which to assume that the rate of reduction calculated for 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 from 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 should 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* D.I. 335 at 3. Thus, combining the higher rate of reduction of Lot 35550 with

[13] 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 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.

This leads to a third problem with the use of predictive modeling in this case. Modeling can be misleading when the purpose for which the modeling is designed requires a high degree of precision, yet the data being used to generate the model is scattered. The sensitivity of the value of the slope that Dr. Myerson calculated based on his modeling illustrates this problem. Assuming a constant rate of increase in the QH ratio over time, Dr. Myerson calculated the required QH ratios on the date of manufacture that would be required to reach 90 percent within 18 or 36 months by multiplying the applicable slope by 545.5 days (18 months) and 1,095 days (36 months), and subtracting that product from 90 percent. *See* TD2 at 462:3–463:25. A slope of 0.0158 percent (Dr. Myerson's 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 81.39 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. By comparison, a slope of 0.019 percent (the slope Dr. Myerson calculated based on the first and last point method), 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. Even accepting all of Dr. Myerson's assumptions as correct, the necessary QH ratio at manufacture varies between 79.6 to 81.25 percent for products with an 18-month shelf life and 69.19 to 72.7 percent for products with a 36-month shelf life.

In addressing his linear regression analysis, Dr. Myerson admitted that the rates of reduction reflected in the data for Lot 35550 "are very scattered" and "the correlation coefficient

is only .7879 for the least square[s] analysis." TD2 450:17–19. As Dr. Myerson admitted on cross-examination, he did not rely on his linear regression analysis in his expert report, because "I decided that looking at it, that the fit wasn't very good." TD2 490:10–14. Dr. Myerson testified that because of the degree of scatter in the data he was using for his linear regression analysis, he extrapolated from a line between the first and last data points in the Lot 35550 ambient study and determined the slope of the line between those two points. TD2 490:17–18. According to Dr. Myerson, the only two acceptable methods of calculating the rate of reduction were through the linear regression analysis or the first-and-last-point analysis. *See id*. at 458:2–4. Of those two models, Dr. Myerson made it clear that he believed his first-and-last-point analysis "seemed to be a better way to do the analysis. It kind of eliminated all the scatter." TD2 490:17–21.

Reliance on only two data points, however, has obvious flaws; the use of multiple data points tends to reduce the risk that one or both of the two selected points will be outliers and thus produce an outcome that is not representative of the data as a whole. That is true even if the two points happen to be the first and last points in the sample. And it is no answer to say that the use of two data points "eliminate[s] all the scatter." By definition, a line between two points has no scatter.

The defendants made precisely that point at trial. They introduced statistical literature 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, the defendants' expert, Dr. Banakar, testified that it is desirable to have at least ten data points and that "shelf-life predictions" are prone to error if they are based on fewer than eight 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.

With respect to Dr. Myerson's reliance on only two data points, I credit the testimony of Dr. Banakar, who was highly critical of Dr. Myerson's analysis. Dr. Banakar 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 even if the aim is to observe what happens over a long period of time, it does not make sense to rely on the extreme data points while ignoring all the intermediate data points in the array.

Dr. Banakar testified that the slope of a least squares line is likely to change with an increase in the number of data points considered. He explained that Dr. Myerson's prediction of how many days it would take for the QH ratio to exceed 90 percent would therefore be significantly affected by the number of data points Dr. Myerson considered. *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 burden of proof 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 an extended period of 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 likely to slow down over time, Dr. Myerson responded that Dr. Banakar was "demonstrably incorrect, because if you look at the last two points, the rate[] of change hasn't slowed down at all." TD2 at 458:5–12.

Dr. Myerson's testimony on that issue is unconvincing. Calculating the rate of reduction at different intervals and comparing those rates makes it clear that the rate of reduction in the last three months was not as great 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 three months. *See* PTX 226. Earlier in the testing, the difference between tests conducted after three days (80.1 percent) and after three months (81.7 percent) was 1.6 percent. *See id*. Between one month (81.3 percent) and four months (82.9 percent), the difference was also 1.6 percent. *See id*. However, between two months (80.6 percent) and five months (83.5 percent), the difference was 2.9 percent, and between three months (81.7 percent) and six months (85.3 percent), the difference was 3.6 percent. *See id*. As summarized in the table below, those increases in the QH ratio are about twice as large as the increase between 15 and 18 months.

Times Measured (QH)	Rate of Reduction
3 days (80.1%) to 3 months (81.7%)	1.6%
1 month (81.3%) to 4 months (82.9%)	1.6%
2 months (80.6%) to 5 months (83.5%)	2.9%
3 months (81.7%) to 6 months (85.3%)	3.6%
15 months (86.2%) to 18 months (87.7%)	1.5%

Table 1. Summary of Ambient Stability Testing Rate of Reduction Between Two Points in Time

Kaneka's predictive modeling thus fails to persuade me that the defendants' reformulated products infringe the '080 patent. To summarize, Kaneka has failed to meet its burden to prove that the reformulated products other than Lot 45818 infringe. The only lot found to have a QH ratio higher than 90 percent under ambient conditions was Lot 45818, which was not representative of the reformulated product. Every other lot tested by Triclinic had a QH ratio under ambient conditions that stayed below 90 percent. Next, the QH ratio of Lot 35550 exceeded 90 percent only under accelerated conditions in the defendants' stability testing, which for the reasons discussed above does not reliably establish that the QH ratio of the same lot would exceed 90 percent under ambient conditions. Finally, 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, especially when accounting for the fundamental lack of evidence at the trial regarding the underlying chemistry of the reduction reactions over time.

The defendants argue that even if the reformulated products were found to infringe, the defendants cannot be held liable for direct infringement, because they no longer have those products in their possession when those products would reach an infringing QH ratio. That

argument presents a peculiar scenario in which a non-infringing product is sold before the expiration of its shelf life but then becomes infringing within the period remaining in its shelf life. Because I find Kaneka has not met its burden to prove the reformulated products infringe at any point within their shelf lives, I decline to address whether the defendants' "early sales" theory of defense against liability for direct infringement would have been viable if the reformulated products had been found to infringe prior to the end of their shelf life but after the defendants had sold them.

III. Damages

Based on the finding of infringement at the Phase 1 trial in this case, I find that Kaneka is entitled to damages for the defendants' sales of the original products that were produced prior to the defendants' reformulation of its ubiquinol products as of October 1, 2023. *See* D.I. 249 at 45–46. In addition, Kaneka is entitled to damages for the reformulated products that were sold from Lot 45818, as found above. For the reasons discussed below, I find that Kaneka has met its burden of showing entitlement to certain damages in the form of lost profits for the original products sold during the period of October 1, 2020, through September 30, 2023. With respect to the products at issue in Phase 2 of the case other than those in Lot 45818, however, I find that Kaneka has not proved infringement and thus is not entitled to damages. And with respect to Kaneka's claim of willful infringement for the products at issue in both Phase 1 and Phase 2 of the case, I find that Kaneka has not met its burden under 35 U.S.C. § 284 of showing willful infringement for which enhanced damages may be awarded.

A. Legal Standard

Following a finding of infringement, the court is required to "award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the

use made of the invention by the infringer, together with interest and costs as fixed by the court." 35 U.S.C. § 284. Whether a patentee sells its patented invention "is not crucial in determining lost profits damages." *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1548 (Fed. Cir. 1995) (en banc). As the Supreme Court has explained, the lost profits question is: "Had the Infringer not infringed, what would the Patent Holder-Licensee have made?" *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964) (quoting *Livesay Window Co. v. Livesay Indus., Inc.*, 251 F.2d 469, 471 (5th Cir. 1958)). A plaintiff can establish the right to lost profits damages by showing "(1) demand for the patented product; (2) absence of acceptable non-infringing substitutes; (3) manufacturing and marketing capability to exploit the demand; and (4) the amount of the profit [the patentee] would have made." *Rite-Hite Corp.*, 56 F.3d at 1545 (citing *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978)).

"The amount of damages 'is a finding of fact on which the plaintiff bears the burden of proof by a preponderance of the evidence. The amount is normally provable by the facts in evidence or as a factual inference from the evidence.'" *Rex Med., L.P. v. Intuitive Surgical, Inc.*, 156 F.4th 1289, 1298 (Fed. Cir. 2025) (quoting *Promega Corp. v. Life Techs. Corp.*, 875 F.3d 651, 660 (Fed. Cir. 2017)) (citations omitted). "The determination of a damage award is not an exact science," and the trial court may approximate damages, if required. *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1327 (Fed. Cir. 1987) (citations omitted).

B. Analysis

To be entitled to lost profits damages for the defendants' infringement by making and selling the original products, Kaneka was required to show there was a reasonable probability that but for the defendants' infringement Kaneka would have made greater profits as a result of the sales of ubiquinol. *See Rite-Hite Corp.*, 56 F.3d at 1545. Even if Kaneka is entitled to lost profits

damages, the amount of the lost profits damages award to which Kaneka is entitled cannot be less than what a reasonable royalty would have been for the sales made by the defendants. *See* 35 U.S.C. § 284; *see Del Mar Avionics, Inc.*, 836 F.2d at 1326 (citation omitted) ("the purpose [of section 284 of the Patent Act is] to set a floor").[14]

Calculating Kaneka's lost profits is not a straightforward task. Although Kaneka is the owner of the '080 patent, Kaneka's subsidiary Kaneka North America ("KNA") is responsible for the sales of Kaneka's ubiquinol products in the United States.[15] *See* TD1 85:20–86:25, 167:7–11. Thus, Kaneka may establish that it is entitled to damages in the form of lost profits only if it can show (1) that there is a reasonable probability that KNA would have made the defendants' sales "but for" the defendants' infringement, and (2) that the profits lost by KNA would necessarily translate into profits lost by Kaneka. I find that Kaneka has met its burden of showing that absent the defendants' infringement, KNA would reasonably be expected to have made the sales that were made by the defendants. As indicated below, however, I do not find that Kaneka has proved that all the profits lost by KNA translate into profits lost by Kaneka.

The evidence at trial showed that during the infringement period Kaneka and the defendants were the only producers of ubiquinol on the American market. *See* TD2 541:8–15 ("Kaneka was the only seller of ubiquinol in the country . . . . [T]he only source of the defendants

[14] Phase 2 of this litigation did not address the reasonable royalty issue. In advance of the Phase 2 trial, I advised the parties that if the need arose, I would hold additional proceedings to determine whether Kaneka is entitled to a reasonable royalty. D.I. 377 at 4. In the event that it appears reasonably likely that relief in the form of a reasonable royalty would be more beneficial to Kaneka than an award based on lost profits, Kaneka may request that such a proceeding be held. *See* D.I. 477 at 4.

[15] Kaneka Nutrients, a division of KNA, manufactures and sells ubiquinol products in the United States pursuant to a nonexclusive license to the '080 patent. Under the terms of that license, KNA pays a three percent royalty on its sales of ubiquinol. That royalty payment, however, is not the entire compensation paid by KNA to other Kaneka entities in connection with the sales of ubiquinol by KNA. *See* TD1 87:11–88:22, 114:18–115:5; 165:5–10.

to acquire ubiquinol would be from Kaneka other than through the infringement, as I understand."); TD2 545:15–17 ([T]here was no other source for the defendants to acquire the ubiquinol other than from Kaneka."). When the patent owner and infringers are the only suppliers of the patented product, "it is reasonable to infer that the patent owner would have made the sales made by the infringers." *Del Mar Avionics, Inc.*, 836 F.2d at 1327 (citing *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983)). Thus, it is reasonably likely that but for the defendants' infringement, sales made by the defendants would have been made by KNA. The evidence also showed that there was a demand for the patented product and that there were no other non-infringing substitutes for the infringing products. Therefore, the first two *Panduit* factors are satisfied.

