IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

MEMORANDUM OPINION AND ORDER

Kaneka filed a motion to strike the Opening Invalidity Expert Report of Dr. Umesh Banakar. Dkt. No. 343. For the reasons explained below, the motion is granted.

I. BACKGROUND

On May 16, 2024, in light of the defendants' late disclosure of stability testing data regarding the reformulation of their products, the court bifurcated the trial so that the first phase would address only whether the defendants' original formulation infringed Kaneka's asserted claims and whether those asserted claims were valid. *See* Dkt. No. 203; Dkt. No. 345-1, Exh. A at 24:23–25:13. Kaneka asserted claims 5 and 15 of U.S. Patent No. 7,829,080 ("the '080 patent") in that phase of the action.

The first trial took place in late May and early June 2024. After the four-day bench trial, the defendants argued in their Proposed Findings of Fact and Conclusions of Law that claims 5 and 15 of the '080 patent were invalid on the grounds that: (1) the asserted claims were directed to a patent-ineligible concept under 35 U.S.C. § 101; (2) the asserted claims were anticipated and/or obvious under 35 U.S.C. §§ 102 and 103; and (3) the asserted claims failed to comply with

the written description requirement of 35 U.S.C. § 112. *See* Dkt. No. 231 at 16–37. Although the defendants had argued in their summary judgment motion and had offered evidence at trial in support of their contention that the asserted claims were indefinite under section 112, they did not argue indefiniteness as a ground for invalidating those claims in their Proposed Findings of Fact and Conclusions of Law. *See id.*

In their summary judgment motion, the defendants had argued that the asserted claims were indefinite because the phrase "the total amount of coenzyme Q_{10}" was undefined, and because the parties' experts had competing approaches to how the relative weight percentage of reduced coenzyme Q_9 should be calculated. Dkt. No. 112 at 28–9. I ruled that the defendants were not entitled to summary judgment with respect to either argument. *See* Dkt. No. 141 at 22–24.

At trial, the parties' expert witnesses provided testimony directed to the defendants' theory of indefiniteness. *See* Dkt. No. 236 at 269:1–270:16 (Dr. Richard Taylor's testimony that the asserted claims were indefinite because of lack of clarity about the required amounts of coenzyme Q_{10} and coenzyme Q_9); Dkt. No. 237 at 43:17–44:21 (Dr. Allan Myerson's testimony summarizing and rejecting the defendants' argument on indefiniteness). However, the defendants chose not to advance any argument on indefiniteness in their post-trial briefing or in their oral presentation in support of their invalidity contentions.

On December 20, 2024, I entered findings of fact and conclusions of law based on the first trial. Dkt. No. 249. I rejected each ground of invalidity that the defendants raised in their post-trial briefing and therefore ruled that the defendants had failed to prove that claims 5 and 15 of the '080 patent were invalid. *Id*. at 45.

After Phase One of the case, I entered scheduling orders that made clear that Phase Two would be limited to "damages for the previously adjudicated products and on liability and damages

for the reformulated products, including the plaintiff's motion for a preliminary injunction" regarding the reformulated products. Dkt. Nos. 281, 306. The second bench trial is currently set for the week beginning July 21, 2025. Kaneka continues to assert claims 5 and 15 of the '080 patent in support of its infringement allegations.

On May 16, 2025, the defendants served what was styled "Opening Invalidity Expert Report" by Dr. Banakar, in which Dr. Banakar asserted that claims 5 and 15 of the '080 patent would be indefinite if Kaneka should offer evidence at the Phase Two trial that the reformulated products are infringing. *See* Dkt. No. 341; Dkt. No. 345-3. In his report, Dr. Banakar first noted that although the specification provides a brief description of "HPLC [High Performance Liquid Chromatography] Analysis Conditions," the asserted claims do not require the use of a specific testing method and that neither party used the conditions set forth in the specification in their HPLC testing of the reformulated product. Dkt. No. 345-3, Exh. C at 19–20. Dr. Banakar then pointed out that as of the date of his report, "none of Kaneka's results have shown that the proportion of reduced coenzyme Q_{10} relative to the total amount of coenzyme Q_{10} in the accused products sold after September 2023 exceeds 90%."[1] *Id*. at 21. Nevertheless, he asserted that "to the extent Kaneka obtains results over 90% and [the defendants'] results show that the ratio is under 90%, then, in my opinion, the claims are invalid as indefinite because the different testing methods and conditions produce materially different results and the accused product may infringe the claim under Kaneka's method but not infringe when employing [the defendants'] method." *Id*. at 21.

Kaneka then filed a motion to strike Dr. Banakar's invalidity report. Dkt. No. 343.

[1] The defendants caveat that statement with a footnote stating that the infringement result for one of the lots was "due to a catastrophic equipment failure" and thus is "not representative of the accused product." Dkt. No. 345-3, Exh. C at 21 n.1.

II. DISCUSSION

Kaneka raises multiple grounds for striking Dr. Banakar's invalidity report. Kaneka argues that: (1) invalidity was decided in Phase One and is not within the scope of Phase Two; (2) the defendants waived any invalidity argument not raised during Phase One; (3) Dr. Banakar's opinion is barred by the law of the case; and (4) the defendants should be judicially estopped from raising a new invalidity argument at this point. Dkt. No. 344. Those four grounds are all based on essentially the same point: that the policy against successive litigation directs that, absent exceptional circumstances, issues that were resolved, either by ruling or waiver, at an earlier point in the same case are not permitted to be relitigated later in the proceedings.

The defendants respond that: (1) they have not waived the indefiniteness argument set forth in Dr. Banakar's report, because "Dr. Banakar's opinions are contingent upon Dr. Myerson's infringement opinions" and "could not have been presented in Phase One when reformulated products were not at issue and there were no competing HPLC testing methods"; (2) law of the case principles do not apply here because the court did not address or resolve any claim of indefiniteness in its decision in Phase One; and (3) judicial estoppel does not apply here because the defendants have not taken irreconcilably inconsistent positions in the two phases of the case and have not acted in bad faith. Dkt. No. 359 at 3–5. The defendants do not dispute that the court's bifurcation order and subsequent scheduling orders made clear that invalidity was an issue for Phase One, and Phase One alone.

1. The law-of-the-case doctrine "expresses the practice of courts generally to refuse to reopen what has been decided" earlier in the same case. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988) (cleaned up); *see also Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1582 (Fed. Cir. 1994) ("The law of the case does not involve preclusion after final judgment,

but rather it regulates judicial affairs before final judgment."). Although a "court has the power to revisit prior decisions of its own . . . as a rule courts should be loath to do so in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous and would work a manifest injustice." *Christianson*, 486 U.S. at 817 (cleaned up); *see also United States v. Quintieri*, 306 F.3d 1217, 1225 (2d Cir. 2002) (The law-of-the-case doctrine "holds that when a court has ruled on an issue, that decision should generally be adhered to by that court in subsequent stages in the same case, unless cogent and compelling reasons militate otherwise.") (cleaned up). "The doctrine of law of the case was created to ensure judicial efficiency and to prevent the possibility of endless litigation." *Toro Co. v. White Consolidated Indus., Inc.*, 383 F.3d 1326, 1335 (Fed. Cir. 2004) (cleaned up). "Its elementary logic is matched by elementary fairness—a litigant given one good bite at the apple should not have a second." *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 900 (Fed. Cir. 1984).

The defendants raised patent invalidity in Phase One of this case, and that issue was decided against them. The defendants have pointed to no extraordinary circumstances that would warrant revisiting the validity of the asserted claims. The defendants have not identified any previously unavailable evidence or any supervening new law, nor have they made a showing that the court's earlier decision on invalidity was clearly erroneous and would work a manifest injustice. *See Pub. Interest Rsch. Grp. of New Jersey, Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 116–17 (3d Cir. 1997) (Extraordinary circumstances that warrant reconsideration of an issue decided earlier in the case "include situations in which: (1) new evidence is available; (2) a supervening new law has been announced; or (3) the earlier decision was clearly erroneous and would create manifest injustice."); *see also Mendenhall*, 26 F.3d at 1582 (Extraordinary circumstances exist for reconsideration of an issue when "the evidence on a subsequent trial was substantially different,

controlling authority has since made a contrary decision of the law applicable to such issues, or the decision was clearly erroneous and would work a manifest injustice.") (cleaned up).

2. The defendants merely raise a new argument on invalidity, which they have waived by not raising it in Phase One. *See Lee v. Chicago Youth Ctrs.*, 69 F. Supp. 3d 885, 887 n.1 (N.D. Ill. 2014) ("Parties should not have a second go at an issue that was raised in the original briefing and which they had every incentive and opportunity to brief. Lawyers are obligated to present their best arguments in a comprehensive fashion when filing or objecting to a motion of any kind."); *Cochran v. Quest Software, Inc.*, 328 F.3d 1, 11 (1st Cir. 2003) ("Litigants normally must frame the issues in a case before the trial court rules. After that point, a litigant should not be allowed to switch from theory to theory like a bee in search of honey. Against this backdrop, the district court scarcely can be said to have abused its discretion in refusing to reconsider its decision based on the plaintiff's newly raised argument.").

The defendants' position is that they could not have raised their current indefiniteness argument in Phase One, but that contention makes little sense. The defendants argued indefiniteness in their summary judgment motion, and their expert witness testified on indefiniteness at the first bench trial. That the reformulated products were not at issue in Phase One makes no difference to the validity of the asserted claims, as the same claims are at issue in Phase Two as in Phase One. As for the absence of competing HPLC testing methods in Phase One, the defendants chose to challenge the reliability of Kaneka's testing at the time without presenting evidence of their own testing. *See* Dkt. No. 249 at 10 ("The defendants presented no affirmative evidence of noninfringement based on any testing they may have conducted.").[2]

[2] The defendants' contention that Dr. Banakar's opinions depend on Dr. Myerson's testing results also makes little sense, since the defendants assert that the claims would be indefinite only if Dr. Myerson's testing proves infringement, which the defendants state has not been the case thus

The circumstances of this case are not like those in *Cordis Corp. v. Medtronic Ave, Inc.*, No. Civ. 97-550, 2005 WL 283525 (D. Del. Jan. 27, 2005), where the district court reconstrued the relevant claim limitations after remand and broadened the scope of the asserted claims. In light of that procedural history, the court in *Cordis* rejected the plaintiff's argument that the defendants had waived their new arguments on obviousness. Instead, the court found that it was "unrealistic to have expected [the defendant] to present invalidity arguments in the original trial if it thought such arguments were futile based on the narrower claim construction at issue" and "unfair to hold [the defendant] to this broader claim construction now." *Id*. at *2.

In this case, there is nothing unrealistic or unfair about having expected the defendants to present any and all indefiniteness arguments in Phase One, where the issue of patent validity was to be presented and resolved. If anything, "it would be grossly unfair to allow a plaintiff to go to the expense of trying a case only to be met by a new defense after trial." *Bradford-White Corp. v. Ernst & Whinney*, 872 F.2d 1153, 1161 (3d Cir. 1989).

3. More basically, the defendants' arguments rest on a misunderstanding of the doctrine of indefiniteness. "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). Claims 5 and 15 of the '080 patent do not fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention: they recite the names and ratios of chemical compounds that make up the claimed composition, none of which terms are abstract and undefined. The defendants' argument that different HPLC analysis

far. The defendants' indefiniteness argument thus depends on conditions that they claim the evidence does not sustain.

conditions could detect different ratios of reduced coenzyme Q_{10} in a given sample of the accused product is an argument that goes to the reliability of testing methodology and thus to proof of infringement, not to the indefiniteness of the claims.

The defendants' theory of indefiniteness is that if different testing methodologies produce different results, such that one testing protocol shows infringement and another shows no infringement, the claim language at issue must be indefinite. That theory is fundamentally flawed. As long as the claim defines infringement according to a single measurable standard, the fact that two different testing protocols may produce different results creates only an issue of infringement. It does not create an issue of claim indefiniteness.

In such a case, if two measurement techniques produce different results—one infringing and the other not—the task of the litigants and the fact-finder is to determine which of the two techniques is the more accurate, and to base a judgment of infringement on that finding. *See Presidio Components v. Am. Tech. Ceramics,* 875 F.3d 1369, 1377 (Fed. Cir. 2017) ("To be sure, even where the claims require a particular test result, there may be (and often are) disputes between the parties as to the proper application of the test methodology in the circumstances of an individual case. But those disputes are disputes about whether there is infringement, not disputes about whether the patent claims are indefinite."). In this case, the limitation at issue requires Kaneka to prove that "the proportion of reduced coenzyme Q_{10} relative to the total amount of coenzyme Q_{10} is not less than 90 wt %." That is a fixed ratio with a single value for a specific chemical compound. Different testing methods, or testing done at different times and under different conditions, may produce varying results, either above or below the 90 wt % figure. But that is just to say that different testing procedures may be more or less accurate, and that particular samples of the accused product may infringe or not infringe depending on the conditions under which they

are tested. But inconsistency in the results does not indicate that the claim limitation is indefinite, as 90 wt % of reduced coenzyme Q_{10} has only a single meaning, even though different tests at different times and under different conditions may produce results on either side of the 90 wt % value, which is fixed and definite.

The problem of inconsistency in test results is entirely different from the problem of indefiniteness found in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335 (Fed. Cir. 2015). In that case, the Federal Circuit held that a claim reciting a polymeric material having "a molecular weight of about 5 to 9 kilodaltons" was invalid as indefinite. Neither the claim nor the specification defined "molecular weight," and it was undisputed that "molecular weight" could be ascertained by any of three measures (peak average molecular weight, number average molecular weight, or weight average molecular weight), and there was no single clear meaning of that term to one of skill in the art. *Id*. at 1341. It was further undisputed that "each of these measures is calculated in a different way and would typically yield a different result for a given polymer sample." *Id*. at 1341. The court thus held that there was no reasonable certainty about how molecular weight should be measured, and that the claim was therefore indefinite. *Id*. at 1345. *Teva*, in other words, involved a definitional problem, where a term was capable of multiple correct meanings and those meanings were tied up with methods of measurement.

The same is true of *Dow Chemical Co. v. Nova Chemicals Corp.*, 803 F.3d 620, 624–25 (Fed. Cir. 2015), where the court held that claims reciting "a slope of strain hardening coefficient" were invalid as indefinite. There was ambiguity in the meaning of "slope of strain hardening" because "the strain hardening region is curved in most instances" and it therefore "does not have a single slope." *Id*. at 632 ("Typically, the curve will get steeper as more force is applied."). The record reflected at least four different methods of calculating the slope of strain hardening, each of

which method would produce "a different slope." *Id*. at 633 (describing the "10% secant tangent method, "final slope method," "most linear method," and a method invented by the patentee's expert). As in *Teva*, to say that there were multiple methods of measurement was to say that there were multiple ways to define "slope of strain hardening."[3]

That is not the case here. The names and ratios of chemical compounds recited in the asserted claims have a fixed and singular meaning. And the existence of different HPLC methods to measure the ratio of reduced coenzyme Q_{10} does not introduce any ambiguity about the scope of the 90 wt % claim limitation that would render the asserted claims indefinite. *See W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, No. 11-515, 2015 WL 12831300, at *4 (D. Del. Sept. 28, 2015) ("[T]he instant case does not involve an abstract and undefined claim limitation, as in *Dow*. To the contrary, a thickness of 0.1 mm is clear . . . ."); *Fieldturf USA v. Astroturf LLC*, No. 10-cv-12492, 2015 WL 13047923, at *2 (E.D. Mich. Oct. 1, 2015) ("Instead of a definitional problem, the current case only involves different ways to measure the depth of infill. Unlike in *Teva* and *Dow Chemical*—cases involving multiple correct definitions of a given term—there is only one correct measurement of infill at any given point on a field. . . . [T]he existence of multiple tools to measure the depth does not present the definitional problem that rendered the patents in *Teva* and *Dow Chemical* indefinite."); *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 240 F. Supp. 3d 605, 633 (E.D. Tex. 2017) ("[I]n this case the standard is clear: to fall within the scope of the claim, the accused product must have a potency ratio of at least 20:1 . . . . The fact that experimental measurements of those values may be difficult to calculate with precision in some cases does not

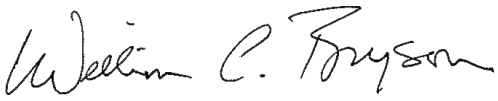
[3] Similarly, in *Saso Golf, Inc. v. Nike, Inc.*, 843 F. App'x 291 (Fed. Cir. 2021), the court held that the claim was indefinite because the terms "toe" and "heel" were undefined and susceptible to multiple interpretations, and there were thus multiple methods of calculating the recited radii of curvature.

render the claim language indefinite."); *Parking Tech. Holdings LLC v. Park Assist, LLC*, No. 20 Civ. 3156, 2024 WL 1885334, at *10 n.4 (S.D.N.Y. Apr. 30, 2024) ("The method of segmentation is not specified, but that does not render the language indefinite, because the claim language and specification clearly delineate the scope of the disputed term.").

In sum, the defendants may not raise indefiniteness as part of Phase Two of this case, for three reasons: first, they have waived their right to raise invalidity based on indefiniteness; second, the court's previous ruling on invalidity is law of the case; and third, even if I were to consider Dr. Banakar's theory of indefiniteness on the merits, I would reject it. Kaneka's motion to strike Dr. Banakar's invalidity report is therefore granted.

IT IS SO ORDERED.

SIGNED this 16th day of June, 2025.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE