

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NATERA, INC.,

Plaintiff,

v.

CAREDX, INC.,

Defendant.

Civil Action No. 20-38-CFC-CJB
(CONSOLIDATED)

MEMORANDUM ORDER

I held a five-day jury trial in this patent infringement case filed by Plaintiff Natera, Inc. against Defendant CareDx, Inc. The asserted patents are directed to methods of observing DNA in samples taken from patients. Natera asserted five claims at trial: claims 21, 26, and 27 of U.S. Patent No. 11,111,544 (the #544 patent) and claims 14 and 15 of U.S. Patent No. 10,655,180 (the #180 patent). In the first phase of trial, the jury found that CareDx's AlloSure and AlloSeq tests (the Accused Products) each infringed the three asserted claims of the #544 patent but did not infringe the two asserted claims of the #180 patent. D.I. 460 at 1–2. The jury also found that the asserted claims were not invalid for obviousness or lack of written description. D.I. 460 at 4–5. In the second phase of trial, the jury awarded Natera with approximately \$96 million in damages. *See* D.I. 462.

Pending before me is Plaintiff Natera, Inc.’s Renewed Motion for Judgment as a Matter of Law Pursuant to Fed. R. Civ. P. 50(b) or New Trial Pursuant to Fed. R. Civ. P. 59 (D.I. 489). Natera seeks by its motion a judgment of infringement of claims 14 and 15 of the #180 patent by the Accused Products. D.I. 489. It asks in the alternative for a new trial. D.I. 489.

I. Legal Standards

A. Judgment as a Matter of Law

“[A] judgment notwithstanding the verdict may be granted under Fed. R. Civ. P. 50(b) only if, as a matter of law, the record is critically deficient of that minimum quantity of evidence from which a jury might reasonably afford relief.” *In re Lemington Home for the Aged*, 777 F.3d 620, 626 (3d Cir. 2015) (quoting *Trabal v. Wells Fargo Armored Serv. Corp.*, 269 F.3d 243, 249 (3d Cir. 2001)). In resolving such a motion, “all evidence and inferences most favorable to the party against whom the motion is made must be indulged.” *Mihalchak v. Am. Dredging Co.*, 266 F.2d 875, 878 (3d Cir. 1959). “When evaluating ‘whether the evidence is sufficient to sustain liability, the court may not weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury’s version.’” *Kars 4 Kids Inc. v. Am. Can!*, 8 F.4th 209, 218 n.8 (3d Cir. 2021) (quoting *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993)).

As the plaintiff and holder of the #180 patent, Natera had the burden of proving by a preponderance of the evidence that CareDx infringed the #180 patent. “Either directing a verdict or entering a judgment notwithstanding the verdict for the party having the burden of proof is rare, reserved for extreme circumstances.” *Fireman’s Fund Ins. Co. v. Videofreeze Corp.*, 540 F.2d 1171, 1177 (3d Cir. 1976) (footnote removed). The standard by which a district court in this Circuit considers a motion for judgment as a matter of law brought by the claimant differs from the standard by which the court considers such a motion brought against the claimant:

Yet though a motion for directed verdict in favor of the proponent of an issue is cast in the same form as when made by the defending party, it requires the judge to test the body of evidence not for its insufficiency to support a finding, but rather for its overwhelming effect. He must be able to say not only that there is sufficient evidence to support the finding, even though other evidence could support as well a contrary finding, but additionally that *there is insufficient evidence for permitting any different finding. The ultimate conclusion that there is no genuine issue of fact* depends not on a failure to prove at least enough so that the controverted fact can be inferred, but rather *depends on making impossible any other equally strong inferences once the fact in issue is at least inferable.*

Mihalchak, 266 F.2d at 877 (footnote removed) (emphasis added).

B. New Trial

Rule 59(a) permits a district court judge, “on motion,” to grant a new trial “for any reason for which a new trial has heretofore been granted in an action at

law in federal court.” Fed. R. Civ. P. 59(a). A new trial may be granted when the verdict is contrary to the evidence, where a miscarriage of justice would result if the jury’s verdict were to stand, or when the court believes the verdict results from confusion. *Brown v. Nutrition Mgmt. Servs. Co.*, 370 F. App’x 267, 270 (3d Cir. 2010).

II. Discussion

As noted above, Natera accused CareDx of infringing claims 14 and 15 of the #180 Patent. Claim 14 reads:

A method for measuring an amount of DNA in a biological sample, the method comprising:

(a) performing a targeted PCR amplification for more than 100 SNP loci on one or more chromosomes expected to be disomic in a single reaction mixture using more than 100 PCR primer pairs, wherein the reaction mixture comprises cell-free DNA extracted from a biological sample of a subject comprising DNA of mixed origin, wherein the DNA of mixed origin comprises DNA from the subject and DNA from a genetically distinct individual, wherein neither the subject nor the genetically distinct individual is a fetus, wherein the DNA of mixed origin comprises DNA from a transplant, and wherein the amplified SNP loci comprise SNP loci on at least chromosome 1, 2, or 3;

(b) measuring a quantity of each allele at a plurality of amplified SNP loci that comprise an allele present in the genetically distinct individual but not the subject, wherein the quantity of each

allele at a plurality of amplified SNP loci are measured by high-throughput sequencing;

(c) measuring an amount of the DNA from the genetically distinct individual in the biological sample using the quantity of each allele at the SNP loci and an expected quantity of each allele at the SNP loci for different DNA fractions,

wherein the method is performed without prior knowledge of genotypes of the genetically distinct individual.

#180 patent at claim 14. Before trial, the parties stipulated that all elements of claim 14 were met by the Accused Products except for the “wherein” clause of claim step 14(b). *See* D.I. 426-1 ¶¶ 11–15. CareDx also agreed that dependent claim 15 of the #180 patent “is not infringed only because the CareDx Accused Products do not practice claim 14.” D.I. 426-1 ¶ 16.

Natera’s motion therefore concerns the following language in claim 14:

A method for measuring an amount of DNA in a biological sample, the method comprising:

* * * *

(b) measuring a quantity of each allele at a plurality of amplified SNP loci that comprise an allele present in the genetically distinct individual but not the subject, **wherein the quantity of each allele at a plurality of amplified SNP loci are measured by high-throughput sequencing;**

#180 patent at claim 14 (emphasis added). I will refer to this bolded claim element as the “measuring-by-sequencing claim element.” \

A. Judgment as a Matter of Law

Natera argues that “the jury was presented with overwhelming evidence that CareDx’s Accused Products infringed asserted claims 14 and 15 of the [#]180 Patent.” D.I. 490 at 1. But the evidence cited by Natera in support of this contention was not so overwhelming that it “ma[de] impossible” a rational inference by the jury that Natera did not prove infringement by a preponderance of the evidence. *Mihalchak*, 266 F.2d at 877.

The subject matter of step 14(b) is highly technical, and the parties understandably relied on the testimony of their competing experts to make their respective cases about whether the Accused Products measure “the quantity of each allele at a plurality of amplified SNP loci” “by high-throughput sequencing.” CareDx’s expert, Dr. Brian Van Ness, testified that allele quantities are measured by the Accused Products after the “raw data” from the sequencing is put through software called the “DNAnexus Cloud Service Program.” *See* 1.24.24 Trial Tr. 906:8–11 (docketed as D.I. 468). According to Dr. Van Ness, the sequencing in the AlloSure test “doesn’t give you any information other than the raw DNA that you’ve sequenced,” 1.24 Tr. 903:10–11, and “AlloSure is simply measuring the amount of DNA from [a] donor recipient; it’s not quantifying each allele in a genetic analysis,” 1.24 Tr. 902:12–14. In Dr. Van Ness’s opinion, after the AlloSure sequencing is completed, “you go through . . . multiple steps of cleaning

the data, doing quality controls, [and] getting . . . pile-up counts in order to get the number of code counts that gives you the information about the transplant.” 1.24 Tr. 903:15–18. Dr. Van Ness further testified that this same software process applied to the AlloSeq test. *See* 1.24 Tr. 906:21–24.

