No.

In the Supreme Court of the United States

D R BURTON HEALTHCARE LLC,
Petitioner,
v.
TRUDELL MEDICAL INTERNATIONAL INC.,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a district court's order changing the time to trial in its case management order from at least 326 days to 146 days, and its time for completion of all discovery (including expert discovery) from 231 days to 108 days, constitutes a fair legal procedure under the due process clause of the Fifth Amendment?

CORPORATE DISCLOSURE STATEMENT

There are no parent companies of D R Burton Healthcare, LLC. No publicly held company owns 10% or more of the corporation's stock.

LIST OF DIRECTLY RELATED PROCEEDINGS IN FEDERAL TRIAL AND APPELLATE COURTS

1. *Trudell Medical International v. D R Burton Healthcare LLC*; Civil Action No. 4:18-cv-00009; United States District Court for the Eastern District of North Carolina; Judgment entered November 10, 2022.

2. *Trudell Medical International v. D R Burton Healthcare LLC*; Case No. 2023-1777, -1779; United States Court of Appeals for the Federal Circuit; Judgment entered February 7, 2025; Order denying petition for panel rehearing entered April 1, 2025.

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2. Revised Scheduling Order of 8/27/22; 4:18-cv-00009; Document No. 229.

3. Judgment of 11/10/22; 4:18-cv-00009; Document No. 308.

4. Opinion of 2/7/25; *Trudell Medical International Inc. v D R Burton Healthcare, LLC*, 127 F.4th 1340 (Fed. Cir. 2025).

5. Judgment of 2/7/25; 2023-1777, Document No. 55.

6. Order denying request for rehearing of 4/1/25; 2023-177, Document No. 62.

BASIS FOR JURISDICTION

The United States Court of Appeals for the Federal Circuit entered judgment and its order on February 7, 2025.

The United States Court of Appeals for the Federal Circuit entered its order denying rehearing on April 1, 2025.

This Court's jurisdiction is invoked under 28 U.S.C. § 1254.

CONSTITUTIONAL PROVISIONS AND FEDERAL RULES INVOLVED

The Constitution of the United States, Amendment 5.

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of war or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

Federal Rule of Civil Procedure 1. Scope and Purpose.

These rules govern the procedure in all civil actions and proceedings in the United States district courts, except as stated in Rule 81 . They should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding.

STATEMENT OF THE CASE

In 2018, Trudell Medical International filed a lawsuit alleging that D R Burton Healthcare, LLC had infringed U.S. Patent No. 9,808,588. In December 2018, the district court issued its Case Management Order. (Appx26-42). The order set forth deadlines for the parties to follow, consistent with the Eastern District of North Carolina's Local Patent Rules, which issued one month later in January 2019.

Local Patent Rules are fairly common at the district court level. Typically, the rules set forth proposed deadlines that the parties are to follow, with a first phase including fact and expert discovery, leading up to a hearing where the district court defines certain terms in the patent claims, then followed by a second phase including additional fact and expert testimony, leading to trial.

The Case Management Order in this case called for discovery related to preliminary infringement and invalidity contentions, as well as preliminary claim construction, leading to a claim construction hearing. Following the issuance of a claim construction order, the Case Management Order called for final infringement contentions 30 days after issuance of the order, final invalidity contentions 50 days after that,

and additional fact discovery for 120 days after issuance of the order. (Appx40). Initial expert disclosures by the party bearing the burden of proof were then due 30 days after the close of fact discovery, expert disclosures where the opposing party bears the burden of proof were due 30 days after that, and rebuttal expert disclosures were due 14 days after that. (Appx40-41). Following that, expert discovery remained open for 37 days. (Appx41). Thus, the Case Management Order called for 231 days (120+30+30+14+37) for the parties to complete their final contentions and complete their fact and expert discovery.

Following the close of expert discovery, the Case Management order called for 30 days for the parties to prepare their dispositive and *Daubert* motions, with 21 days for response briefs and 14 days for reply briefs. (Appx41). Once the Court acted on those motions, the Case Management Order specified that the parties make their pretrial disclosures 28 days before the final pretrial conference, submit their objections to the pretrial disclosures 21 days before the final pretrial conference, and present the proposed final pretrial order 7 days before reopening the final pretrial conference. (Appx41). Thus, even assuming the unlikely scenario where the Court ruled on the dispositive and *Daubert* motions the day after

reply briefs were filed, set the pretrial conference for the minimum 28 days from issuance of ruling on the dispositive and Daubert motions, and set trial for the very next day, trial would not begin until 95 days (30+21+14+1+28+1) after the close of expert discovery, or 326 days (231+95) after the close of claim construction.

In this case, the court entered is final claim construction order on June 14, 2022. However, without warning, and in response to a joint motion to extend the mediation deadline, on August 26, 2022, the District Court unilaterally shortened the post-claim construction schedule to trial so that all discovery would be completed by September 30th (less than one month later), dispositive motions would be filed no later than October 10th, responses would be due October 21st, replies would be due by October 26th, and trial would begin on November 7th, 2022 (108 days after the final claim construction order). (Appx43-44).

REASONS FOR GRANTING THE WRIT

This case presents an important question regarding the extent of discretion given to a district court to significantly shorten the time to trial without good cause.

As Trudell Medical noted in its appeal to the Federal Circuit, "the District Court was more interested in a fast trial, than a fair trial." (Appellant Brief at 3). Trudell then noted examples demonstrating the Court's intent to remove the case from the Court's docket, regardless of the consequences.

> Shortly thereafter, at a routine status conference held on August 24, 2022, the court expressed frustration at the parties for the case having been pending for so long, and suddenly announced that it intended "to get [this case] off [his] report" by September 30 and set a new expedited trial schedule. Appx1722(6:1-3). At the time, fact discovery had not closed and expert discovery had not commenced. Nevertheless, the court reset the close of all discovery for September 30, 2022 and set trial to commence on November 7, 2022. Appx1744.