Kaneka submitted evidence that KNA had the capacity to produce enough ubiquinol to cover the sales made by the defendants. Kaneka's damages expert testified that KNA had the capacity to produce 500 to 1,000 additional kilograms of ubiquinol per year. TD2 541:16–18, 542;11–12. According to Kaneka, the defendants sold 2,451 kilograms of the original ubiquinol products between October 1, 2020, and September 30, 2023, and 1,893 kilograms of the reformulated ubiquinol products between October 1, 2023, and May 31, 2025. *See* PTX 324; PTX 325; D.I. 428 at 33–35. The defendants did not challenge KNA's capacity to produce that amount of additional ubiquinol products. It seems reasonably likely then that KNA would have made sales equal to the defendants' infringing sales of the original products and the reformulated products in Lot 45818.

The remaining issue concerns the fourth *Panduit* factor, the amount of profit lost because of the defendants' infringement. Setting aside for a moment the question of which entity within

the Kaneka corporate family suffered the loss, the calculation of the amount of the loss from the defendants' sales of the original products is relatively straightforward.

Kaneka bears the burden of proving the amount of the profits Kaneka lost as a result of the defendants' infringement. With only two producers of ubiquinol products in the relevant market, it is reasonable to assume that any ubiquinol sales made by the defendants would have been made by KNA. Kaneka argues that lost profits damages can be calculated as the product of (i) the volume of the infringing products sold by the defendants and (ii) the price the defendants historically would have paid KNA for ubiquinol ([redacted] per kilogram) less KNA's costs of production [redacted] per kilogram). Kaneka's baseline for calculating lost profit damages is therefore [redacted] per kilogram. Multiplying that per kilogram baseline by the 2,451 kilograms of the original product sold by the defendants between October 1, 2020, and September 30, 2023, results in a total of [redacted] The defendants, however, purchased 870 kilograms of ubiquinol from KNA for use in creating the infringing product, a purchase that would not have occurred but for the defendants' infringement.[16] TD2 538:21–24, 548:19–549:11. Thus, the lost profits must be reduced by [redacted] to account for KNA's profits from its sale of ubiquinol to the defendants. Deducting the additional profit of [redacted] that KNA made by selling ubiquinol to the defendants during that period, I find that the amount of lost profits that KNA reasonably would have made, but for the actionable infringement by the defendants' original products was $2,832,501.

The defendants argue that because Kaneka failed to separate the damages attributable to the original products (sold prior to October 2023) and the reformulated products (sold after that

[16] Kaneka's January 9, 2026, letter to the court confirmed that the accounting for the 870 kilograms of ubiquinol sold to defendants occurred during the period in which the defendants' original products were produced and sold. D.I. 476 at 3. The defendants have not disputed that representation.

date) until the post-trial briefing, Kaneka failed to prove that KNA suffered lost profits from the defendants' sales of the original products.[17] While Kaneka's damages expert testified to an overall damages value for both periods, dividing damages into the two designated periods was the result of a straightforward calculation supported by evidence that was admitted at trial. Two spreadsheets, PTX 324 and PTX 325, which were admitted at trial, contained detailed data about the defendants' sales of the infringing products. The amount of ubiquinol in each infringing product was the result of a per capsule calculation. *See* PTX 53; PTX 159 at 19; TD2 531:1–7 (deposition of Mr. Stanczak).[18]

The defendants are also subject to liability for lost profits with respect to the one infringing lot of the reformulated products, the anomalous Lot 45818. The valuation of the lost profits for those products, however, was not resolved at trial. Determining the amount of the lost profits attributable to products from Lot 45818 that have been sold requires additional calculations. The parties will be required to conduct further proceedings, outlined below, directed to an accounting of the lost profits for products sold from Lot 45818.

[17] Among other issues raised about the period of sale of the reformulated products, the defendants contest the accuracy of Kaneka's projection of sales for June and July 2025 based on average sales figures. Because I find that among the reformulated products only the anomalous Lot 45818 was shown to infringe, I need not reach the projection issue for the remaining reformulated products. Likewise, I find it unnecessary to reach the other issues raised by the defendants pertaining to the time period during which reformulated products were sold, including the issues raised in the defendants' January 12, 2026, letter to the court, D.I. 475.

[18] The defendants contend that certain exhibits used in those calculations were not relied upon by Kaneka's damages expert at trial. However, the defendants do not contest that those documents were admitted into evidence and are thus available for the court's consideration. *See* D.I. 235 at 98:13–24 (PTX 53); TD2 422:15–17, 477:12–478:25; (PTX 159); TD2 478:12–25 (PTX 225). Even though Kaneka did not separate the total of lost profits into the two periods prior to the post-trial briefing, the underlying data necessary to calculate the two different amounts was in the record as admitted evidence.

1. Inexorable Flow

The most difficult issue bearing on the question of damages is whether Kaneka is entitled to an award of damages for the profits lost by its subsidiary, KNA, as a result of the defendants' infringement. Addressing that question requires an understanding of Kaneka's corporate structure and the flow of profits within the parent-subsidiary relationships in the Kaneka corporate family.

As the patent owner, Kaneka granted Kaneka Nutrients, a division of KNA, a non-exclusive license to the '080 patent. PTX 198–200; TD1 87:11–88:22. Kaneka is a separate corporate entity from KNA. A third related corporate entity is Kaneka Americas Holdings ("KAH"). That company is a holding company that serves as the corporate parent of KNA and is a wholly owned subsidiary of Kaneka. TD1 85:20–86:25.