During his testimony, Dr. Van Ness identified five steps after sequencing that he said occur on the DNAnexus Cloud Service Program and are necessary to quantify the alleles. *See* 1.24 Tr. 903:19–906:6. His testimony was supported by two internal CareDx products introduced into evidence at trial that listed these five post-sequencing steps. DTX-61-008; DTX-61-009. CareDx referred to these exhibits as the “software workflow.” *See* DTX-61-008; D.I. 507 at 7.

According to Dr. Van Ness, at the first step, “you have raw data that comes out of the sequencer. It’s that raw data that first has to be put into a computer file, which is called a FASTQ file.” 1.24 Tr. 903:22–25. At the second step, which Dr. Van Ness called a “quality control step,” “there is a method to clean the data to get rid of any of the poor quality sequences” and “the poor quality sequences are being removed.” 1.24 Tr. 904:10–12, 15–16. At the third step, the software “aligns [the sequences] to a reference that tells you where you are in the genome. This is the region of DNA that this sequence represents. So it’s an alignment step to give you a location of a segment of DNA.” 1.24 Tr. 905:1–4. At the fourth step, a software

package “generat[es] a pile-up count,” 1.24 Tr. 905:13, and at the fifth step a software script “gives you . . . the quantity of allele counts,” 1.24 Tr. 905:21–22.

Dr. Van Ness emphasized repeatedly in his testimony that the quantity of alleles is not determined until all five software steps are completed. *See* 1.24 Tr. 903:19–906:15. Viewing his testimony in the light most favorable to CareDx, the jury could reasonably have concluded that the Accused Products do not measure the quantity of each allele at a plurality of amplified SNP loci by high-throughput sequencing and that therefore they do not infringe claims 14 and 15 of the #180 patent.

Natera insists that statements in CareDx’s internal documents show that AlloSure (i.e., sequencing) measures the quantity of alleles. *See* D.I. 490 at 8–10. But the jury was free to evaluate Dr. Van Ness’s explanation of the DNAnexus Cloud Service Program as more credible evidence. *See LePage’s Inc. v. 3M*, 324 F.3d 141, 146 (3d Cir. 2003) (“[R]eview of a jury’s verdict is limited to determining whether some evidence in the record supports the jury’s verdict.”) (citation omitted); *Bonjorno v. Kaiser Aluminum & Chem. Corp.*, 752 F.2d 802, 811 (3d Cir. 1984) (“Normally, when the evidence is contradictory, [judgment as a matter of law] is inappropriate. The assumption is that the jury should decide factual issues involving contradictory evidence.”) (citation omitted).

Natera also argues that Dr. Van Ness “admitted” in the following exchange at trial that “CareDx’s documents describe AlloSure as measuring allele quantities by sequencing,” D.I. 490 at 9–10:

Q. And could you just read the first sentence to me, please.

A. ‘AlloSure measures the amount of donor-derived cell-free DNA relative to the total amount of cell-free DNA in a plasma sample by sequencing 405 SNPs having an average minor allele frequency greater than 40 percent.’

Q. And you agree that that statement is accurate as far as you are concerned?

A. As far as I know.

1.24 Tr. 918:14–22. But as CareDx points out, a reasonable jury could have interpreted Dr. Van Ness’s answer to be “confirm[ing] that the examining lawyer read quotes from CareDx’s AlloSure Test description correctly” rather than making a “smoking-gun admission” that AlloSure practices the sequencing-by-synthesis claim element. *See* D.I. 507 at 14.

Natera further argues that CareDx relied on “non-evidentiary demonstratives, conclusory expert opinions, and erroneous claim interpretation¹ at

¹ Natera briefly argues that CareDx “argued for non-infringement based purely on an unorthodox claim construction that it did not seek from the Court[.]” D.I. 490 at 6; *see also* D.I. 490 at 20 n.5. But Natera did not make this argument during its Rule 50 motion at trial, *see* D.I. 451, and therefore has waived the argument. *See Kars 4 Kids Inc.*, 8 F.4th at 220 (“A post-trial Rule 50 motion can only be made on grounds specifically advanced in a motion for a directed verdict at the end of [the]

trial.” D.I. 490 at 11 (capitalization removed) (footnote added). But Dr. Van Ness’s opinion was neither conclusory nor solely supported by non-evidentiary demonstratives. Instead, Dr. Van Ness’s opinion on the purported allele measurement performed by the DNAnexus Cloud Service Program was explained in detail and supported by the “software workflow” evidence provided to the jury. *See* 1.24 Tr. 902:3–907:9; DTX-61-008; DTX-61-009.

In sum, CareDx presented sufficient testimony through Dr. Van Ness and the “software workflow” steps for the jury to conclude that the Accused Products do not practice the measuring-by-sequencing claim element. “[V]iewing the evidence in the light most favorable to [CareDx] and giving it the advantage of every fair and reasonable inference,” I do not find that there is “insufficient evidence from which a jury reasonably could find” noninfringement of the #180 patent. *Lightning Lube*, 4 F.3d at 1166. I will therefore deny Natera’s renewed motion for judgment as a matter of law.

B. Motion For New Trial

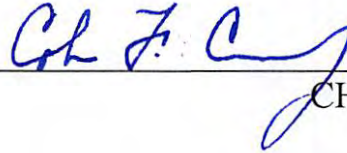
For the reasons discussed above with respect to Natera’s motion for renewed judgment as a matter of law, I will not grant Natera’s motion for a new trial.

plaintiff’s case.”) (quotation and citation omitted); *see also Conoco, Inc. v. Energy & Env’t Int’l, L.C.*, 460 F.3d 1349, 1359 (Fed. Cir. 2006) (“[L]itigants waive their right to present new claim construction disputes if they are raised for the first time after trial.”) (citation omitted).

Natera argues that “allowing the verdict to stand would be a miscarriage of justice” because “the jury’s verdict goes against the clear weight of the evidence presented at trial to demonstrate infringement.” D.I. 490 at 21 (some capitalization removed). Natera then points to the testimony of its expert, Dr. John Quackenbush. *See* D.I. 490 at 21–22 (“The evidence presented by Dr. Quackenbush was sufficient for a finding of infringement of the [#]180 Patent[.]”). But I cannot grant a new trial even if the testimony of Natera’s expert was more persuasive than that of CareDx’s experts. *See Brown*, 370 F. App’x at 270. As discussed above, Dr. Van Ness provided a sufficient basis for a reasonable jury to decide that the Accused Products do not infringe the #180 patent. I also find Natera’s other argument for a new trial—that “CareDx’s attorney’s closing argument improperly misled the jury,” D.I. 490 at 22 (some capitalization removed)—conclusory and unavailing. *See* D.I. 490 at 22–23 (“Despite the fact that infringement of the [#]180 Patent was not rebutted by CareDx’s witnesses with actual evidence, CareDx’s counsel improperly argued in its closing that there *was* evidence demonstrating non-infringement of the [#]180 Patent.”) (emphasis in the original). And I do not believe that the jury’s verdict constituted a miscarriage of justice.

* * * *

NOW THEREFORE, at Wilmington on this Third Day of January in 2025, it is HEREBY ORDERED that Plaintiff Natera, Inc.'s Renewed Motion for Judgment as a Matter of Law Pursuant to Fed. R. Civ. P. 50(b) or New Trial Pursuant to Fed. R. Civ. P. 59 (D.I. 489) is DENIED.

A handwritten signature in blue ink, appearing to read "Ch. F. C.", is written over a horizontal line.

CHIEF JUDGE