> The court also made clear that it sought to rush this case to conclusion —no matter the means—for the sole purpose of removing this case from is Civil Justice Reform Act reporting requirements. Appx1722(6:1-4). A few exemplary comments made by the court during the status hearing include:
>
> - "This case has gone on way, way too long." Appx1719(3:9).
> - "You got all kinds of horizontal movement and no vertical movement. And I'm going to settle this case or resolve it or dismiss it by September 30th. Just—that's a head's up." Appx1719(3:14-17).
> - "Forget about the claims. What are they going to do, reverse me? It goes to the Federal Circuit, doesn't it?" Appx1721(5:13-15).
> - "But I have to report this case by September 30th and I'm going to get it off my report. That's the problem you have. Did you know that?" Appx1722(6:1-3).
> - (Appellant Brief at 12-13).

On remand, the Federal Circuit citing many of the same quotes, reassigned the case to

another district court judge, finding that “”from the moment this case fell into his lap, the trial judge’s statements indicate that he did not intend to manage a fair trial with respect to the issues in this case.” (*Trudell Medical Int’l Inc. v. D R Burton Healthcare, LLC*, 127 F.4th 1340, 1352 (Fed. Cir. 2025)(Appx21-22)).

Rule 1 of the Federal Rules of Civil Procedure states that the rules “govern the procedure in all civil actions and proceedings in the United States district courts, except as stated in Rule 81” and “should be construed, administered and employed but eh court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding.” Fed. R. Civ. P. 1.

And the Fifth Amendment to the Constitution requires that “no person . . . shall be deprived of life, liberty, or property, without due process of law.” United States Constitution, Fifth Amendment.

Here, the district court’s decision to significantly shorten the time to trial violated the parties’ due process right to a fair trial. Even Trudell Medical, as noted above, which was represented by at least five attorneys who actively participated in preparations for trial, believed the schedule set by the district court

was based more on the desire to hold a fast trial, rather than a fair one. But at least Trudell had a sufficiently large law firm to meet the demands of the accelerated schedule.

In contrast, D R Burton was represented by present counsel, a sole practitioner, who was forced to make decisions about what could or could not be done in order to put D R Burton in the best position for trial.

While some of those decisions were the basis for Trudell's successful appeal to the Federal Circuit, they were also were made out of necessity, and would never have been required had the district court maintained its original post- claim construction schedule and allowed D R Burton sufficient time to prepare its case.

* * *

"The touchstone of due process is protection of the individual against arbitrary action of government." *Dent v. West Virginia*, 129 U.S. 114, 123 (1889). Procedural due process, which is applicable in civil as well as criminal proceedings requires government officials to follow fair procedures before depriving a person of life, liberty, or property." "The fundamental requirement of due process is the opportunity to be heard "at a

meaningful time and in a meaningful manner." *Matthews v. Eldridge*, 424 U.S. 319, 333 (1976) (quoting *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965). "

> Due process, unlike some legal rules, is not a technical conception with a fixed content unrelated to time, place and circumstances. [D]ue process is flexible and calls for such procedural protections as the particular situation demands. More precisely, our prior decisions indicate that identification of the specific dictates of due process generally requires consideration of three distinct factors: First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens the the additional or substitute procedural requirement would entail. "*Matthews v. Eldridge*, 424 U.S. 319, 334-35(1976) (internal citations omitted).

"[P]rocedural due process rules are shaped by the risk of error inherent in the truth-finding process . . . ." *Matthews v. Eldridge*, 424 U.S. 319, 344 (1976).

Here, the Federal Circuit addressed the unfairness of the proceeding as it pertained to Trudell, but did not address the overall unfairness of the proceeding as it pertained to D R Burton. The lack of meaningful time to complete its obligations to the Court and to prepare for trial in the substantially reduced time frame set forth by the court was a violation of D R Burton's due process rights.

CONCLUSION

This Court should issue a writ of certiorari to determine whether the district court's actions in substantially reducing the time to trial violated D R Burton's right to due process.

June 30, 2025 s/*Albert P. Allan*

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APPENDIX

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TRUDELL MEDICAL INTERNATIONAL INC., Plaintiff-Appellant v. D R BURTON HEALTHCARE, LLC, Defendant/Counter-Claimant-Cross-Appellant

2023-1777

2023-1779

United States Court of Appeals, Federal Circuit

Decided: February 7, 2025

[*1344] Appeals from the United States District Court for the Eastern District of North Carolina in No. 4:18-cv-00009-BO, Judge Terrence William Boyle.

Laura A. Lydigsen, Crowell & Moring, LLP, Chicago, IL, argued for plaintiff-appellant. Also represented by William Harry Frankel, Judy He, David Lindner.

Albert P. Allan, Allan Law Firm, PLLC, Charlotte, NC, argued for defendant/counter-claimant-cross-appellant. Also represented by William Robert Terpening, Terpening Law PLLC, Charlotte, NC.

Before Moore, Chief Judge, Chen and Stoll, Circuit Judges.

Moore, Chief Judge.

Trudell Medical International Inc. (Trudell) appeals the United States District **[*1345]** Court for the Eastern District of North Carolina's decision to allow D R Burton Healthcare, LLC (D R Burton) to present infringement testimony by Dr. John Collins at trial. Trudell also appeals the denial of a motion for judgment as a matter of law (JMOL) on infringement of claims 1-7, 9, and 18 of U.S. Patent No. 9,808,588 or, in the alternative, a new trial on infringement of claims 1-18 and 20-26 of the '588 patent (the Asserted Claims). *See Trudell Med. Int'l v. D R Burton Healthcare LLC*, No. 4:18-cv-00009, 2023 WL 2315391 (E.D.N.C. Mar. 1, 2023) (*Post-Trial Order*). We reverse the district court's admission of Dr. Collins' testimony and its denial of a new trial on infringement, and we remand the case to be reassigned.1

BACKGROUND

Trudell owns the '588 patent, which relates to portable devices for performing oscillatory positive expiratory pressure (OPEP) therapy. '588 patent at 1:16-18, 50-51. OPEP therapy loosens secretions from airways to improve respiration. *See id.* at 1:22-46. The three independent claims read:

> 1. A respiratory treatment device comprising:

an inlet configured to receive exhaled air into the device;

an outlet configured to permit air to exit the device;

an opening positioned in an exhalation flow path defined between the inlet and the outlet;

a blocking segment configured to *rotate relative to the opening* between a closed position where the flow of air through the opening is restricted, and an open position where the flow of air through the opening is less restricted; and,

a vane configured to rotate the blocking segment between the closed position and the open position in response to the flow of air through the opening;

wherein a size of a blocking surface of the blocking segment is equal to or greater than a size of the opening.

9. A respiratory treatment device comprising:

an inlet configured to receive exhaled air into the device;

an outlet configured to permit air to exit the device;

an opening positioned in an exhalation flow path defined between the inlet and the outlet, the opening having a *generally oblong cross-sectional shape* comprising a shorter first dimension and an elongated second dimension perpendicular to the first dimension; and,

a blocking segment configured to *translate relative to the opening* along the shorter first dimension between a closed position where the flow of air through the opening is restricted, and an open position where the flow of air through the opening is less restricted;

wherein a size of a blocking surface of the blocking segment is equal to or greater than a size of the opening. **[*1346]**

18. A respiratory treatment device comprising:

an inlet configured to receive exhaled air into the device;

> an outlet configured to permit air to exit the device;
>
> an opening positioned in an exhalation flow path defined between the inlet and the outlet, and,
>
> a blocking segment configured to *translate relative to the opening* between a closed position where the flow of air through the opening is restricted, and an open position where the flow of air through the opening is less restricted;
>
> wherein a side profile of the blocking segment is shaped to mate with a side profile of the opening, when the blocking segment is in the closed position; and,
>
> wherein a size of a blocking surface of the blocking segment is equal to or greater than a size of the opening.

Id. at 12:12-26, 49-63, 13:25-14:5 (emphases added). D R Burton sells OPEP devices, including the vPEP®, vPEP® HC, iPEP®, PocketPEP®, and PocketPEP® Advantage products (collectively, the Accused Products).

On January 29, 2018, Trudell sued D R Burton for infringement of certain claims of the '588 patent. After a claim construction hearing in October 2020,

the case was reassigned in January 2021 to United States District Court Judge Terrence Boyle. Judge Boyle assigned a new magistrate judge, who issued a Memorandum and Recommendation (M&R) regarding claim construction. J.A. 23-63. The district court adopted the M&R in its entirety.

On August 26, 2022, the district court amended the case schedule. At that time, fact discovery had not closed and expert discovery had not yet commenced. J.A. 1740 at 24:20-24. The district court set the close of all discovery for September 30, 2022 and set trial to start on November 7, 2022. Before the September 30 discovery deadline, Trudell submitted expert reports on infringement and damages. On October 21, 2022, D R Burton filed a seven-page declaration from Dr. Collins in support of its opposition to Trudell's motion for summary judgment on infringement. The district court denied Trudell's summary judgment motion.

Leading up to trial, Trudell filed motions in limine seeking to exclude testimony from Dr. Collins on invalidity and noninfringement and to exclude testimony from any D R Burton witnesses on claim construction. The district court did not rule on Trudell's motion in limine until the pre-trial conference on Friday, November 4, 2022. At the pre-trial conference the district court initially denied the motion in limine, J.A. 2035 at 3:1-2, then on Monday, November 7, 2022—the first day

of trial—the district court reversed itself and granted the motion in limine after Trudell filed a motion for reconsideration, J.A. 2073 at 2:3-12. The district court then doubled back moments later, "reserv[ing] a ruling on [i]t until the end of plaintiff's case." J.A. 2079 at 8:25-9:2. On the third and final day of trial, after Trudell presented its case, but before lunch, the district court ruled that Dr. Collins would testify after the lunch break. J.A. 2476-77 at 36:24-37:15.

After a three-day trial, the jury returned a verdict that the Asserted Claims were valid but not infringed. Trudell filed a renewed motion for JMOL of infringement or, in the alternative, a new trial. The district court denied the motion. *Post-Trial Order*, at *1-5. Trudell appeals the district court's decision to allow Dr. Collins **[*1347]** to provide noninfringement testimony at trial, as well as its denial of JMOL or a new trial. Trudell requests that, should this case be remanded to the district court for further proceedings, the case be reassigned to a different district court judge. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Expert Testimony

We review a district court's decision to admit or exclude evidence under the law of the regional

circuit. *Siemens Med. Sols. USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1284 (Fed. Cir. 2011). The Fourth Circuit reviews a district court's decision to admit expert testimony for abuse of discretion. *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 280 (4th Cir. 2021). "A district court abuses its discretion when it misapprehends or misapplies the applicable law." *Wickersham v. Ford Motor Co.*, 997 F.3d 526, 538 (4th Cir. 2021) (cleaned up).

Federal Rule of Civil Procedure 26 requires parties to identify expert testimony for use at trial, and, subject to exceptions not present here, "this disclosure must be accompanied by a written report." FED. R. CIV. P. 26(a)(2)(B). The report must contain:

> (i) a complete statement of all opinions the witness will express and the basis and reasons for them;
>
> (ii) the facts or data considered by the witness in forming them;
>
> (iii) any exhibits that will be used to summarize or support them;
>
> (iv) the witness's qualifications, including a list of all publications authored in the previous 10 years;

> (v) a list of all other cases in which, during the previous 4 years, the witness
>
> testified as an expert at trial or by deposition; and
>
> (vi) a statement of the compensation to be paid for the study and testimony in the case.

Id.

Federal Rule of Civil Procedure 37(c)(1) states that "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." FED. R. CIV. P. 37(c)(1). The Fourth Circuit has held the following factors should be considered in determining whether a party's nondisclosure is substantially justified or harmless for purposes of Rule 37(c)(1): "(1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the nondisclosing party's explanation for its failure to disclose the evidence." *S. States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 597 (4th Cir. 2003). The first four factors relate

primarily to the harmlessness exception, and the fifth factor relates primarily to the substantial justification exception. *Id.*

Trudell argues the district court should have excluded Dr. Collins' testimony on noninfringement because he did not timely serve an expert report on noninfringement, and failure to comply with Rule 26 was neither substantially justified nor harmless. To the extent any of the declarations submitted by Dr. Collins are considered **[*1348]** an expert report, Trudell argues Dr. Collins' testimony should have nonetheless been excluded under Federal Rule of Evidence 702 as unreliable and misleading.

D R Burton filed three declarations with testimony from Dr. Collins. In May 2019, D R Burton filed a declaration in support of its motion to amend its invalidity contentions. In November 2019, D R Burton filed an expert report by Dr. Collins in support of its opening claim construction brief. On October 21, 2022, D R Burton filed a seven-page declaration from Dr. Collins in support of its opposition to summary judgment of infringement.

We hold the district court abused its discretion in allowing noninfringement testimony by Dr. Collins. D R Burton did not disclose Dr. Collins' noninfringement opinion in a timely expert report, as required by Rule 26 and Fourth Circuit law. It is undisputed Dr. Collins did not submit an expert

report on noninfringement during the discovery period. Dr. Collins' seven-page declaration, to the extent it could be considered an expert report, was submitted almost a month after the close of discovery on September 30, 2022. Under Rule 37, therefore, the proper result is exclusion of Dr. Collins' noninfringement testimony absent a showing that the failure to disclose was either substantially justified or harmless.

The district court did not, nor could it, explain why allowing Dr. Collins' untimely noninfringement testimony was substantially justified or harmless. In its order denying Trudell's renewed motion for JMOL, the district court "reaffirm[ed] its decision to allow Dr. Collins's testimony." *Post-Trial Order*, at *4. The district court, however, provided no reasoning why D R Burton's failure to submit a timely expert report by Dr. Collins on noninfringement was substantially justified. Nor does D R Burton make a colorable substantial justification argument on appeal. D R Burton references the accelerated discovery and trial schedule, Appellee's Response Br. 18, but after the district court amended the case schedule, D R Burton indicated it did not intend to submit a noninfringement expert report, J.A. 2031. The accelerated case schedule therefore does not provide substantial justification for D R Burton's failure to disclose.

While the district court did not expressly state that Dr. Collins' untimely testimony was harmless, the district court reasoned that large portions of Dr. Collins' testimony had been disclosed in his seven-page declaration, and the district court's decision to reserve ruling on Trudell's motion in limine provided notice that Dr. Collins might testify at trial. *Post-Trial Order*, at *4. But it is undisputed that Dr. Collins' testimony constituted nearly all D R Burton's evidence of noninfringement, Oral Arg. at 24:02-20, and Trudell was afforded no opportunity to depose him on the issue because Dr. Collins' only declaration on noninfringement was served weeks after the close of discovery. While Trudell cross-examined Dr. Collins on noninfringement, "the ability to simply cross-examine an expert concerning a new opinion at trial is not the ability to cure." *S. States Rack & Fixture*, 318 F.3d at 598.

D R Burton also argues Trudell was not prejudiced by Dr. Collins' late declaration because Trudell also submitted late expert reports. Appellee's Response Br. 15, 18-19. Due to the accelerated discovery schedule, D R Burton argues, expert reports from both parties were untimely under Rule 26 and exclusion of Dr. **[*1349]** Collins' testimony would have also resulted in exclusion of testimony from Trudell's experts. We do not agree. Trudell submitted an infringement expert report on September 20, 2022 and a damages expert report

on September 29, 2022. D R Burton contends these reports were untimely under Rule 26(a)(2)(D)(i) because they were served less than ninety days before the start of trial on November 7, 2022. Appellee's Response Br. 7. Importantly, however, the ninety-day deadline expressly applies "[a]bsent a stipulation or a court order." FED. R. CIV. P. 26(a)(2)(D). The district court's August 26, 2022 scheduling order allowed for discovery until September 30, 2022, by which time Trudell had submitted its expert reports. J.A. 1744. To the extent D R Burton argues it was harmed by Trudell's submission of its damages expert report one day before the close of discovery, this is belied by the parties' email communications indicating D R Burton expressly stated that it did not intend to conduct a deposition of this expert. J.A. 2031.

Finally, Dr. Collins' testimony exceeded the scope of his declaration. *Compare*, *e.g.*, J.A. 2532-33 at 92:8-13, 92:23-93:3 (Dr. Collins' trial testimony as to whether the Accused Products "translate" as required by the claims), *with* J.A. 1949-55 (Dr. Collins' declaration which lacks reference to the "translate" limitation). Even if Dr. Collins' seven-page declaration was a timely filed, fully compliant expert report, it failed to fully disclose the noninfringement testimony given at trial. To the extent the district court reasoned Dr. Collins' untimely declaration sufficed to give Trudell notice of his noninfringement testimony, significant

portions of his trial testimony went beyond the bounds of the declaration.

Under these circumstances, Dr. Collins' untimely report was neither harmless nor substantially justified. Accordingly, the district court abused its discretion by failing to exclude Dr. Collins' testimony under the Federal Rules of Civil Procedure and Fourth Circuit law. *See* FED. R. CIV. P. 26(a)(2)(B), 37(c)(1); *S. States Rack & Fixture*, 318 F.3d at 597.

The district court also abused its discretion by failing to exclude Dr. Collins' testimony because—even if his noninfringement declaration is viewed as an expert report—his noninfringement declaration was unreliable under Federal Rule of Evidence 702. Rule 702 requires:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Because expert testimony "can be both powerful and quite misleading," the district court's gatekeeping function under Rule 702 is an important one. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 595, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993) (citation omitted); *see Sardis*, 10 F.4th at 283.

Here, Dr. Collins' noninfringement declaration was untethered from the district **[*1350]** court's claim constructions. For example, the district court construed the term "a vane" as "a blade or plate whose primary purpose is to convert kinetic energy in the form of fluid movement into rotational movement" and noted that this construction should be understood broadly to include "one or more vanes." J.A. 38. Dr. Collins, however, opined in his declaration that the accused products do not infringe because the patent "requires more than one vane." J.A. 1953 n.1. Similarly, the district court construed the term "rotate relative to the

opening" as "move a fixed body relative to the opening about a point at a fixed radius" and rejected D R Burton's argument that the term required "a full revolution." J.A. 38-42. But Dr. Collins opined in his declaration that "rotate relative to the opening" in the context of the '588 patent meant "the vanes rotate in one direction during expiration, round and round in a circular manner," J.A. 1953 ¶ 11.2 The methodological unsoundness of Dr. Collins' declaration provides an independent basis by which the district court abused its discretion in allowing Dr. Collins to testify at trial. Therefore we vacate the jury's finding of infringement and remand for a new trial.

II. JUDGMENT AS A MATTER OF LAW

Trudell argues that a new trial is unnecessary because the district court erred in denying JMOL of infringement. We review denial of JMOL under the law of the regional circuit. *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1343 (Fed. Cir. 2012). The Fourth Circuit reviews denial of JMOL de novo, applying the same standard as the district court. *Johnson v. MBNA Am. Bank, NA*, 357 F.3d 426, 431 (4th Cir. 2004). JMOL is granted if, "viewing the evidence in a light most favorable to the non-moving party and drawing every legitimate inference in that party's favor, the court determines that the only conclusion a reasonable jury could have reached is one in favor of the moving party."

Saunders v. Branch Banking & Trust Co. of VA., 526 F.3d 142, 147 (4th Cir. 2008). The Fourth Circuit has acknowledged that JMOL "may not be granted lightly," and has indicated that a party seeking JMOL who also bore the burden of proof faces a particularly formidable burden. *Thornhill v. Donnkenny, Inc.*, 823 F.2d 782, 786 (4th Cir. 1987) ("The only possible basis for judgment n.o.v. on the breach of contract claim is Donnkenny, Inc.'s breach of fiduciary duty defense. We are satisfied that the evidence supporting Donnkenny, Inc.'s affirmative defense was not so overwhelming that we cannot uphold the jury's rejection of that defense.") (citing 9C C. WRIGHT & A. MILLER, *Federal Practice and Procedure* § 2535 (1971)).

Trudell argues the district court erred in denying its renewed motion for JMOL of infringement. Trudell contends the only evidence of noninfringement was Dr. Collins' testimony. Had this testimony been properly excluded, Trudell argues, the jury would have lacked a sufficient evidentiary basis to find noninfringement. D R Burton argues that, even without Dr. Collins' testimony, there remains sufficient **[*1351]** evidence to support the jury's verdict of noninfringement. Appellee's Response Br. 19-20. In addition to testimony from Dr. Collins, D R Burton presented testimony from its founder and president, Gregory Lau. *See*, *e.g.*, J.A. 2503-04 at 63:19-64:25. Mr. Lau testified that, after reviewing

the patent, he believed Trudell's invention was a "day and night differen[ce]" from D R Burton's devices. J.A. 2503-04 at 63:19-64:4. D R Burton contends this evidence supports a finding of noninfringement.

Though we agree with Trudell that, without Dr. Collins' testimony, D R Burton is left with minimal evidence of noninfringement, the jury was free to discredit the testimony of Trudell's expert, Dr. Durgin, and find that Trudell failed to meet its affirmative burden to prove infringement. For example, D R Burton's cross-examination of Dr. Durgin challenged his infringement testimony particularly regarding the "generally oblong cross-sectional shape" limitation. J.A. 2365-66 at 142:8-143:1. Credibility determinations are within the sole province of the jury, and we do not reweigh the evidence presented at trial. *United States Sec. & Exch. Comm'n v. Clark*, 60 F.4th 807, 812 (4th Cir. 2023). We hold that Trudell has not established entitlement to JMOL of infringement and therefore affirm the district court's denial of Trudell's JMOL motion.

III. NEW TRIAL

We review a district court's denial of a motion for a new trial under the law of the regional circuit. *Apple Inc. v. Wi-LAN Inc.*, 25 F.4th 960, 975 (Fed. Cir. 2022). The Fourth Circuit reviews such denials

for abuse of discretion. *United States v. Perry*, 335 F.3d 316, 320 (4th Cir. 2003). A new trial is warranted if the verdict is against the clear weight of the evidence; is based upon evidence which is false; or will result in a miscarriage of justice, even though there may be substantial evidence which would prevent the direction of a verdict. *Minter v. Wells Fargo Bank, N.A.*, 762 F.3d 339, 346 (4th Cir. 2014).

Trudell argues the district court abused its discretion in denying the motion for a new trial on infringement because the verdict is against the clear weight of the evidence and resulted in a miscarriage of justice. We agree.

The harmful and prejudicial admission of Dr. Collins' testimony warrants a new trial on infringement. The district court abused its discretion in admitting Dr. Collins' noninfringement testimony because it was untimely, failed to comply with Federal Rule of Civil Procedure 26, and was unreliable under Federal Rule of Evidence 702. We vacate the district court's denial of the motion and remand for a new trial.

On remand, the record should be confined to evidence already produced and admitted, with exclusion of Dr. Collins' noninfringement testimony. At this juncture, it would be improper to

reopen discovery where D R Burton previously indicated to Trudell that it did not intend to

produce additional expert reports or depose Trudell's experts. *See* J.A. 2031. Under these circumstances, D R Burton should not now be permitted to cure its failure to comply with the disclosure requirements of Rule 26.

IV. REASSIGNMENT

We evaluate a request to reassign a matter to a different judge on remand under the law of the regional circuit. ***[*1352]*** *TriMed*, *Inc. v. Stryker Corp.*, 608 F.3d 1333, 1343 (Fed. Cir. 2010). Fourth Circuit law provides for reassignment where "both for the judge's sake and the appearance of justice an assignment to a different judge is salutary and in the public interest, especially as it minimizes even a suspicion of partiality." *G.G. ex rel. Grimm v. Gloucester Cnty. Sch. Bd.*, 822 F.3d 709, 726 (4th Cir. 2016) (quoting *United States v. Guglielmi*, 929 F.2d 1001, 1007 (4th Cir. 1991)), *vacated on other grounds by* 580 U.S. 1168, 137 S.Ct. 1239, 197 L.Ed.2d 460 (2017). In determining whether reassignment is warranted, the Fourth Circuit considers: "(1) whether the original judge would reasonably be expected upon remand to have substantial difficulty in putting out of his or her mind previously expressed views or findings determined to be erroneous or based on evidence

that must be rejected, (2) whether reassignment is advisable to preserve the appearance of justice, and (3) whether reassignment would entail waste and duplication out of proportion to any gain in preserving the appearance of fairness." *Id.*

Trudell argues that reassignment to a different trial judge is appropriate and necessary on remand. Trudell points out that this case is particularly analogous to a Fourth Circuit case, *Beach Mart, Inc. v. L&L Wings, Inc.*, 784 F. App'x 118 (4th Cir. 2019), in which the court ordered reassignment to a different district court judge on remand. Indeed, the same judge presided over both this trial and the initial trial in *Beach Mart*. Trudell argues that, in this case, the district court judge made objectionable statements similar to those on which the Fourth Circuit based its reassignment decision. Several such statements in this case include:

> "And I'm going to settle this case or resolve it or dismiss it by September 30th. Just - that's a heads up." J.A. 1719 at 3:15-17.
>
> "How about if I try the first case in early September and forget about your mediation." J.A. 1722-23 at 6:25-7:1.
>
> "[O]ur duty is to get this case done. And

> if you can't get it done, then I will. You can get it done by settling it. I can get it done by having a verdict in it." J.A. 2052 at 20:14-16.

We agree with Trudell that the statements of the trial judge in this case are so similar to those in *Beach Mart*, undermining the appearance of justice and fairness, and we see no reason to decide this case differently. *See* 784 F. App'x at 130. This case is unique in that, as in *Beach Mart*, from the moment this case fell in his lap, the trial judge's statements indicate that he did not intend to manage a fair trial with respect to the issues in this case. *See*, *e.g.*, J.A. 1722 at 6:1-3 ("But I have to report this case by September 30th and I'm going to get it off my report. That's the problem you have. Did you know that?"). Likewise, the trial judge's statements at trial in the presence of the jury "undermin[ed] the appearance of fairness," 784 F. App'x at 130. *See*, *e.g.*, J.A. 2305 at 82:1-8 ("The jury's just being tolerant of this, and it's painful. My gosh. I should have put time limits . . . . I don't think they understand they have to get through this case."); J.A. 2356 at 133:3-6 ("THE COURT: You [Trudell's counsel] can't do anything quickly. What do you [the jury] want, do you want to hear this stuff or do you want it kept moving along in the case? SOME JURORS: Move along."). As in *Beach Mart*, given the strength of his statements, there is sufficient reason to believe that the trial

judge's conviction to quickly terminate the case will be no different on remand. Finally, **[*1353]** as in *Beach Mart*, reassignment would not result in undue delay or wasted judicial resources, as the trial judge presided over this case for only one of the four years of this litigation. 784 F. App'x at 130. For these reasons, we remand the case for trial before a different district court judge.3

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the foregoing reasons, we reverse the district court's decision admitting Dr. Collins' noninfringement testimony and its denial of Trudell's motion for a new trial on infringement. We affirm the district court's denial of Trudell's motion for JMOL of infringement. We remand for a new trial on infringement consistent with this decision.

AFFIRMED-IN-PART, **REVERSED-IN-PART**, **AND REMANDED**

COSTS

Costs to Trudell.

1. D R Burton cross-appealed the jury's verdict that the Asserted Claims of the '588 patent were not shown to be invalid. We need not reach this issue,

however, as D R Burton withdrew the cross-appeal at oral argument in light of its failure to file a renewed motion for JMOL pursuant to Federal Rule of Civil Procedure 50(b). Oral Arg. at 27:20-28:09, available at https://oralarguments.cafc.uscourts.gov/default.aspx?fl=23-1777_10092024.mp3; *A Helping Hand, LLC v. Baltimore Cnty., Md.*, 515 F.3d 356, 369-70 (4th Cir. 2008) ("a party's failure to file a postverdict motion under Rule 50(b) leaves an appellate court without power to direct the District Court to enter judgment contrary to the one it had permitted to stand" (quoting *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 546 U.S. 394, 400-01, 126 S.Ct. 980, 163 L.Ed.2d 974 (2006)) (internal quotation marks omitted))).

2. Moreover, Dr. Collins also improperly compared the accused products to the figures in the specification rather than the claim language. J.A. 2520-23 at 80:8-83:25, 2528-29 at 88:19-89:4; *Int'l Visual Corp. v. Crown Metal Mfg. Co.*, 991 F.2d 768, 772 (Fed. Cir. 1993) (per curiam) ("Infringement is determined on the basis of the claims, not on the basis of a comparison with the

patentee's commercial embodiment of the claimed invention." (cleaned up)).

3. At oral argument, D R Burton indicated a related case before the same trial judge is stayed pending the outcome of this appeal. Oral Arg. at 26:09-37. Judicial efficiency usually counsels consolidation of related cases with a single judge. As the stayed case is not before us, we have no power to order reassignment of that case.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH
CAROLINA EASTERN DIVISION
No. 4:18-CV-9-H-KS

TRUDELL MEDICAL INTERNATIONA Plaintiff, v. D R BURTON HEALTHCARE LLC Defendant.	))))) **CASE**) **MANAGEMENT**) **ORDER**) (Patent) Infringement))

This matter has been referred to the undersigned for pretrial case management by Senior United States District Judge Malcolm J. Howard. Pursuant to Fed. R. Civ. P. 26(f) and this court's Local Civil Rule 302.1, the parties have conducted a scheduling conference by telephone and submitted to the court a Joint Rule 26(f) Report and Discovery Plan. Having reviewed the parties' proposed discovery plan and having discussed it with the

parties at a telephonic, non-final pretrial conference held on December 17, 2018, the court hereby ORDERS as follows:

I. Discovery

A. Initial Disclosures

Initial disclosures required by Rule 26(a)(1) shall be made by **January 4, 2019**. Any party making an appearance after this order has been entered shall be required to confer with the other parties and make disclosures pursuant to Fed. R. Civ. P. 26(a)(1) within twenty-one (21) days after the party's appearance. Such party shall be bound by the terms of this order unless the party moves for and obtains amendment of this order by the court.

B. Subjects of Discovery

Discovery will be needed on the subjects

listed in Section 3 of the parties' Joint Rule 26(f) Report and Discovery Plan.

C. ESI/Protective Orders

The parties shall confer and submit, as soon as reasonably practicable, any jointly proposed orders governing disclosure of confidential information and/or electronic discovery. Any proposed protective order shall set forth (i) the basis for a finding of good cause for issuance of a protective order; and (ii) the procedure for filing under seal documents containing protected information in accordance with Section V.G. of the court's Electronic Case Filing Administrative Policies and Procedures Manual, which is available on the court's website at http://www.nced.uscourts.gov/pdfs/cmecfPolicyManual.pdf.

D. Discovery Limitations

Unless otherwise agreed by the parties or ordered by the court, the following discovery limitations shall apply:

1. No party shall serve more than twenty-five (25) interrogatories, including discrete subparts, to any other party, except that each party shall be permitted to serve up to an additional five (5) interrogatories for the sole purpose of identifying proper custodians, proper search terms, and proper timeframes for separate email production requests.

2. No party shall serve more than fifty (50) requests for admission to any other party, except that there shall be no limit as to the number of requests for admission posed for the sole purpose of the authentication of documents.

3. Each Rule 30(b)(1) deposition shall be limited to seven (7) hours in duration.

4. Depositions of witnesses by a party pursuant to Rule 30(b)(1) and 30(b)(6) shall not exceed a total of eighty (80) hours, inclusive of one deposition per party to identify proper custodians, proper search terms, and proper timeframes for email production requests.

5. There shall be no limit to the number of requests for production of documents.

E. Supplementation

Supplementation must be made promptly after receipt of the supplementary information by a party or its counsel in accordance with Fed. R. Civ. P. 26(e).

F. Modification of Discovery Deadlines or Procedures

Pursuant to Rule 29 of the Federal Rules of Civil Procedure, the parties need not seek court approval of any agreements modifying the procedures or deadlines for discovery, except that the parties must obtain court approval of any agreement that would interfere with the time set for completion of discovery, for hearing of a motion, or for trial.

G. Discovery Disputes

Prior to the filing of any motion concerning discovery, the parties shall meet and confer, *in person or by telephone*, in an attempt to resolve any disputed issues including, without limitation, the scope or proportionality of requested discovery and any claim of privilege or need for a protective order. In the event the parties are unable to resolve any

disputes through the meet-and- confer process, the parties shall request a discovery conference with the undersigned by filing a joint motion with the court advising the court of the general nature of any disputes, the efforts taken to resolve such disputes, and the need for the court's involvement in resolving any such disputes.

Upon the court's receipt of a request for discovery conference, the court may direct the parties to submit short letter briefs or a joint report outlining the parties' respective positions and may hold a telephone or in-person discovery conference. Alternatively, the court may direct any party seeking relief to file a discovery motion.

II. Alternative Dispute Resolution

A. Mediation

This action has been selected for mediation pursuant to the court's Alternative Dispute Resolution Rules, Local Civil Rules 101-101.3, E.D.N.C. If the parties are able to agree on a mediator, they shall file a statement identifying the selected mediator and meeting the other applicable requirements within twenty-one (21) days after entry of this Order, in accordance with Local Civil Rule 101.lc(a). If a statement is not timely filed, the Clerk will appoint a mediator from the list of court-certified mediators, in accordance with Local Civil Rule 101.1c(b). An initial mediated settlement conference shall be conducted by June 17, 2019, and mediation shall be

concluded within sixty-five (65) days following entry of the claim construction order.

B. Other Settlement Assistance

The parties may request the court's assistance with settlement negotiations or other alternative dispute resolution, such as a court-hosted settlement conference or summary jury trial, by making available a judge other than the trial judge to explore these possibilities.

C. Notification of Settlement

The parties shall promptly notify the court of any settlement reached in the case.

III. Non-final Pretrial Conferences

Due to the complex nature of this case, the court finds that efficient case administration will be facilitated by conducting non-final pretrial conferences on a regular basis

to address matters that may arise during the course of the litigation. Five days prior to any such status conference, the parties shall confer and jointly submit a report outlining (i) any discovery disputes, scheduling issues or other matters the parties desire to have addressed at the pretrial conference; (ii) the parties' respective positions with regard to such matters; and (iii) the efforts made to resolve any disputes without court intervention. In the event there are no outstanding disputed issues, the parties may jointly request a telephonic status/scheduling conference in lieu of an in-person, Rule 16 pretrial conference by filing with the court a joint motion at least two business days prior to the scheduled conference.

IV. Motions & Pretrial Deadlines

A. Joinder/Amendment

Any motion for leave to join additional parties or to amend pleadings must be made promptly after the information giving rise to the motion becomes known and in no event later than May 27, 2019.

B. Dispositive Motions

All potentially dispositive motions shall be filed within thirty (30) days of the close of expert discovery.

C. *Daubert* Motions

All motions to exclude testimony of expert witnesses pursuant to Fed. R. Evid. 702, 703, or 705, *Daubert v Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993), *Kumho Tire Co. v. Carmichael*,

526 U.S. 137 (1999), or similar case law shall be

filed within thirty (30) days of the close of expert discovery.

D. Claim Construction & Other Deadlines

Subject to further order of the court, the following deadlines shall apply in this case:

ACTION	DEADLINE
Rule 26(a)(1) Initial Disclosures	January 4, 2019
Statement of Parties' Selection of Mediator (LR	January 17, 2019
Disclosure of Asserted Claims & Preliminary Infringement Contentions	January 25, 2019
Preliminary Invalidity Contentions and associated document production (LR	March 11, 2019
Non-final Pretrial Conference with the	**March 13, 2019 at 11:00 a.m.**
Exchange of Proposed Terms and Claim	April 1, 2019

Exchange of Preliminary Claim Constructions and Extrinsic Evidence (LR	April 22, 2019
Joint Claim Construction Statement (LR 304.3)	May 10, 2019

Non-final Pretrial Conference with the	**May 21, 2019 at 11:00 a.m.**
Motions to Join Additional Parties or to Amend Pleadings	May 27, 2019
Completion of Claim Construction Discovery (LR 304.4)	June 10, 2019
Initial Mediated Settlement Conference	June 17, 2019
Opening Claim Construction Briefs (LR	June 24, 2019
Responsive Claim Construction Briefs (LR	July 15, 2019
Exchange of Privilege Logs	7 days before deposition to which documents are applicable and in no

Non-final Pretrial Conference with the Court in preparation	**August 6, 2019 at 11:00 a.m.**
Claim Construction Hearing (if necessary)	**August 27, 2019, at 10:00 a.m.**
Final Infringement Contentions (LR 303.6(a))	30 days following entry of claim
Final Invalidity Contentions (LR 303.6(b))	50 days following entry of claim
Conclusion of Mediation	65 days following entry of claim
Post-Claim Construction	**TBD (approximately 15 days after mediation**
Disclosure of Opinions of	30 days prior to fact
Fact Discovery Closes	120 days following entry of claim
Initial Expert Disclosures by Party Bearing Burden	30 days after close of fact discovery
Expert Disclosures Where Opposing Party Bears	30 days after service of initial expert disclosures

Rebuttal Expert Disclosures (LR 305.1(d))	14 days after service of expert disclosures
Expert Discovery Closes (LR 305.2)	Within 37 days of rebuttal expert
Dispositive Motions & *Daubert* Motions (LR	30 days after close of expert discovery
Rule 26(a)(3) Pretrial	28 days before the final
Objections to Pretrial Disclosures (LR 16.1b)	21 days before the final pretrial conference
Proposed Final Pretrial	7 days prior to the final

Final Pretrial Conference (LR 16.1) & Motions Hearing	To be set by separate scheduling order following the post-claim

V. Other Matters

The parties are reminded that on consent of all parties, and with the concurrence of the District Judge, this case may be referred to a

Magistrate Judge for trial with a peremptory trial setting and the right of direct appeal to the Fourth Circuit. Should the parties desire to have this case heard by a Magistrate Judge, they should complete and file in CM/ECF a Consent and Reference to Magistrate Judge form. A copy of the form may be obtained from the clerk or downloaded at http://www.uscourts.gov/forms/civil-forms/notice-consent-and-reference-civil-action-magistrate-judge.

This 27th day of December 2018.

KIMBERLY A. SWANK
United States Magistrate Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH
CAROLINA EASTERN DIVISION
No. 4:18-CV-9-BO

TRUDELL MEDICAL INTERNATIONAL, Plaintiff, v. D R BURTON HEALTHCARE, LLC, Defendant.	)))))))	 ORDER

This cause comes before the Court on the parties' joint motion to extend the mediation deadline. [DE 226]. A hearing was held on the matter before the undersigned on August 24, 2022, at Raleigh, North Carolina. For the reasons discussed at the hearing, the scheduling order in this matter is AMENDED as follows:

- All discovery shall close on September 30, 2022;

- Dispositive motions must be filed not later than October 10,2022;

- Responses to dispositive motions must be filed not later than October 21, 2022;

- Replies to dispositive motions must be filed not later than October 26,2022;

- The jury trial in this matter shall commence on Monday, November 7, 2022, at 10:00 a.m. at the United States Courthouse at Elizabeth City, North Carolina; and

- The parties are free to mediate at any time with a mediator of their choosing.

In light of the foregoing, the parties' motion to extend the mediation deadline [DE 226] is DENIED AS MOOT.

SO ORDERED, this 26th day of August 2022.

s/TERRENCE W. BOYLE /
UNITED STATES DISTRICT JUDGE

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

TRUDELL MEDICAL INTERNATIONAL INC.,
Plaintiff-Appellant

v.

D R BURTON HEALTHCARE, LLC,
Defendant/Counter-Claimant-Cross-Appellant

2023-1777, 2023-1779

Appeals from the United States District Court for the Eastern District of North Carolina in No. 4:18-cv-00009- BO, Judge Terrence William Boyle.

ON PETITION FOR PANEL REHEARING

Before MOORE, *Chief Judge*, CHEN and STOLL, *Circuit Judges*.

PER CURIAM.

O R D E R

D R Burton Healthcare, LLC filed a petition for panel rehearing.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

FOR THE COURT

Jarrett B. Perlow
Clerk of Court

April 1, 2025
Date