As a non-exclusive licensee of the '080 patent, KNA does not have standing to sue for patent infringement. *Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 402 F.3d 1198, 1203 (Fed. Cir. 2005) (citing *Intellectual Prop. Dev. Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1345 (Fed. Cir. 2001)) ("It is well-settled that non-exclusive licensees do not have constitutional standing to sue."); *Rite-Hite Corp.*, 56 F.3d at 1551–52. Kaneka, then, must show that Kaneka itself—not just one of its subsidiaries—experienced lost profits and that those lost profits were attributable to sales that would have been made by KNA (through its division Kaneka Nutrients). That is to say, Kaneka must show that KNA's lost profits translate to lost profits suffered by Kaneka.

The defendants argue that because of the corporate structure of the Kaneka entities and KNA's nonexclusive patent license, Kaneka is precluded from claiming that the profits lost by KNA are Kaneka's lost profits. But regardless of the corporate structure and the licensing arrangement, Kaneka is entitled to lost profits damages if it can show that the profits lost by KNA

are inherently profits that would have gone to Kaneka based on what is referred to as an "inexorable flow" of profits from the subsidiary company to the parent.

Courts have alluded to the "inexorable flow" doctrine at various times, but the doctrine is not well developed in the case law. In *Poly-America, L.P. v. GSE Lining Technology, Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004), the Federal Circuit held that the relationship of two collaborating sister corporations with a common parent was not enough to enable one of the subsidiaries—the patent owner—to claim as damages the lost profits suffered by the other. Four years later, in *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1367 (Fed. Cir. 2008), the Federal Circuit acknowledged the potential availability of recovery under an "inexorable flow" theory, but determined that the court did not have to "decide whether a parent company can recover on a lost profits theory when profits of a subsidiary actually *do* flow inexorably to the parent" because it was clear that the profits of the wholly owned subsidiary in that case did not flow inexorably to Mars. *Id.* (citing *Poly-America*, 383 F.3d at 1311). Even though there was a parent-subsidiary relationship between the two corporations, and even though the two companies had consolidated financial statements, the license in *Mars* was a "traditional royalty-bearing license agreement" that required a sales-based royalty payment, which did not reflect a transfer of the subsidiary's profits to the parent. *Id.*

In a 2025 case, the Federal Circuit applied the *Mars* holding that a corporate relationship alone is insufficient to establish inexorable flow in rejecting a jury's award of lost profits for a wholly owned subsidiary as unsupported by substantial evidence. *Roland Corp. v. inMusic Brands, Inc*., No. 2023-1327, 2025 WL 926703, *12 (Fed. Cir. Mar. 27, 2025) (nonprecedential). Like the court in *Mars*, the court in *Roland* did not "delineate what types of evidence would be sufficient to establish inexorable flow." *Id.*

A number of district courts have addressed the inexorable flow principle as well. In *Schwendimann v. Arkwright Advanced Coating, Inc.*, 220 F. Supp. 3d 953, 973–75 (D. Minn. 2016), Judge Tunheim surveyed the approach of several district courts to inexorable flow and concluded that the Federal Circuit's decisions did not foreclose that theory of recovery given the right facts. Citing *Kowalski v. Mommy Gina Tuna Resources*, 574 F. Supp. 2d 1160, 1163 (D. Haw. 2008), the *Schwendimann* court recognized that "[m]ere ownership and control" of a subsidiary by a parent was not enough to demonstrate an "inexorable flow" of profits from the subsidiary to the parent. However, the court in *Schwendimann* recognized that "contractual, structural, or historical" evidence that profits flowed from the subsidiary entity to the parent could do so. *Id*. In a subsequent case, Judge Tunheim found "a history of inexorable flow of profits, and a structural relationship—a shared bank account" to be sufficient to overcome the defendant's motion for summary judgment precluding lost profits damages to a corporation based on lost profits affecting the corporation's wholly owned subsidiary. *Polaris Indus., Inc. v. Arctic Cat Inc.*, No. 15-4129, 2019 WL 1118518, at *7–8 (D. Minn. Mar. 11, 2019). In the course of that ruling, the court noted the declaration of the parent corporation's chief financial officer that all "revenue, costs, or profits" that were received by the wholly owned subsidiary "were recorded and accounted for" by the parent. *Id.* at *6–8.

In a case from the Northern District of New York, the court addressed the application of the inexorable flow doctrine in a situation in which sales were made by local subsidiaries of the patentee. The profits from those sales flowed from the local subsidiaries to an intermediate subsidiary and then to the parent corporation, which was the named plaintiff in the case. The court explained that "'[i]nexorable' means that the profits flow automatically from the subsidiary to the parent; in other words, the subsidiary's profits *are* the parent's profits." *Advanced Fiber Techs.*

Trust v. J & L Fiber Servs., Inc., No. 1:07-cv-1191, 2015 WL 1472015, at *25 (N.D.N.Y. Mar. 31, 2015). In that case, the court found that "the structure of the relationship between [the patent owner] and its European and Asian subsidiaries is such that the profits for all Durashells sold in Europe or Asia flow to [the patent owner] by intercompany sale." *Id.* Accordingly, the court relied on the inexorable flow theory in denying the defendant's motion for summary judgment to preclude lost profits damages.

In other cases, courts have relied on the same reasoning to reach similar results. *See Callaway Golf Co. v. Achushnet Co.*, 691 F. Supp. 2d 566, 575 (D. Del. 2010) ("[W]here the profits of a wholly-owned subsidiary flow up to the parent, inclusion of such profits [in calculating lost profits] is appropriate."); *Corning Optical Commc'ns Wireless Ltd. v. SOLID, Inc.*, No. 5:14-cv-3750, 2015 WL 5723403, at *7 (N.D. Cal. Sept. 16, 2015) (Corning can establish a right to lost profits for sales by an affiliated company if it can prove that sales by the affiliated company "result in an inexorable flow of revenue to Corning"); *In re Biogen '755 Patent Litig.*, No. 10-2734, 2018 WL 3586271, at *19 (D.N.J. July 26, 2018) ("[T]he court finds that Biogen has produced enough evidence that a rational juror could conclude that the profits of U.S. Corp. flow inexorably to Biogen."); *see also Fisher-Price, Inc. v. Safety 1st, Inc.*, 109 F. App'x 387, 397 (Fed. Cir. 2004) (nonprecedential) (upholding a lost profits award to a subsidiary (Fisher-Price), even though the parent (Mattel) owned the patent in suit, relying on evidence that "anything Fisher-Price sells, technically, Mattel sells").

Kaneka's corporate structure involves three levels of corporate entities with relationships between those entities that the court must examine. First, there is the relationship between KNA, the entity that sells ubiquinol-containing products through its division Kaneka Nutrients, and KAH, the holding company. Second, there is the relationship between KAH and Kaneka. In order

for the inexorable flow theory to apply, both of those relationships must be characterized by an inexorable flow of profits from the subsidiary to the parent. That is, in order to be entitled to an award of the full amount of the profits lost to KNA, Kaneka must show that KNA's profits from the sale of the patented products will ultimately and necessarily flow through KAH and then to Kaneka.

a. The KNA and KAH relationship

KAH has four subsidiaries. One of those is KNA. TD1 86:3–7. KNA is wholly owned by KAH. TD2 297:4–6. Despite being a separate corporate entity, KNA—like the subsidiary companies in the *Polaris* case—does not have its own bank account. TD1 164:21–165:3, 167:24–168:3; TD2 562:15–16. Ronald Martin, a former employee of KNA, testified that any income earned by KNA "goes straight into Kaneka Americas Holdings," even though a portion of that income "is called an internal dividend after the fact." TD1 164:21–165:3, 167:24–168:3, 231:4–7. In addition, KNA does not file a separate tax return; instead KAH files a consolidated return that includes KNA, and KNA reimburses KAH for the taxes paid on KNA's behalf. TD3 606:8–607:2.

KNA is subject to Kaneka's written dividend policy, which applies generally to all of Kaneka's wholly owned subsidiaries. *See* PTX 124; TD1 89:10–90:1, 169:2–11. According to that dividend policy, a Kaneka subsidiary pays a dividend equal to "the greater of 50 percent of profit after taxes or 80 percent of the previous year's dividend as long as [the subsidiary has] retained earnings." TD1 168:19–21; *see* TD1 90:19–92:2; TD2 554:20–24; PTX 124. In the event the subsidiary company's dividend obligation is greater than its retained earnings (such as when the subsidiary company suffers a loss in a year following a year in which it incurred a large dividend obligation, and its retained earnings in the loss year are less than 80 percent of its dividend

obligation in the prior year), the subsidiary company would not be obligated to pay a dividend greater than its retained earnings. TD1 89:10–90:1; PTX 124.

The dividend obligations from KNA to KAH were recorded on the books of both companies, but they were not reflected in actual payments from KNA to KAH. Both the defendants' damages expert, Neil Zoltowski, and Kaneka's damages expert, Sam Rosenfarb, characterized the dividend payment between KNA and KAH as a "paper exercise" or a "paper transaction."[19] TD3 620:24–621:13; TD4 1021:7–11. As Mr. Rosenfarb explained, in describing a schedule calling for the payment of an annual dividend by KNA to KAH, "when I say 'paid,' it was accounted for within the accounting records of KNA and KAH, because KNA has no ability to receive any funds. All the funds [received by KNA] are collected by KAH." TD3 589:3–7. Mr. Zoltowski agreed with Mr. Rosenfarb that "there is no effective dividend from KNA to KAH." TD4 1026:12–20.

As shown in PTX 160, a corporate planning development document that tracked KNA's dividend obligations, KNA was recorded as having followed Kaneka's dividend policy between fiscal years 2015 and 2024. *See* TD1 170:18–187:7. The minutes from the KAH Board of Director meetings held on June 30, 2020, June 30, 2021, and June 30, 2022, include attachments that also show the KNA dividend calculations for Fiscal Years 2020, 2021, and 2022. PTX 147–49. Because of losses suffered by KNA in some years, the dividends KNA paid to KAH between fiscal year 2014 and fiscal year 2023 (the last year for which such evidence was available) were almost exactly the same as the amount of KNA's adjusted net income. Over that period, KNA's total

[19] The transcript of Mr. Rosenfarb's testimony refers to a "payment exercise," TD3 620:22–25, but the context makes it clear that the word "payment" was a transcription error, and that the word Mr. Rosenfarb used was "paper." *See* TD3 621:7–11, 638:15–118 (referring to "that paper exercise").

adjusted net income was [redacted], and the total amount of its dividends paid to KAH was [redacted]. *See* PDX 5.11; PTX 181; PTX 151–157; PTX 135–137, PTX 140–143; TD2 562:8–563:22; TD3 587:5–590:16; TD4 1045:25–1046:7.

The evidence thus demonstrates that KNA's profits flowed directly to its parent, KAH. While KNA and KAH are legally separate entities, the profits from sales made by KNA became KAH's profits when deposited in the joint bank account that KAH maintained for both companies. Thus, KAH had control of KNA's profits from the time they were made, even if the corporate accounting practice was to list those funds in separate spreadsheet columns. Accordingly, I find that Kaneka has proved there was an inexorable flow of profits to KAH from sales of the patented products by KNA.

b. The KAH and Kaneka relationship

In order for Kaneka to be entitled to lost profits on an inexorable flow theory, Kaneka must also show that profits from KNA's sales of the patented products inexorably flowed from KAH to Kaneka.

According to Kaneka's corporate representative at trial, Dr. Iwao Funahashi, "Kaneka Americas Holdings is basically Kaneka." TD1 86:3–4. KAH is a wholly owned subsidiary of Kaneka, TD1 167:5–8, and Kaneka Corporation is KAH's "sole shareholder." TD1 202:1–2; PTX 148. Like KNA, KAH is subject to Kaneka's written dividend policy for wholly owned subsidiaries, which requires that KAH pay an annual dividend to Kaneka. That dividend is calculated as a function of KAH's fiscal year profits, the prior year's dividend, and retained earnings, all subject to the approval of KAH's Board of Directors. TD1 168:5–169:4, 255:8–24.

The defendants contend that the flow of profits from KAH to Kaneka was not automatic, both because of the "approval process in place at KAH before the dividend is paid to Kaneka

Corporation," TD1 255:18–24, and because the profits and losses from the various KAH subsidiaries were combined within KAH before KAH's annual dividend to Kaneka was calculated. But the defendants point to no evidence that the KAH Board of Directors have ever failed to approve a dividend payment to Kaneka, something that would be surprising in light of the fact that Kaneka is KAH's sole shareholder. And the fact that KAH aggregated the profits and losses of all its subsidiaries before calculating the dividend owed to Kaneka would not necessarily undermine Kaneka's "inexorable flow" argument. Even if the additional profits KNA made from the sale of ubiquinol in a particular year in the absence of infringement were outweighed by the losses suffered by other KAH subsidiaries, the additional KNA profits would be reflected in a lower net loss for KAH, which in turn would ultimately result in higher dividends paid to Kaneka in later years. To determine whether the profits that KNA would have made in the absence of the defendants' infringement would have inexorably flowed to Kaneka requires a more granular examination of the facts of this case.

Plaintiff's Trial Exhibit 180, shown below, lists KAH's net profit (and loss) after taxes for each fiscal year between 2016 and 2023, along with the dividend KAH paid to Kaneka for each of those years. As in the case of the dividends that KNA paid to KAH, the amounts vary widely from year to year, and as the exhibit shows, the amount of KAH's dividend obligation was not always lower than its net profits.

PTX 180 (notes omitted).

Broadly viewed, because KAH was essentially KNA's banker, the profits of KNA were the profits of KAH. And because KAH was a holding company with no other economic activity of its own, TD there was no other place for the KNA profits to flow other than, ultimately, to Kaneka. That was the conclusion that Mr. Martin reached in response to the court's question at the conclusion of his testimony (TD1 257:14–24):

> The Court: So if you had events that added value to KNA's profit line . . . wouldn't it inexorably be the case that if you added, say $100 million of profit at some point that KAH and Kaneka would ultimately benefit from that $100 million?
>
> The Witness: Yes, definitely.

Carrying that hypothetical one step farther, an example will show how it is possible for Kaneka's policy to result in all the profits from its subsidiaries ultimately flowing to Kaneka. Suppose the simplest possible transaction: KNA made a one-time profit of $10 million in year one but made no profits at all in any subsequent year. Under Kaneka's dividend policy, KNA would deposit the $10 million into the consolidated bank account kept by KAH. Suppose further than KAH had no profits or losses from any other subsidiary. In that event, KAH would pay a dividend of $5 million to Kaneka in year one (50 percent of its profits, as directed by the Kaneka

dividend policy). In year two, when KNA made no profit and so deposited no funds into KAH's bank account, KAH would pay a dividend of $4 million to Kaneka (80 percent of the prior year's dividend, as directed by the alternative method of calculating dividends under the Kaneka dividend policy). And in the third year, with KNA again making no profits and depositing no funds into KAH's bank account, KAH would pay $1 million to Kaneka. Under the Kaneka dividend policy, in that year KAH would again owe 80 percent of the prior year's dividend, which would be $3.2 million, but since KAH at that point would have only $1 million in retained earnings, the provision of the policy limiting the dividend to the company's retained earnings would apply. The net effect would be that within three years KAH (and thus KNA) would have transferred to Kaneka all the original $10 million in profits made in the first year.

A different hypothetical, however, illustrates that Kaneka's dividend policy would not invariably result in the transfer to all of KAH's profits to Kaneka. Suppose KAH had profits of $10 million in each year for a series of years. In that situation, the dividend payable to Kaneka would be $5 million each year, resulting in an accumulation of profits in KAH of $5 million for each year that KAH's profits continued at the $10 million level. In the absence of some further mechanism other than the Kaneka dividend policy for transferring the accumulating assets from KAH to Kaneka, the profits earned by KNA and passed to KAH would not all be transferred to Kaneka. Kaneka's dividend policy therefore does not guarantee that all of KAH's profits will inevitably be transferred to Kaneka, although that may happen in some circumstances.

A third hypothetical, which is a variant of the first, shows another circumstance in which Kaneka's dividend policy would fail to ensure that all of KAH's profits would ultimately make their way to Kaneka. Suppose that KAH had a profit of $10 million in year one and paid Kaneka a dividend of $5 million. Suppose further that KAH suffered a $6 million loss in year two, which

wiped out KAH's retained earnings. In that setting, KAH would not owe any dividend to Kaneka, because Kaneka's dividend policy requiring the payment of a dividend of at least 80 percent of the previous year's dividend does not apply if the subsidiary has no retained earnings. Nor would the dividend policy provide a means for Kaneka to recoup the shortfall in future years, because the rule requiring the payment of at least 80 percent of the previous year's dividend applies only to the dividend obligation for the immediately following year. TD1 90:19–91:5.

The facts of this case show that this is not one of those circumstances in which Kaneka's dividend policy ensures that all of KAH's profits will flow to Kaneka. The three years that are at issue with respect to the infringement of the original products are October 1, 2020, through September 30, 2023. That period overlaps with the period between the second half of Kaneka's fiscal year 2020 and the first half of Kaneka's fiscal year 2023. TD1 171:16–18. As shown in PTX 180 above, KAH had an adjusted net profit after tax of [redacted] in fiscal year 2021. Pursuant to Kaneka's dividend policy, KAH paid half of that amount (rounded to the nearest $1000), or [redacted] to Kaneka for that year. In the next two years, fiscal years 2022 and 2023, KAH suffered large losses, in excess of [redacted]. KAH paid no dividends to Kaneka for those years. Thus, viewing those three years collectively, KAH suffered a net loss of [redacted], yet it paid Kaneka a total of [redacted] in dividends.

While that calculation makes it appear that Kaneka received more than 100 percent of KAH's profits for that three-year period, the question the court has to answer is a different one: If the lost profits from the infringement by the defendants' original products were added to KAH's profits during the three-year infringement period, how much of that amount would be passed on to Kaneka as a result of the dividend policy?

We begin with the total lost profits to KNA (and thus to KAH) of $2,832,501 for the defendants' infringement in fiscal years 2021 through 2023. Assuming that one-third of that amount was lost in fiscal year 2021, a total of [redacted] would be added to KAH's profits for that year. That increase in KAH's profits (from [redacted]) would result in an increase in KAH's dividend to Kaneka for that year from [redacted] (rounding to the nearest $1000, as prescribed by Kaneka's dividend policy). The increase in the dividend to Kaneka would therefore be [redacted]. Because KAH had no retained earnings after its large loss in fiscal year 2022, the requirement that it pay a dividend of 80 percent of its prior year's dividend did not go into effect, and it did not pay a dividend to Kaneka in either fiscal year 2022 or fiscal year 2023. As further discussed below, however, this analysis is incomplete.

The assumption that one-third of the sales for the three-year infringement period for the original products were made in each year is likely inaccurate, particularly in light of the fact that KNA's ubiquinol sales in the two latter years of the infringement period were significantly affected by the COVID-19 pandemic. *See* TD2 561:2–11. In addition, the fact that the infringement period for the original products does not align precisely with Kaneka's fiscal years introduces a further complication in determining exactly what Kaneka's lost profits were for the infringement period. Finally, because the amounts of KAH's adjusted net income and dividend payments for fiscal year 2024 and later were not in evidence, the calculations set forth above do not include the effects of the lost profits on the KAH's retained earnings in those years and thus do not take account of the possible increases in dividends that would have been paid by KAH to Kaneka in later years based on the carryover effect from the additional profits KNA would have made during the infringement period.

The defendants have suggested that if the court determines that Kaneka is entitled to lost profits for sales of the original products during fiscal year 2021, "the parties' experts can prepare a post-trial accounting to quantify damages over the pertinent time period." D.I. 422 at 40 n.13; *see also* D.I. 439 at 17; D.I. 475 at 1. I agree with that proposal and will conduct an accounting proceeding to determine as accurately as possible what effect, if any, KNA's loss of $2,832,501 in profits would have had on Kaneka, other than an increase in KAH's dividend payment for fiscal year 2021. That proceeding will need to take into account and adjust for the fact that the fiscal years do not align with the years of infringement, and it will require consideration of any provable carryover effect on later years' dividends based on the profits that KNA would have made but for the defendants' infringement.

Because Kaneka has relied on its dividend policy to prove that all of KNA's profits were effectively transferred to Kaneka, and because I have found Kaneka's proof on that issue to be insufficient to show that all of KNA's profits necessarily became Kaneka's profits, I conclude that Kaneka has not met its burden to show that all of KNA's profits would "inexorably flow" to Kaneka. Other evidence in the case, such as Dr. Funahashi's testimony that KAH "is basically Kaneka" and Mr. Martin's unelaborated statement that profits to KNA would "ultimately benefit" Kaneka is not sufficient to satisfy the "extremely high bar" of showing an inexorable flow of all the profits from a subsidiary to a parent corporation. *Roland Corp.*, 2022 WL 22907270, at *7 (citing *Polaris*, 2019 WL 1118518, at *8). At this point, Kaneka has shown only that its lost profits consist of the increase in the dividend payment from KHA to Kaneka for fiscal year 2021 that Kaneka would have experienced in the absence of infringement by the defendants' original products. In the accounting proceeding, the parties will have the responsibility to establish the

amount of that loss and to identify (and quantify) any other loss to Kaneka stemming from the defendants' infringement, in accordance with the rulings in this opinion.

2. Enhanced Damages

Kaneka argues that the defendants' infringement was willful, and that Kaneka is entitled to enhanced damages as a result. *See* 35 U.S.C. § 284. Following the Phase 1 trial, I found that Kaneka had not proved willfulness for the infringement attributed to the original product. D.I. 249 at 45 ("Kaneka has failed to prove, by a preponderance of the evidence, that the defendants' infringement of the '080 patent was willful"). The lost profits damages to which Kaneka is entitled for the sales of the original product are therefore not eligible for enhancement.

In Phase 2, I found that with the exception of Lot 45818, Kaneka failed to meet its burden to prove infringement by the defendants' reformulated products. Thus, for purposes of the infringement at issue in Phase 2, only the damages attributable to the sales of products from Lot 45818 would be potentially eligible for enhanced damages.

"To establish willfulness, the patentee must show the accused infringer had a specific intent to infringe at the time of the challenged conduct." *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 987 (Fed. Cir. 2021) (citing *Halo Elecs., Inc. v. Pulse Elecs.*, 579 U.S. 93, 105–06 (2016)). "Knowledge of the asserted patent and evidence of infringement is necessary, but not sufficient, for a finding of willfulness. Rather, willfulness requires deliberate or intentional infringement." *Id.* at 988 (citing *Eko Brands, LLC v. Adrian Rivera Maynez Enters., Inc.*, 946 F.3d 1367, 1378 (Fed. Cir. 2020)).

Ms. Karas testified that after DFH became aware that the products from Lot 45818 had a QH of more than 90 percent, DFH did not continue to sell that material. TD3 678:2–16; TD 3 679:3–7; TD3 706:17–20 ("Q. After it came to DFH's attention that lot 45818 exceeded the 90

percent ratio, did it continue to sell those lots? A. No, it put the material on hold."). According to Ms. Karas, the lots were erroneously reviewed and released on December 23–24, 2024. TD3 701:6–8, 702:14–22. The problem with Lot 45818 was documented on March 24, 2025.[20] TD3 700:25–701:5; DTX 235. The remaining unsold products from Lot 45818 were destroyed in accordance with the defendants' prescribed procedures on April 17, 2025, less than a month after discovery of the problem. TD3 701:9–25, 706:23–707:3; DTX 464. I credit that account of the defendants' actions with regard to Lot 45818 as accurate.

That course of conduct is not indicative of the "deliberate or intentional infringement" that is required for enhanced damages. *See Bayer Healthcare LLC*, 989 F.3d at 988. Accordingly, Kaneka has failed to establish the willfulness required to justify the imposition of enhanced damages for defendants' infringement by the sale of products from Lot 45818.

IV. Permanent Injunction

In addition to damages, Kaneka requests that the court enter a permanent injunction "enjoining Defendants from making, selling, using or offering to sell the reformulated products." D.I. 428 at 37. Kaneka previously sought an injunction against "any product that infringes the '080 Patent." D.I. 267-1 at 1–2. I denied that request because Kaneka failed to make "a clear showing that it was entitled to preliminary injunctive relief," and the defendants raised a substantial question of infringement as to the reformulated products, D.I. 413 at 24. Kaneka now seeks a permanent injunction directed against the defendants' reformulated products.

"To show entitlement to a permanent injunction, a plaintiff must establish: '(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are

[20] Although the first page of DTX 235 is dated March 24, 2024, the signature blocks are consistent with the testimony of Ms. Karas that the date was March 24, 2025. TD3 700:25–701:5.

inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction' ('the *eBay* factors')." *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 136 F.4th 1075, 1082 (Fed. Cir. 2025) (quoting *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 381 (2006)).

With the exception of the anomalous Lot 45818, Kaneka has failed to prove that the defendants' reformulated products infringe. Without proof of infringement, Kaneka cannot show that it is suffering an irreparable injury by the defendants' manufacture, use, or sale of the defendants' reformulated products. As for Lot 45818, monetary damages are adequate to compensate for the defendants' infringement by that lot, and it appears that no further sales of products from Lot 45818 are likely. Lot 45818 is unrepresentative of the reformulated products, and issuing a permanent injunction for any reformulated products based on a single unrepresentative lot would run afoul of the requirement to "restrict the scope of the injunction to the particular adjudicated infringing activity." *Id.* at 1082 (citing *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1344 (Fed. Cir. 2012) (collecting cases)). Because Kaneka has not satisfied the first two *eBay* factors, it is not necessary to consider the factors relating to the balance of hardships or the public interest.

Kaneka's request for a permanent injunction is denied.

CONCLUSION

Based on the foregoing findings and legal analysis, I conclude as follows:

1. Kaneka has not proved, by a preponderance of the evidence, that the reformulated products other than those derived from Lot 45818 infringe claims 5 or 15 of the '080 patent;

2. Kaneka has proved, by a preponderance of the evidence, that lost profits should be awarded for infringement by the defendants' original products prior to the reformulation and for the products sold from Lot 45818 of the reformulated products.
3. The total amount of the lost profits to KNA resulting from the infringement by the defendants' original products is $2,832,501. Kaneka, however, has not shown that it is entitled to an award of the entire amount of the lost profits under the "inexorable flow" theory, because it has not shown that all of KNA's lost profits would have inexorably flowed to Kaneka. Nonetheless, there are unresolved facts relating to the amount of lost profits to which Kaneka is entitled. The amount of the damages to be awarded to Kaneka for the infringement by the original products will be determined in an accounting proceeding. The parties are directed to meet and confer by April 10, 2026, regarding how they propose to proceed and to submit a joint status report to the court with such a proposal by April 17, 2026. In addition, at that time the parties should also advise the court whether they wish to present the issue of reasonable royalties to the court for adjudication.
4. Damages for the infringement by the defendants' products that were sold from Lot 45818 will be determined in the accounting proceeding referred to in paragraph 3.
5. The court previously held that Kaneka has not shown that the defendants' infringement by the original products justifies the imposition of enhanced damages. The court adheres to that ruling.
6. The court holds that Kaneka has not shown that the defendants' infringement by the sale of products derived from Lot 45818 justifies the imposition of enhanced damages.
7. Kaneka has not proved entitlement to a permanent injunction.

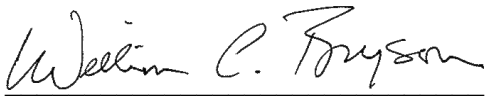
This order constitutes a final judgment except for the accounting directed by in paragraph 3, above. *See* 28 U.S.C. § 1292(c)(2); *see Mondis Tech. Ltd. v. LG Elecs. Inc.*, 6 F.4th 1379 (Fed. Cir. 2021); *Robert Bosch, LLC v. Pylon Mfg. Corp*., 719 F.3d 1305, 1313 (Fed. Cir. 2013) (en banc). The issues of costs and interest will be addressed in a later order.

* * * * *

Many of the parties' post-trial submissions were 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 23d day of March, 2026.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE