Appeal No. 2021-1864

In the United States Court of Appeals for the Federal Circuit

NIAZI LICENSING CORPORATION,

Plaintiff-Appellant,

v.

ST. JUDE MEDICAL S.C., INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the District of Minnesota, No. 0:17-cv-05096-WMW-BRT.
The Honorable **Wilhelmina M. Wright**, Judge Presiding.

CORRECTED BRIEF OF DEFENDANT-APPELLEE ST. JUDE MEDICAL S.C., INC.

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Claim 1. A double catheter, comprising:

an outer, resilient catheter having shape memory and a hook shaped distal end configured for cannulation of the coronary sinus with at least one curved bend;

an inner, pliable catheter slidably disposed in the outer catheter and of greater length than the outer catheter so that a distal end portion of the inner catheter can be extended or retracted from a distal end opening of the outer catheter to vary the overall length of the double catheter, the inner catheter having an internal lumen configured for the introduction of contrast media and a pacing lead into the coronary sinus; and

a mechanism operable from the proximal end of the outer catheter for changing the curvature of the distal end of the outer catheter.

Claim 11. A method for placing an electrical lead in a lateral branch of a coronary sinus vein using a double catheter including an outer catheter and an inner catheter slidably disposed inside the outer catheter, comprising:

inserting the catheter into the coronary sinus;

advancing a guide wire through the catheter into a coronary sinus lateral branch vein;

advancing the inner catheter out of a front end opening of the outer catheter along the guide wire into the branch vein;

inserting the lead through the outer and inner catheters to a target location in the branch vein; and

withdrawing the catheter leaving the lead in the branch vein.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2021-1864

Short Case Caption Niazi Licensing Corporation v. St. Jude Medical S.C., Inc.

Filing Party/Entity St. Jude Medical S.C., Inc.

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1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
St. Jude Medical S.C., Inc.		Abbott Laboratories (NYSE:ABT)
		St. Jude Medical, LLC

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TABLE OF CONTENTS

Certificate of Interest i

Table of Contents iv

Table of Authorities vii

Statement of Related Cases 1

Statement of the Issues 1

Statement of the Case 3

I. U.S. Patent 6,638,268 (The '268 Patent) 3

II. The Accused St. Jude Products 5

III. Procedural History 6

A. Pre-*Markman* Practice 6

B. The Court's Claim Construction Efforts 8

C. Post-*Markman* Motion Practice 11

D. Summary Judgment 12

Summary of the Argument 15

Argument 18

I. "Pliable" And "Resilient" Are Indefinite In Light Of The Intrinsic And Extrinsic Record. 18

A. The Terms "Outer, Resilient Catheter" and "Resilient Tube" Are Indefinite. 20

1. The intrinsic record lacks objective guidance to determine the scope of resiliency. 21

2. Extrinsic evidence, including St. Jude's Expert and NLC's proposed constructions,

confirms that "resilient" is ambiguous, lacks a benchmark, and is used inconsistently..... 23

3. The authorities upon which NLC relies address different contexts and cannot render "resilient" sufficiently definite in the patent at issue. 26

B. The Term "Inner, Pliable Catheter" Is Also Indefinite. 28

1. The intrinsic record shows that "pliable" is used ambiguously and inconsistently and is therefore indefinite. 28

2. The extrinsic record confirms that a POSA cannot determine whether a component is sufficiently "pliable" to fall within the scope of the claims. 30

II. No Evidence Supports NLC's Induced Infringement Claim. 34

A. NLC Waived Any Challenge To the District Court's Findings Regarding Knowledge and Intent. 35

B. Summary Judgment Was Appropriate Because NLC Lacks Evidence of Direct Infringement. 37

1. Step 1 — "Inserting the [double] catheter into the coronary sinus"..... 39

a) The Court's Reading Of St. Jude's IFU Is Not Challenged And Should Not Be Disturbed. 39

b) The Court Did Not Construe "Inserting" During Summary

Judgment And NLC Waived Any Argument Thereto. 40

2. Step 2 — "Advancing a guidewire through the [double] catheter into a coronary sinus lateral branch vein" 44

a) The District Court's Factual Findings Are Proper and Warrant Affirmance. 45

b) The District Court Did Not Construe "Advancing" During Summary Judgment and NLC Waived Any Argument Thereto. 47

3. Step 3 — "Advancing the inner catheter out of a front end opening of the outer catheter along the guidewire into the branch vein" 49

a) The District Court's Factual Findings Are Proper and Warrant Affirmance. 49

b) The District Court Did Not Construe "Advancing" During Summary Judgment and NLC Waived Any Argument Thereto. 52

4. Step 5 — "Withdrawing the [double] catheter" 54

III. The District Court Did Not Abuse Its Discretion By Excluding Untimely Disclosed Evidence. 56

IV. The District Court Did Not Abuse Its Discretion By Excluding NLC's Damages Expert's Royalty Base Testimony. 67

Conclusion 71

TABLE OF AUTHORITIES

Page(s)

Cases

A. Schulman, Inc. v. Polyone Corp., Inc.,
No. 1:15 CV 1760, 2017 WL 2805857 (N.D. Ohio Apr. 27, 2017), *aff'd sub nom. A. Schulman, Inc. v. Polyone Corp.*, 712 Fed. Appx. 1007 (Fed. Cir. 2018) 22

Absolute Software, Inc. v. Stealth Signal, Inc.,
659 F.3d 1121 (Fed. Cir. 2011) 34

Application of Lechene,
277 F.2d 173 (C.C.P.A. 1960) 22, 25

Becton Dickinson & Co. v. C.R. Bard, Inc.,
922 F.2d 792 (Fed. Cir. 1990) 36, 37

Berkheimer v. HP Inc.,
881 F.3d 1360 (Fed. Cir. 2018) 30

Bicon, Inc. v. Straumann Co.,
441 F.3d 945 (Fed. Cir. 2006) 26

Bio-Rad Labs., Inc. v. ITC,
998 F.3d 1320 (Fed. Cir. 2021) 35

Biosig Inst., Inc. v. Nautilus, Inc.,
783 F.3d 1374 (Fed. Cir. 2015) 22

Cablz, Inc. v. Chums, Inc.,
708 Fed. Appx. 1006 (Fed. Cir. 2017) 27

CSIRO v. Cisco Sys.,
809 F.3d 1295 (Fed. Cir. 2015) 67

Deere & Co. v. Bush Hog, LLC,
703 F.3d 1349 (Fed. Cir. 2012) 53

Dillion v. Nissan Motor Co.,
986 F.2d 263 (8th Cir. 1993) 57

E-Pass Techs. Inc. v. Com Corp.,
473 F.3d 1213 (Fed. Cir. 2007) 55, 56

Excel Corp. v. Bosley,
165 F.3d 635 (8th Cir. 1999) 67

Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp., LLC,
879 F.3d 1332 (Fed. Cir. 2018) 70, 71

GE Lighting Sols., LLC v. Lights of Am. Inc.,
663 Fed. Appx. 938 (Fed. Cir. 2016) 22

Global-Tech Appliances, Inc. v. SEB S.A.,
563 U.S. 754 (2011) 35

Interactive Gift Express, Inc. v. CompuServe Inc.,
256 F.3d 1323 (Fed. Cir. 2001) 42, 47, 52

Interval Licensing LLC v. AOL, Inc.,
766 F.3d 1365 (Fed. Cir. 2014) 19

LaserDynamics, Inc. v. Quanta Comput., Inc.,
694 F.3d 51 (Fed. Cir. 2012) 69

Level Sleep LLC v. Sleep No. Corp.,
__ Fed. Appx. __, 2021 WL 2934816 (Fed. Cir. 2021) 44, 45

Limelight Networks, Inc. v. Akamai Techs.,
572 U.S. 915 (2014) 38, 40, 41

Lucent Techs., Inc. v. Gateway, Inc.,
580 F.3d 1301 (Fed. Cir. 2009) 38, 68

Mantech Envtl. Corp. v. Hudson Envtl. Servs., Inc.,
152 F.3d 1368 (Fed. Cir. 1998) 41

MBO Labs., Inc. v. Becton, Dickinson & Co.,
474 F.3d 1323 (Fed. Cir. 2007) 32

Mirror Worlds, LLC v. Apple Inc.,
692 F.3d 1351 (Fed. Cir. 2012) 56

Nautilus, Inc. v. Biosig Instruments, Inc.,
572 U.S. 898 (2014) 1, 15, 19

O2 Micro Int'l, Ltd. v. Monolithic Power Sys.,
467 F.3d 1355 (Fed. Cir. 2006) 66

Pac. Coast Bldg. Prod., Inc. v. Certainteed Gypsum, Inc.,
No. 18-CV-00346-LHK, 2018 WL 6268880 (N.D. Cal. Nov. 29, 2018) 25, 31

Radiance Capital Receivables Eighteen, LLC v. Concannon,
920 F.3d 552 (8th Cir. 2019) 35, 38

In re Rambus,
694 F.3d 42 (Fed. Cir. 2012) 54, 55

Rawlplug Co. v. Ill. Tool Works, Inc.,
11 F.3d 1036 (Fed. Cir. 1993) 27

Riles v. Shell Exploration & Prods. Co.,
298 F.3d 1302 (Fed. Cir. 2002) 70

Rodime PLC v. Seagate Tech., Inc.,
174 F.3d 1294 (Fed. Cir. 1999) 57

SanDisk Corp. v. Memorex Prods., Inc.,
415 F.3d 1278 (Fed. Cir. 2005) 65

Sonix Tech. Co. v. Publ'ns Int'l, Ltd.,
844 F.3d 1370 (Fed. Cir. 2017) 33

SSL Servs., LLC v. Citrix Sys.,
769 F.3d 1073 (Fed. Cir. 2014) 67

Teva Pharm. USA, Inc. v. Sandoz, Inc.,
574 U.S. 318 (2015) 19, 20

Teva Pharm. USA, Inc. v. Sandoz, Inc.,
789 F.3d 1335 (Fed. Cir. 2015) 32

Transtex Inc. v. Laydon Composites Ltd.,
848 Fed. Appx. 901 (Fed. Cir. 2021) 26, 27

Trustees of Columbia Univ. in City of New York v. Symantec Corp.,
811 F.3d 1359 (Fed. Cir. 2016) 25

VirnetX, Inc. v. Cisco Sys., Inc.,
767 F.3d 1308 (Fed. Cir. 2014) 68, 69, 70

Vita-Mix Corp. v. Basic Holding, Inc.,
581 F.3d 1317 (Fed. Cir. 2009) 34

Wing Enters. v. Tricam Indus.,
829 Fed. Appx. 508 (Fed. Cir. 2020) 67

Statutes

35 U.S.C. § 112 19

Other Authorities

Rule 37(c)(1) 2, 13, 14, 61

STATEMENT OF RELATED CASES

There is no other appeal in or from the proceeding in the United States District Court for the District of Minnesota ("the district court") that gives rise to this appeal. Other than the district-court case, counsel for Defendant-Appellee St. Jude Medical S.C., Inc. ("St. Jude") is aware of no case in any court that will directly affect or be directly affected by this Court's decision in the pending appeal.

STATEMENT OF THE ISSUES

1. Under *Nautilus*, patent claims and the corresponding specification must inform a person of ordinary skill in the art ("POSA") of the scope of the claims with reasonable certainty. The claims of U.S. Patent No. 6,638,268 use the terms "resilient" and "pliable," but the specification offers no measurements or other descriptors to inform a POSA how resilient or pliable the materials must be. Did the district court correctly find these terms of degree too indefinite to meet the reasonable-certainty standard?

2. An induced infringement claim requires evidence of direct infringement, knowledge, intent, and evidence demonstrating active encouragement. NLC lacked direct evidence that St. Jude induced

infringement of the method claims, so NLC instead offered St. Jude's Instructions For Use ("IFUs") as circumstantial evidence. Those instructions, however, direct users to use the products differently from the claimed method. Did the district court correctly conclude that St. Jude never instructed, encouraged, or recommended infringement?

If the Court answers the first two issues in the affirmative, it need not address the remaining issues.

3. Rule 37(c)(1) bars a party from using information that a party fails to properly disclose. NLC issued factual disclosures well past the applicable deadlines and then sought to have its technical and damages experts rely on that information. Did the district court abuse its discretion in excluding that evidence and forbidding experts to rely on it?

4. Rule 37(c)(1) also authorizes a district court to award attorneys' fees as a sanction when a party attempts to use improperly disclosed evidence in a motion. After the district court excluded evidence because NLC failed to timely disclose it, NLC relied upon the excluded evidence to support its dispositive briefing. Did the district court abuse its discretion in awarding St. Jude its reasonable attorneys' fees for having to move to strike the court-ordered excluded evidence?

5. To be admissible, all patent damages opinions must separate the value of the infringing features from the value of all other non-patented features. NLC's damages expert admitted that he did not apportion value and therefore his royalty base reflected more than the economic footprint attributable to the method claimed. Did the district court abuse its discretion in excluding the expert's non-apportioned royalty base opinion?

STATEMENT OF THE CASE

I. U.S. Patent 6,638,268 (The '268 Patent)

The '268 patent includes apparatus and method claims covering a specific dual catheter assembly, and specific methods, for accessing the heart's coronary sinus. *See* Appx292 (7:63-8:10). At issue are apparatus claims 1 and 10, and method claims 11 and 24.[1] Claim 1 is an apparatus claim. It recites:

1. A double catheter, comprising:

[1] NLC initially asserted infringement of apparatus claims 1, 10, 13-15, 18-19, and 23 and method claims 11 and 24-27; however, its subsequent expert report limited its assertions to claims 1, 10-11, and 24. *See* Appx1493; *see also* Appx399. The Court's subsequent claim construction eliminated all but claim 11. Appx42.

> an outer, resilient catheter having shape memory and a hook shaped distal end configured for cannulation of the coronary sinus with at least one curved bend;
>
> an inner, pliable catheter slidably disposed in the outer catheter and of greater length than the outer catheter so that a distal end portion of the inner catheter can be extended or retracted from a distal end opening of the outer catheter to vary the overall length of the double catheter, the inner catheter having an internal lumen configured for the introduction of contrast media and a pacing lead into the coronary sinus; and
>
> a mechanism operable from the proximal end of the outer catheter for changing the curvature of the distal end of the outer catheter.

Appx291-292. The remaining asserted apparatus claim, claim 10, depends on claim 1.

Claims 11 and 24 are method claims that share the same steps as is relevant to the issues on appeal. Claim 24 further includes the terms found to be indefinite. For purposes of this appeal, the parties focus on claim 11:

> 11. A method for placing an electrical lead in a lateral branch of a coronary sinus vein using a double catheter including an outer catheter and an inner catheter slidably disposed inside the outer catheter, comprising:
>
> [Step 1] inserting the catheter into the coronary sinus;
>
> [Step 2] advancing a guide wire through the catheter into a coronary sinus lateral branch vein;

> [Step 3] advancing the inner catheter out of a front end opening of the outer catheter along the guide wire into the branch vein;
>
> [Step 4] inserting the lead through the outer and inner catheters to a target location in the branch vein; and
>
> [Step 5] withdrawing the catheter leaving the lead in the branch vein.

Appx292 ("Step No." added).

II. The Accused St. Jude Products

St. Jude manufactures and sells a wide variety of medical devices including electrical pacing leads, defibrillator leads, catheters, introducers, guidewires, and other surgical equipment used in cardiac-pacing procedures. *See, e.g.*, Appx1426-1427; Appx1633-1636. Indeed, St. Jude has been a pioneer in the field of coronary pacing technology for decades. Neither party contends that St. Jude itself performs the relevant medical procedures. Appx256.

NLC accused select St. Jude outer guide catheters, inner catheters, guidewires, and electrical pacing leads of infringing the asserted claims of the '268 patent. Appx1493-1494. NLC, however, does not provide these catheters as a dual-catheter system nor did it identify specific combinations of St. Jude products that allegedly constituted the claimed

dual catheter assemblies. Appx1435; Appx1439. Importantly, St. Jude manufactures a variety of catheter products, which are all sold and packaged separately, and physicians select which components to use during any given procedure. Appx776; Appx2696.

III. Procedural History

A. Pre-*Markman* Practice

NLC's Complaint alleged that St. Jude directly infringed certain apparatus claims and induced infringement of select method claims. Appx3431 (¶¶ 20-25). NLC, however, neither alleged nor identified an actual direct infringer in its induced infringement claim. *See id.* Accordingly, St. Jude moved to dismiss the complaint under Rule 12(b)(6). Appx2868. Specifically, St. Jude argued that NLC's induced infringement claim was deficient because NLC "cannot establish direct infringement by St. Jude" and alleged no facts "as to purported knowledge, intent or any other required factual prerequisites required to sustain" an induced infringement claim. Appx2869; Appx2884-2886. The district court denied St. Jude's motion, but noted that NLC's factual allegations "are not particularly comprehensive or specific." Appx2912.

NLC subsequently served its Initial Infringement Contentions, asserting infringement of '268 patent claims 1, 10-11, 13-15, 18-19, and 23-27—eight apparatus claims and five method claims. Appx1493. NLC's contentions were similarly deficient and St. Jude notified NLC of the persisting issue. *See* Appx1435; Appx1439.

St. Jude moved to strike NLC's Final Infringement Contentions, when the deficiency remained uncured, arguing that NLC's "contentions do not identify a single instance of direct infringement necessary to sustain a claim of indirect infringement." Appx2938; Appx2947-2951. Although the court denied St. Jude's motion, NLC was on notice of St. Jude's concerns. Appx32.

Before the September 13, 2019 close of fact discovery, Appx2923, NLC's Rule 26 disclosures identified only two fact witnesses: Dr. Imran Niazi and Mr. Robert Stawicki. *See* Appx447. Neither testified to having used St. Jude's accused products in an allegedly infringing manner. Indeed, NLC admitted that it "cannot point to a specific example of a physician doing it." *See, e.g.*, Appx1933 (141:13-21).

Over one month later, on October 15, NLC served its Opening Expert Report on Infringement, in which it limited the asserted claims to

claims 1, 10-11, and 24. Appx642. NLC's expert, Dr. Burke, included in his report a section titled "Evidence of Direct Infringement," wherein he alleged his unspecified past use was directly infringing. Appx666; Appx1446 (99:24-100:16). Dr. Burke claimed that he had personally used St. Jude's products and knew about various aspects of purported infringing use in the field based on various undisclosed hearsay conversations, interactions, and discussions with other electrophysiologists. *See, e.g.*, Appx666. NLC had not previously disclosed any purported direct infringement of the asserted claims.

St. Jude successfully moved to strike Dr. Burke's disclosure of purported use and discussions with others in the field as untimely. Appx376; Appx140 (95:14-109:11).

B. The Court's Claim Construction Efforts

Claim construction proceeded alongside fact and expert discovery. The parties identified 21 terms in dispute, within the 13 asserted claims. Appx2962. In connection with St. Jude's opening and responsive briefs, *see* Appx2977; Appx3436, St. Jude provided two expert declarations from its expert, Dr. Arthur Erdman to support its claim construction positions. Appx3025; Appx3137. NLC submitted no expert declarations; instead, it

offered a declaration from the named inventor, Dr. Imran Niazi. St. Jude subsequently deposed Dr. Niazi regarding claim construction.

After the parties submitted briefing materials and expert declarations, the district court held a full-day claim construction hearing. Appx3145-3394; Appx3434. The hearing covered all of the arguments for the disputed terms, including St. Jude's indefiniteness positions. *Id.* Accordingly, the parties addressed the intrinsic and extrinsic evidence, including St. Jude's expert testimony. *Id.*

The district court's claim construction order held that the terms "pliable" and "resilient" are indefinite under 35 U.S.C. § 112(b). Appx42. Specifically, the court found that the patent disclosure "does not provide a 'meaningfully precise claim scope' on its face." Appx38-42. The court further found that the '268 patent specification does "not establish objective boundaries as to the range of pliability being claimed." Appx39. NLC now appeals the court's construction of "pliable" and "resilient."

Only claim 11 survived the district court's claim construction ruling. *Id.* As to that claim, the parties' dispute consisted of two primary issues. First, the proper construction of "the catheter" as recited in the

claimed steps. Appx43-44; Appx3006-3007. Second, whether the claim must be performed in the order of steps recited. Appx44; Appx3018-3020.

As to "the catheter" in claim 11, St. Jude argued that the term was indefinite for lack of antecedent basis. Appx43. NLC contended that the term was not indefinite, but rather "the catheter" meant "the double catheter." *Id.* The district court agreed with St. Jude that the "term 'the catheter' creates a degree of ambiguity within Claim 11," because it "arguably may refer to the double, outer, or inner catheter." Appx43-44. However, the court determined that "a person with ordinary skill in the art would understand that Claim 11's reference to 'the catheter' describes the double catheter system." Appx44. NLC does not appeal this construction.

Regarding the order-of-steps dispute, the court found that "[l]ogic dictates that the inner catheter can be advanced 'along the guide wire into the branch vein' only if the guide wire has itself already been advanced through the outer catheter" and therefore "Step 3 of Claim 11 must be performed after Step 2." Appx45. Thus, the court concluded "that Claim 11 is only infringed when the steps are performed in the order listed." *Id.* NLC also does not appeal this construction.

NLC sought reconsideration of the district court's claim construction opinion only as to "pliable" and "resilient." Appx370. The district court denied NLC's request. Appx545.

C. Post-*Markman* Motion Practice

After ruling on claim construction, the court turned to St. Jude's motion to strike NLC's experts' untimely factual assertions. As set forth above, St. Jude moved to strike Dr. Burke's untimely factual disclosures, including, *inter alia*, that he himself is a direct infringer, along with other undisclosed hearsay interactions, conversations, and discussions with electrophysiologists in the field. Appx378. St. Jude also moved to strike portions of NLC's damages expert's report that relied on allegedly "comparable" licenses that were not disclosed or produced, and were otherwise unavailable for St. Jude to examine. Appx391.

After a hearing, the magistrate judge granted St. Jude's motion, striking NLC's only alleged evidence of direct infringement. Appx140-154 (95:11-109:11). NLC admitted at the hearing that it had uncovered no evidence of direct infringement during the litigation:

> And, you know, as I explained to Your Honor, you know, it's not as if we were just sitting on our hands not trying to uncover evidence of direct infringement, we were walking

> down different paths. And, you know, ***those paths were dead ends***.

Appx137 (92:20-24) (emphasis added).[2] Likewise, the magistrate judge granted St. Jude's motion to exclude NLC's untimely document production, served three weeks after NLC's expert damages report. Appx140-154 (95:11-109:11); Appx77 (32:15-22). NLC challenged these rulings, and the district court affirmed. Appx2638.

St. Jude also sought to exclude under *Daubert* NLC's damages expert's testimony as to his reasonable royalty opinion. Appx608. NLC's damages expert, Brad Carlson, failed to apportion value, and his royalty base reflected more than the economic footprint of the method in the marketplace. *Id.* The district court held a *Daubert* hearing and concluded that "Carlson's calculation of the royalty base does not comport with settled principles of apportionment and, therefore, must be excluded." Appx251.

D. Summary Judgment

The parties ultimately filed cross motions for summary judgment. Appx899; Appx1001. St. Jude sought summary judgment of non-

[2] All emphases added unless otherwise noted.

infringement of method claim 11, as well as two discrete damages issues. Appx1001. NLC moved for summary judgment of induced infringement of claim 11 and on patent validity. Appx899.

In support of its positions, NLC submitted a declaration from Dr. Burke again alleging that he had personally used St. Jude's products and basing other factual assertions upon undisclosed hearsay conversations, interactions, and discussions with other electrophysiologists. *See, e.g.*, Appx1744 (¶¶ 12, 13, 26, 36). Because these precise factual allegations had been stricken, St. Jude moved to enforce the court's prior ruling and for sanctions under Rule 37(c)(1). Appx3395.

The magistrate judge granted St. Jude's motion. After hearing arguments from both sides, she reiterated that "Dr. Burke was precluded from offering testimony of fact in this case because he was not timely disclosed as a fact witness" and determined that "the insertion of facts into the Burke declaration violates this Court's order." Appx219 (62:9-18). The court therefore struck this aspect of Dr. Burke's declaration and granted St. Jude's request for reasonable attorneys' fees stemming from NLC's violation. Appx220 (63:23-64:3). NLC again challenged the magistrate judge's decision. Appx2646. The district court affirmed,

finding that "NLC's interpretation [of the prior exclusion order] is not reasonable" and that "the imposition of sanctions against NLC for the willful violation of the December 2, 2019 Order was neither clearly erroneous nor contrary to law." Appx2653 (fn. 2). Importantly, the district court noted that "[i]n its appeal, NLC *does not dispute* that it violated the magistrate judge's December 2, 2019 Order." Appx2649.

The district court ultimately denied NLC's summary judgment motion and granted St. Jude's motion as to non-infringement. Appx270. In a fulsome opinion, the court addressed the procedural history, scope of patent claims asserted, and the specifics of the accused products. Appx253-270. NLC's positions regarding induced infringement ostensibly rested on St. Jude's Instructions For Use ("IFUs"). On that score, the court found: 1) St. Jude's IFUs were substantively different from the steps of claim 11; 2) even if St. Jude's IFUs did teach the steps of claim 11, which they do not, NLC failed to present evidence that St. Jude instructed its customers to perform those steps in the precise order as listed in claim 11; and 3) St. Jude's IFUs cannot be the basis for infringement because several steps are described as optional prefaced with language of "if desired." Appx269 (citing *HZNP Meds. LLC v.*

Actavis Labs. UT, Inc., 940 F.3d 680, 701 (Fed. Cir. 2019)). This Court should affirm.

SUMMARY OF THE ARGUMENT

The district court correctly weighed the intrinsic and extrinsic evidence to conclude that "outer, resilient catheter" and "inner, pliable catheter" are indefinite under *Nautilus* and its progeny. The court analyzed these limitations in the context of the patent as a whole, ultimately determining they fail to provide to one of ordinary skill in the art the scope of these key structural limitations with reasonable certainty. The court found that this uncertainty was clear and convincing because of the particular interactions and relationship of the claimed system, and the inconsistent record regarding the same. Appx42.

Indeed, these structures are described as having "a certain degree of stiffness," yet the inner catheter is to be "pliable" as opposed to other components, described as being constructed from the same material, that are "very pliable." Appx290-291 (4:5-6, 5:28-31). The intrinsic record provides no objective delineation between these claimed characteristics. Adding to the confusion, these catheters are further used together such that the system has certain characteristics, *e.g.*, it "maintain[s] such

shape during manipulation," while also being "flexible enough to bend when required," and each catheter has different characteristics as to the other. Appx291 (5:3-13, 5:14-27). The corresponding deficiencies caused by the ambiguous intrinsic record were confirmed through expert testimony, leading to the proper determination that these limitations are indefinite.

As to the remaining asserted claim, claim 11, the district court correctly found that the record contains insufficient evidence of direct infringement. Appx269. The court scrutinized St. Jude's IFUs but determined they do not teach infringement of the claimed method as construed. Coupled with NLC's admission that it could not identify a specific infringing instance and that its search for such evidence led to "dead ends," the district court appropriately found that the record contains insufficient evidence of direct infringement. And, the court found that NLC failed to present evidence to support the knowledge and intent prongs of an induced infringement claim. These determinations were made on factual bases for which NLC has not and cannot identify clear error by the district court. Instead, NLC improperly applies the

abuse of discretion standard ostensibly by creating nonexistent legal disputes. This Court should reject NLC's improperly raised arguments.

As to the evidentiary determinations, NLC failed to demonstrate how the district court abused its discretion in excluding admittedly untimely and highly prejudicial factual disclosures. Indeed, NLC does not dispute that such information was untimely produced. Rather, NLC's argument rests on the contention that it "acted reasonably under the circumstances." Not so. As the magistrate judge found, NLC's untimely disclosures were "inexcusable." Appx146 (101:5-6). The district court then rejected NLC's arguments on appeal because the "record supports the magistrate judge's finding that NLC was not diligent in discovery." Appx2644. Thus, NLC failed to show any abuse of discretion.

Along the same lines, the district court's subsequent award of sanctions due to NLC's use of the excluded discovery in dispositive briefing was not an abuse of discretion. NLC now appeals that determination on the basis that the exclusion order was somehow vague and ambiguous as to its scope. It was not. One thing is for certain: the magistrate judge clearly precluded NLC's expert, Dr. Burke, from testifying as a fact witness—precisely the relief St. Jude sought.

Appx140 (95:17-18). The court could not have been more clear. Again, NLC appealed the magistrate judge's determination. And again, the district court affirmed because NLC's interpretation of the exclusion order "is not reasonable" and "NLC does not dispute that it violated the magistrate judge's December 2, 2019 Order." Appx2649; Appx2653 (fn. 2).

As with nearly every issue in this appeal, NLC has filed either a request for reconsideration or has lodged an objection with the district court. Thus, nearly every issue has already twice been decided. As more fully explained below, this Court should affirm the district court's factual determinations and legal conclusions.

ARGUMENT

I. "Pliable" And "Resilient" Are Indefinite In Light Of The Intrinsic And Extrinsic Record.

The two legs upon which nearly all asserted claims seek to stand are indefinite, causing the claims to collapse. The first leg is an "inner, pliable catheter"; the second, an "outer, resilient catheter." Together, they form a system that can be negotiated within a patient's cardiovascular system as well as within one another. The intrinsic record, however, is unclear—in fact inconsistent—as to the

corresponding application of "pliable" and "resilient." Thus, a person of ordinary skill in the art does not have reasonable certainty of the scope of these key structural features of the claim when considered in context. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). This confusing intrinsic record, as St. Jude's expert corroborated, renders these terms indefinite under 35 U.S.C. § 112.

This Court reviews *de novo* the district court's claim construction determinations, including as to indefiniteness. *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1365, 1370 (Fed. Cir. 2014). But overturning the judge's resolution of an underlying factual dispute requires a showing of clear error. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326-27 (2015).

Here, the district court analyzed the terms "pliable" and "resilient" in the context of the claims and the intrinsic record as a whole, including the parties' expert testimony. Appx33-42; Appx3145.[3] All of the subsidiary factual findings are entitled to deference on appeal. *Teva Pharm.*, 574 U.S. at 332-33.

[3] NLC's contention that "the district court did not make any factual findings that underly [sic] its indefiniteness determination," Br. at 15, is incorrect.

A. The Terms "Outer, Resilient Catheter" and "Resilient Tube" Are Indefinite.

The district court correctly concluded that "resilient," as used in the context of the asserted claims, is indefinite. Appx40-42. By way of background, the outer catheter is used to traverse the cardiovascular system to ultimately lead to the coronary sinus. Appx290 (3:39-48). It thereby creates the primary pathway or tunnel into the coronary sinus. *Id.* (3:19-21). Depending on the resultant reach of the outer catheter, a physician will then determine whether there is a need for an inner catheter or guidewire, and the corresponding technique for application for ultimate introduction into the target location in the coronary sinus. *See, e.g.*, Appx291 (5:47-54, 5:63-64); Appx1455 (261:2-24). The outer catheter's physical properties, particularly in relation to the inner catheter, are critical to both functionality and safety. Appx290-291 (3:11-13, 5:3-14). The patent claims this "outer, resilient catheter" in conjunction with an "inner, pliable catheter." However, the record establishes that "outer, resilient catheter" and "inner, pliable catheter" are indefinite in this context. St. Jude begins with "outer, resilient catheter."

1. The intrinsic record lacks objective guidance to determine the scope of resiliency.

Turning first to the intrinsic record, the '268 patent lacks any objective guidance for a POSA to determine whether an outer catheter is sufficiently "resilient" to fall within or outside the scope of the claims. For example, the '268 patent specification states that the outer catheter has "stiffness necessary for manipulation … [and] safe cannulation of the coronary sinus and advancement of catheter 11 into the distal coronary sinus for purposes of support." Appx290 (3:14-22). But it specifies neither the requisite stiffness nor the parameters for allowing simultaneous manipulation and safe cannulation. Indeed, this characteristic in no way explains what is meant by "resilient," as both the "inner and outer catheters 11, 12 preferably have a predetermined shape and *a certain degree of stiffness* to maintain such shape during manipulation in the heart, but still flexible enough to bend when required." Appx290 (4:4-8).

The specification is also inconsistent. Initially, the specification provides "outer catheter 11 is made of a braided silastic or similar material to allow torque control and stiffness." Appx290 (3:11-13). But later, "[i]n one example, outer guiding catheter 51 is 2.9 mm in outer

diameter, 2.6 mm inner diameter. It is *relatively stiff* and has a braided design, which lends support and one-for-one torque control." Appx291 (5:3-6). There is no definition of "resilient" and the patent's discussion regarding stiffness ranges from "a certain degree of stiffness" to "allow torque control and stiffness" to "relatively stiff."[4]

The inner catheter exacerbates this confusion. After all, the "resiliency" must withstand the pressure of an inserted inner catheter, which necessarily affects the resiliency of the material. As such, the term "outer, resilient catheter" creates a zone of uncertainty and improperly introduces subjectivity. *See, e.g.*, *Application of Lechene*, 277 F.2d 173, 176 (C.C.P.A. 1960) (claim for "stiff, resilient" fibers too indefinite a distinction to render claim patentable over prior art where such terms were relative); *A. Schulman, Inc. v. Polyone Corp., Inc.*, No. 1:15 CV

[4] NLC argues that these are not terms of degree; St. Jude disagrees. "Resilient" is expressly addressed as "a certain degree of stiffness." Appx290 (4:4-8); *see Biosig Inst., Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1378 (Fed. Cir. 2015) (terms of degree must provide "some standard for measuring that degree" or are otherwise indefinite if the claim language fails to "provide[] enough clarity to one of skill in the art when read in the context of the invention."). Importantly, a term need not be one of degree to be indefinite. *See, e.g.*, *GE Lighting Sols., LLC v. Lights of Am. Inc.*, 663 Fed. Appx. 938, 940 (Fed. Cir. 2016) ("[e]ven if a claim term's definition can be reduced to words, the claim is still indefinite if a [POSA] cannot translate the definition into meaningfully precise claim scope.").

1760, 2017 WL 2805857, at *4 (N.D. Ohio Apr. 27, 2017), *aff'd sub nom. A. Schulman, Inc. v. Polyone Corp.*, 712 Fed. Appx. 1007 (Fed. Cir. 2018) (terms "a DOI of 70 or greater" and "a DOI of 85 or greater" indefinite because patentee failed to disclose how to measure DOI ("distinctiveness of image") when multiple methods to determine DOI existed).

2. Extrinsic evidence, including St. Jude's Expert and NLC's proposed constructions, confirms that "resilient" is ambiguous, lacks a benchmark, and is used inconsistently.

Extrinsic evidence confirms that "resilient" is indefinite. St. Jude's expert, Dr. Arthur Erdman, reviewed the intrinsic record. Dr. Erdman—the University of Minnesota's Richard C. Jordan Professor and Morse Alumni Distinguished Teaching Professor of Mechanical Engineering—concurred that this term is indefinite in this context in two expert declarations during claim construction. *See, e.g.*, Appx3026 (¶¶ 4, 19, 29); Appx3140 (¶¶ 10-12). An undisputed POSA during the relevant period, Dr. Erdman explained that resilience can be objectively measured and described, but the '268 patent simply fails to provide the corresponding delineations. *Id.*[5]

[5] In denying NLC's motion to exclude Dr. Erdman, the court found: "a POSITA, according to NLC, an 'engineer would have to have been

The extrinsic record also shows that the patent could have benchmarked resilience but failed to. For instance, the Applicant could have benchmarked resilience based on extrusion durometer (hardness) and/or braid "picks per inch" (PPI) in the recommended material. Appx3030 (¶¶ 24-25). Or, at the scientific level, as a range within Young's modulus or the modulus of resilience. *Id.* But the '268 patent offers no corresponding benchmark, leaving a POSA unable to determine whether a catheter is adequately "resilient" within the "certain degree of stiffness" required so as to be "relatively stiff" (*e.g.,* to allow "torque control" and yet allow "manipulation … [and] safe cannulation of the coronary sinus and advancement of catheter 11 into the distal coronary sinus"). *Id*.

NLC's own proposed construction confirms that "resilient" is indefinite. NLC asserts that "outer, resilient catheter" means a "catheter that is able to return to its original shape when undistorted." Br. at 23. That construction is unworkable; it merely swaps an ambiguous term,

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familiar with the anatomy of the coronary sinus of a normal heart, as understood at the time, as well as with the then existing procedures conducted within the coronary sinus by electrophysiologists'" and that "NLC identifies no evidence that, as a biomedical engineer, Dr. Erdman is not qualified in the relevant art." Appx234.

"resilient," for an ambiguous phrase. *See* Appx3140 (¶¶ 11-12). NLC's construction provides no basis or parameters as to, for example, the margin of error on return (1%, 10%, 25%), or the conditions for this characteristic (in the body, with an inner catheter, etc.). That NLC, as plaintiff, cannot offer a workable construction, is telling. *See, e.g.*, *Lechene*, 277 F.2d at 176; *Pac. Coast Bldg. Prod., Inc. v. Certainteed Gypsum, Inc.*, No. 18-CV-00346-LHK, 2018 WL 6268880, at *12 (N.D. Cal. Nov. 29, 2018) (finding "scored flexible strength" indefinite where patentee failed to inform one of skill in the art with reasonable certainty of the term's scope).

NLC's construction of another term further shows that "resilient" is indefinite at best, and impermissibly redundant at worst. Claim 1 recites an "outer, resilient catheter having shape memory." Appx291 (6:63). Thus, the outer catheter must be both resilient and have shape memory. NLC argues that "shape memory" means "able to return to its original shape when undistorted." Appx2963. But its construction for "resilient" is the same. Br. at 23. NLC's position thereby impermissibly renders "resilient" redundant. Appx2963; Appx3140 (¶¶ 11-12); *Trustees of Columbia Univ. in City of New York v. Symantec Corp.*, 811 F.3d 1359,

1366 (Fed. Cir. 2016) ("byte sequence feature" could not be construed to have the same meaning as the claim term "feature"); *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 951 (Fed. Cir. 2006) (reading term out of a claim would violate the principle that claim language should not be treated as meaningless).

The district court considered all of this evidence and determined that "the term 'resilient' does not, on its face, provide clear notice of the scope of the claim." Appx41. The district court then turned to the specification but further found that it "fails to provide objective criteria for measuring resilience" and that "the example of a 'braided silastic or similar material' does not provide meaningful notice to the public." *Id.* Accordingly, the court correctly found that the term "'resilient'—as used in the terms 'outer, resilient catheter' and 'resilient tube'—renders the claims in which it is found indefinite." Appx42. This Court should affirm.

3. The authorities upon which NLC relies address different contexts and cannot render "resilient" sufficiently definite in the patent at issue.

NLC's cited cases regarding the term "resilient" do not suggest that the '268 patent sufficiently informs a POSA of the scope of the term "resilient"—in the context of the asserted claims—and with reasonable

certainty. For example, the *Transtex* case originated from a PTAB decision regarding an obviousness determination. *Transtex Inc. v. Laydon Composites Ltd.*, 848 Fed. Appx. 901 (Fed. Cir. 2021). Indefiniteness was not an issue; instead, this Court simply affirmed the Board's determination that the prior art disclosed "the use of a resilient material that can be collapsed and then resume its original configuration." *Id.* at 908.

Cablz and *Rawlplug* fare no better. *Cablz* also originated from a PTAB decision regarding an obviousness determination. *Cablz, Inc. v. Chums, Inc.*, 708 Fed. Appx. 1006, 1010 (Fed. Cir. 2017). This Court affirmed the Board's determination, specifically noting that the patentee "in numerous other places, admitted that [the prior art's disclosure] was 'resilient.'" *Id.* at 1012. Likewise, *Rawlplug* had nothing to do with the definiteness of "resilient" as used in the asserted patent, nor anything remotely related to the issue at hand. *Rawlplug Co. v. Ill. Tool Works, Inc.*, 11 F.3d 1036, 1037 (Fed. Cir. 1993). Indeed, none of these cases warrant reversing the district court's ruling. The issue is "resilient" in the context of the claimed invention of the '268 patent, and, in context, the term is indefinite.

B. The Term "Inner, Pliable Catheter" Is Also Indefinite.

Just as the catheters form a layered system, the patent layers one indefinite term upon another. The relevant system also includes an "inner, pliable catheter." The inner catheter sits inside of and is "slidably disposed" within the "outer, resilient" catheter and also has certain claimed physical attributes. Appx291 (5:12-27). Again, the intrinsic record fails to inform a POSA about the scope of this limitation with reasonable certainty, considered in the context of the claimed system as a whole.

1. The intrinsic record shows that "pliable" is used ambiguously and inconsistently and is therefore indefinite.

The intrinsic record shows that "inner, pliable catheter" is indefinite. The specification describes the phrase ambiguously and inconsistently. For example, the inner catheter is "made of soft, pliable material such as silicone." Appx290 (3:13-15). Later, the specification states that the inner catheter has "no longitudinal braiding, which makes it *extremely flexible* and able to conform to various shapes."[6] Appx290-291 (3:13-15, 5:14-18). The specification goes on to describe another

[6] This again demonstrates that "pliable" is used as a term of degree. But whether or not it is so categorized is not dispositive as NLC suggests.

component, the "[o]bturator 53" as "preferably made of *very pliable* silicone." Appx291 (5:29). Yet silicone, recall, is the same material suggested for the inner catheter. Appx290 (3:12-15). Thus, the patent describes "pliable" as "extremely flexible," which apparently is distinct from "very pliable." Likewise, the lone example of the inner catheter fails to provide any specifics: "[i]nner guiding catheter 52 … in this example is 2.6 mm in outer diameter and 2.3 mm in inner diameter." Appx291 (5:14-16). This description says nothing of the material or its relative characteristics or any method of measurement.

Compounding the conundrum, the specification says that the catheters are both stiff and flexible: "inner and outer catheters 11, 12 preferably have a predetermined shape and a certain degree of stiffness to maintain such shape during manipulation in the heart, but [are] still flexible enough to bend when required." Appx290 (4:4-8). Thus, if "resilient," "pliable but not very pliable," and "extremely flexible" were not confusing enough, the system when combined must exhibit a certain flexibility, while maintaining stiffness. But the intrinsic record offers no parameters, benchmarks, and no basis to determine the metes and bounds of these descriptions.

Because the boundaries of these claimed characteristics cannot be gleaned from the intrinsic record with any specificity or objective measure, the term "pliable" is indefinite. Appx3032 (¶¶ 27-29); *see Berkheimer v. HP Inc.*, 881 F.3d 1360, 1363 (Fed. Cir. 2018) (holding "archive exhibits minimal redundancy" indefinite where intrinsic evidence "contains no point of comparison for skilled artisans to determine an objective boundary of 'minimal'" and expert provided uncontested testimony that a POSA would not understand the meaning of such term).

2. The extrinsic record confirms that a POSA cannot determine whether a component is sufficiently "pliable" to fall within the scope of the claims.

The extrinsic evidence also shows that "pliable" is indefinite. St. Jude's expert opined that the '268 patent's specification lacks the requisite specificity for a POSA to determine whether a catheter component (e.g., inner catheter, obturator, or dilator) falls within the scope. Appx3032 (¶¶ 27-29). As Dr. Erdman opined, "stiffness and softness are subjective terms and there can be a wide range of opinion as to what falls inside or outside of these terms." *Id.* (¶ 28). Accordingly, Dr. Erdman opined that:

- "[w]ithout specific guidance as to the meaning of … 'inner, pliable catheter,' one of ordinary skill in the art would lack a fundamental understanding of how to construct a device that falls within or outside the scope of the '268 patent" and

- "practicing the claims of the '268 patent would force [a POSA] to engage in an onerous and ultimately futile exercise of trial and error to design a double catheter which ultimately may or may not fall within the scope of the 'outer, resilient catheter' and the 'inner, pliable catheter.'" *Id.* (¶ 29).

NLC offers no evidence in response. Instead, it rests on attorney argument regarding what a POSA "could readily determine," but that argument misses the mark. Br. at 16, 19. Indeed, NLC cites no support for the proposition that a POSA "could readily determine what materials are and are not sufficiently bendable for this purpose." *Id.* Thus, Dr. Erdman's expert opinion testimony remains unchallenged.

NLC's proposed construction, again, leaves no doubt that this term is indefinite. NLC proposes "easily bent, flexible." Br. at 16. "Easily bent" is itself a term of degree with endless interpretations—easy to bend when made, when used in the patient, when used outside the patient, by a hand, by a certain instrument, etc. This construction offers a POSA no guidance to discern the term's scope, which could be measured in many ways, each of which would result in a different flexibility score. *Certainteed*, 2018 WL 6268880, at *12 ("scored flexible strength"

indefinite); *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1344 (Fed. Cir. 2015) ("molecular weight" indefinite because term could be measured in several ways but patent failed to teach a POSA which method to use).

Further, the specification provides that in at least one embodiment, the inner catheter must be "extremely flexible." If the standard for the term is "flexible," then arguably "extremely flexible" is outside the scope of the claim. A construction that excludes an embodiment is improper. *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007) ("[a] claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct.").

NLC's resort to extrinsic evidence such as the Lurie '107 and Toner '960 patents cannot save these uncertain and unclear terms. Aside from being irrelevant to *the '268 patent's* disclosure, these patents do not even use the term "pliable" in the claims. Nor do they contain additional purportedly counter-opposite terms in the claims, which compounds the confusion and uncertainty. Indeed, the district court considered these disclosures and assigned little weight to NLC's reference to such extrinsic evidence. Appx42 (fn. 5).

NLC's reliance on *Sonix* is also misplaced. In *Sonix*, this Court found probative that the "Appellees themselves did not question the clarity of 'visually negligible' in the first several years of litigation supports the conclusion that the term could be understood with reasonable clarity." *Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1380 (Fed. Cir. 2017). No such similar facts exist here; St. Jude has always maintained the position that "resilient" and "pliable," as used in this context, and in light of the '268 patent's specification, are indefinite. Appx2966.

The district court therefore correctly determined that "'inner, pliable catheter,' does not provide a 'meaningfully precise claim scope' on its face." Appx39 (citing *Halliburton Energy*, 514 F.3d at 1251). After reviewing the '268 patent's specification, the district court concluded that the "descriptors do not establish objective boundaries as to the range of pliability being claimed" and that "the specification creates a 'zone of uncertainty.'" Appx39. As the district court further recognized, "[a]lthough the specification includes an example—a silicone catheter that is 2.6 mm in outer diameter and 2.3 mm in inner diameter—this one

example does not clarify the *scope* of what the '268 Patent claims as the 'inner, pliable catheter.'" Appx39-40 (emphasis in original).

The voluminous intrinsic record and uncontested extrinsic record both support the district court's indefiniteness finding for the terms "pliable" and "resilient." The district court correctly analyzed the terms in the context of the claims, properly consulted the '268 patent's specification for any additional guidance, and thoroughly considered the expert evidence. The Court should affirm.

II. No Evidence Supports NLC's Induced Infringement Claim.

NLC also appeals the district court's grant of summary judgment on NLC's induced infringement claim. The Court reviews summary judgment decisions *de novo*. *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1323 (Fed. Cir. 2009). Summary judgment of non-infringement is appropriate if, after resolving all reasonable factual inferences in favor of the patentee, "no reasonable jury could find infringement." *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1130 (Fed. Cir. 2011). The Eighth Circuit "review[s] the district court's factual findings for clear error and its legal conclusions de novo."

Radiance Capital Receivables Eighteen, LLC v. Concannon, 920 F.3d 552, 559 (8th Cir. 2019).

NLC alone bears the burden of establishing induced infringement. To that end, NLC must establish: "proof of underlying direct infringement, as well as proof that (1) the defendant knew of the patent, (2) the defendant knew or should have known that the induced acts constitute patent infringement, and (3) the defendant possessed specific intent to encourage another's infringement." *Bio-Rad Labs., Inc. v. ITC*, 998 F.3d 1320, 1335 (Fed. Cir. 2021). The district court correctly found no genuine issue of material fact regarding any of these elements. Appx269-270. To succeed here, NLC must identify a genuine issue of material fact regarding all four. NLC cannot meet that burden.

A. NLC Waived Any Challenge To the District Court's Findings Regarding Knowledge and Intent.

NLC has waived any challenge to two elements of its induced infringement claim, thus requiring the Court to affirm. Two elements of induced infringement are (a) knowledge of the patent and (b) intent to encourage infringement. *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 765-66 (2011). To support these elements, NLC asked the

district court to draw inferences from St. Jude's IFUs.[7] The district court scrutinized those instructions and concluded that NLC's position lacked merit on three separate and independent bases. Importantly, NLC does not appeal that decision, so the Court should affirm. *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 800 (Fed. Cir. 1990) ("An issue not raised by an appellant in its opening brief . . . is waived.").

Even if the Court reviews the district court's decision on the merits, it should affirm. St. Jude sought summary judgment of no infringement because NLC offered no evidence of knowledge and intent of the asserted patent or corresponding infringement of the method claim. The district court recognized that (1) the dispute centered on "whether NLC has presented evidence of St. Jude's specific intent to encourage infringement" and (2) NLC's only evidence was St. Jude's IFUs, which NLC offered as circumstantial evidence of intent to induce infringement. Appx268 (citing *Global-Tech*, 563 U.S. 765-66; *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006)).

[7] NLC's Final Invalidity Contentions were based off *different* IFUs (with the claimed steps out of order) from what it would later rely on in dispositive briefing and expert reports (also out of order). *See* Appx1520; Appx642.

The district court concluded that St. Jude's IFUs "do not encourage, recommend, or promote infringement for at least three reasons." Appx269. Namely:

1. The IFUs differ from the patented method's steps in multiple ways.

2. NLC offered no evidence that St. Jude instructed customers to perform the steps in the order listed in Claim 11 of the '268 Patent.

3. Several of the IFUs' steps were optional.

Id. NLC offers no challenge—either factual or legal—to these findings, so the Court should affirm the no-induced infringement determination.

B. Summary Judgment Was Appropriate Because NLC Lacks Evidence of Direct Infringement.

Even if NLC had not waived its challenge to the district court's determination on knowledge and intent, but instead established clear error, affirming the district court would still be appropriate. That is because no genuine issue of material fact exists regarding direct infringement. Appx267. Specifically, NLC challenges the district court's finding that St. Jude's IFUs do not constitute circumstantial evidence of

direct infringement.[8] This Court reviews the district court's factual findings for clear error, not *de novo*, as NLC suggests. *Radiance Capital Receivables Eighteen, LLC v. Concannon*, 920 F.3d 552, 559 (8th Cir. 2019).

Direct infringement—evidence of "performance of all the claimed steps [] attributed to a single person"—is a prerequisite to induced infringement. *Limelight Networks, Inc. v. Akamai Techs.*, 572 U.S. 915, 923 (2014); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009); *see Limelight Networks*, 572 U.S. at 922 ("[W]here there has been no direct infringement, there can be no inducement of infringement under § 271(b)."). After fact discovery closed, NLC admitted that it had tried, but failed, "to uncover evidence of direct infringement," because each attempt was a "dead end[]." Appx137 (92:20-24); *see also* Appx1933 (141:13-21) (NLC admitting it *"cannot point to a specific example of a physician doing it."*). NLC therefore anchored its case on St. Jude's IFUs, which it offered as circumstantial evidence of direct infringement.

[8] NLC does not challenge the district court's finding that NLC failed to provide direct evidence of direct infringement, again waiving any such challenge.

Appx260. The district court's decision to reject that argument, Appx267, was not clear error. Instead, it was proper.

To succeed on appeal, NLC must show that the district court clearly erred in finding each of the five steps in St. Jude's IFUs to be distinct from claim 11's five steps. As explained below, NLC cannot clear these five hurdles.

1. Step 1 — "Inserting the [double] catheter into the coronary sinus"

The district court compared claim 11's first step, as construed, against St. Jude's IFUs. Appx262.[9] The district court concluded that St. Jude's IFUs do not teach this step. *Id*. The district court's conclusion is not clearly erroneous.

a) The Court's Reading Of St. Jude's IFU Is Not Challenged And Should Not Be Disturbed.

The district court began with the IFUs' plain language, determining that they do not include a step for inserting the double catheter. Rather, the district court rightly recognized that St. Jude's IFUs teach away from

[9] As explained above, the district court adopted NLC's construction that "the catheter" means "the double catheter." Accordingly, the district court concluded this first step requires "inserting the [double] catheter into the coronary sinus." Appx44.

this step because before teaching introduction of the inner catheter, St. Jude's written instructions direct users to "[f]ollow normal accepted practice for … outer guide catheter insertion." Appx262; Appx2314. In other words, St. Jude's IFUs disclose that the outer guide catheter is first inserted into the coronary sinus and the inner catheter is later inserted, as opposed to "inserting the [double] catheter into the coronary sinus." Appx262. The district court thus concluded that St. Jude's IFUs are "inconsistent with the claimed method as construed by the Court." *Id*. NLC does not challenge this factual finding, so this Court should affirm.

b) The Court Did Not Construe "Inserting" During Summary Judgment And NLC Waived Any Argument Thereto.

Rather than challenge the district court's factual conclusion regarding this step, NLC instead incorrectly attacks the analysis as latent claim construction, ostensibly to seek *de novo* review. While confusing, NLC appears to suggest the district court improperly construed "the catheter" and the order of steps, as it relates to the term "inserting." The Court should reject NLC's attempt to manufacture a legal issue where none exists.

The parties disputed the construction of the term "the catheter" as recited in claim 11 during the claim construction phase. Appx43. St. Jude argued that the term was indefinite for lacking antecedent basis. *Id.*; Appx2970. NLC argued that the term should be construed as "the double catheter." *Id.* The district court agreed that "'the catheter' creates a degree of ambiguity within Claim 11" because the reference to "'*the* catheter' in Step 1 of Claim 11 arguably may refer to the double, outer, or inner catheter." Appx43-44 (emphasis in original). However, the district court *adopted NLC's proposed construction*, *i.e.*, "the double catheter." *Id.* Thus, the district court held "inserting the catheter" means "inserting the [double] catheter." *Id.* NLC cannot now challenge its own claim construction.[10]

[10] Likewise, the parties disputed the ordered recitation of elements construction. Appx45. The district court held "logic requires the steps of Claim 11 to be performed in the order listed" and therefore "Claim 11 is infringed only when the steps are performed in the order listed." *Id.* NLC did not appeal that construction. Even if this Court considers it now, the claim's plain language necessitates an order as it would be nonsensical, if not impossible to, for example, "withdraw the [double] catheter" before it has been inserted into the coronary sinus as Step 1 requires. Likewise, as the court found, "[l]ogic dictates that the inner catheter can be advanced 'along the guide wire into the branch vein' only if the guide wire has itself already been advanced through the outer catheter. Clearly, Step 3 of Claim 11 must be performed after Step 2." Appx45; *Mantech Envtl. Corp. v. Hudson Envtl. Servs., Inc.*, 152 F.3d 1368, 1375-76 (Fed.

NLC appears to now ask this Court to construe for the first time "inserting" to mean "simultaneous or sequential insertion." NLC's attempt to begin claim construction anew is procedurally deficient. Appx1967; *Interactive Gift Express, Inc. v. CompuServe Inc.*, 256 F.3d 1323, 1344-46 (Fed. Cir. 2001) ("the doctrine [of waiver] has been applied to preclude a party from adopting a new claim construction position on appeal.") (collecting cases).

NLC's newly proposed argument also fails on the merits. As an initial matter, NLC ignores the context of "inserting" and the district court's adoption of NLC's construction for "the catheter." Applying that here, NLC proposes that "inserting the catheter" mean "simultaneous or sequential insertion of the double catheter." This definition cannot stand. "Sequential insertion" of the double catheter is illogical, and to the extent NLC asserts this means inserting the outer or inner catheter one before the other, NLC's construction reintroduces the very ambiguity that renders the claim indefinite for the lack of antecedent basis. Appx3006-3007.

Cir. 1998) (affirming ordered recitation construction because the "sequential nature of the claim steps is apparent from the plain meaning of the claim language").

Further, the intrinsic record belies NLC's new claim construction argument. The '268 patent clearly differentiates references to the inner catheter, outer catheter, and combination, *i.e.,* "the catheter" as it has been construed. For instance, when discussing manipulating the components individually, the specification notes "inner catheter **12** is withdrawn completely into outer catheter **11**, and catheter **10** is inserted through a venous sheath…." Appx290 (4:32-36). However, when they are to be manipulated together:

- "Catheter **10** is rotated…" Appx290 (4:38).
- "Counterclockwise torque is exerted on catheter **10**." Appx290 (4:45-46).
- "Eventually, catheter **10** slips over the tricuspid annulus…." Appx290 (4:46-47).

The intrinsic record establishes that "inserting the catheter" means inserting the double catheter as a whole. *Id.*

NLC ignores the intrinsic record and improperly relies on extrinsic evidence alone for its new construction, namely, the unrelated Norlander '049 patent. But Norlander's disclosure, like the '268 patent, also differentiates manipulation of one catheter from the dual catheter. Appx319-320 (4:60-62). Thus, this Court should reject NLC's belated and

unworkable claim construction arguments. *See, e.g.*, *Level Sleep LLC v. Sleep No. Corp.*, __ Fed. Appx. __, 2021 WL 2934816 (Fed. Cir. 2021) (finding appellant's argument that the district court improperly construed terms on summary judgment "fails" because even if true, the "court was well within its power to clarify, supplement, and even alter its construction … in its summary judgment order").

2. Step 2 — "Advancing a guidewire through the [double] catheter into a coronary sinus lateral branch vein"[11]

NLC's inability to establish Step 1 was enough for the district court to determine summary judgment, but the district court considered each of the five steps of claim 11. Appx262. Step 2 requires advancing a guidewire into the double catheter and ultimately into a lateral branch vein of the coronary sinus. The district court correctly concluded that Step 2 was not disclosed in St. Jude's IFUs.

[11] NLC merges Steps 2 and 3, however, because each is independent and sequential, and because the absence of either establishes no infringement, St. Jude addresses each separately.

a) The District Court's Factual Findings Are Proper and Warrant Affirmance.

NLC does not challenge the court's factual conclusion that the IFUs do not teach "advancing a guidewire … into a coronary sinus lateral branch vein." Therefore, this Court should affirm the district court's factual conclusions that two independent factors establish the IFUs do not recommend, encourage, or instruct Step 2 of claim 11.

First, St. Jude's IFUs "reference the use of a guidewire only *after* first directing users to 'subselect[] the desired coronary sinus branch vein' when inserting the inner catheter." Appx263 (emphasis in original); Appx2314. In other words, the claims require introducing the inner catheter into the coronary sinus branch vein *after* introducing the guidewire therein, whereas St. Jude's IFUs teach the steps in reverse: inserting the inner catheter into the coronary sinus branch vein *before* introducing the guidewire (if any). Appx263; Appx1476; Appx2314.

Second, the district court recognized that St. Jude's IFUs expressly render a guidewire optional. Appx263; Appx2314. St. Jude's IFUs state that a guidewire is elective: "a physician *may* insert a guidewire '[i]f desired.'" Appx263 (emphasis in original). Indeed, NLC's expert agreed that the decision to use a guidewire is "at the physician's discretion" and

that it is an "if-desired methodology." Appx1457 (319:15-18, 321:2-11). The '268 patent confirms that "[g]uide wire 82 is only used if needed; it may be possible to place lead 83 without it." Appx291 (5:63-64). The court thus found that "St. Jude's instructions do not recommend or encourage the use of a guidewire." Appx263. Moreover, the district court also found that "the record undisputably establishes that St. Jude has sold significantly fewer guidewires than inner catheters, which further suggests that St. Jude does not recommend or encourage the use of a guidewire." Appx263. There was no clear error with these factual findings.

NLC thus cannot show clear error with the court's determination that "if desired" "does not recommend or encourage the use of a guidewire." Appx263. Instead, NLC simply argues that "the explicit recitation of a guidewire" is a "question of fact that should go to the jury." Br. at 37. This argument wholly fails to demonstrate clear error with the court's factual determination.

The district court, citing corresponding law, concluded "[e]vidence that a defendant's 'user manuals simply describe[] how to use the product in an infringing manner' without affirmatively *recommending* that

customers do so is insufficient circumstantial proof of infringement." Appx263 (emphasis in original) (quoting *Toshiba Corp.*, 681 F.3d at 1365). Thus, the district court appropriately found that "NLC's evidence does not establish that St. Jude instructed customers to perform the second step of the Claim 11 method because St. Jude's written instructions merely describe the use of a guidewire without recommending or encouraging such use, and the written instructions are not consistent with the order in which the steps of the method are listed in Claim 11." Appx263-264.

b) The District Court Did Not Construe "Advancing" During Summary Judgment and NLC Waived Any Argument Thereto.

As with Step 1, NLC argues that the district court misconstrued Step 2's "advancing" limitation. Br. at 33. Not so. Tellingly, NLC inappropriately merges its discussion and argument of Step 2 and Step 3 into one section and takes issue with the "advancing" term found in both without considering what is being advanced, where, and in what order. And NLC's proposed construction for "advancing" (like the one for "inserting") is procedurally improper, as NLC never raised that construction below. *Interactive Gift Express, Inc. v. CompuServe Inc.*, 256

F.3d 1323, 1344-46 (Fed. Cir. 2001) ("the doctrine [of waiver] has been applied to preclude a party from adopting a new claim construction position on appeal.").

As an initial matter, NLC does not provide any specific construction for the "advancing" limitation found in Step 2. *See* Br. 33-36. Instead, it attempts to combine Steps 2 and 3 but proposes a construction only for the "advancing" limitation found in Step 3. Br. at 34. Thus, NLC purportedly does not challenge the plain language of Step 2, which requires the guidewire be advanced *into a* coronary sinus lateral branch vein — prior to advancement of the inner catheter *along* the guidewire and *into* the branch vein (Step 3).

Equally important, the specification is replete with descriptions of the "advancing" limitation found in Step 2: "advancing a guide wire through the catheter into a coronary sinus lateral branch vein," "[i]nner catheter 52 is designed to advance over a guide wire into a side branch of the coronary sinus," "inner guide 52 … is then passed through outer guide 52 over the 0.038" wire into the target side branch." Appx289 (2:47-49); Appx291 (5:18-20, 5:55-58). NLC's position contradicts the intrinsic

evidence, and the Court should reject its attempt to engage in claim construction on appeal.

3. Step 3 — "Advancing the inner catheter out of a front end opening of the outer catheter along the guidewire into the branch vein"

Next, the district court compared Step 3 of claim 11 with St. Jude's IFUs. Appx264. Specifically, the court considered NLC's reference to St. Jude's technical expert, along with two excerpts from St. Jude's IFUs, and found that "NLC's evidence does not establish that St. Jude instructed customers to perform the third step of the Claim 11 method." Appx264-265. NLC identified no clear error with this conclusion.

a) The District Court's Factual Findings Are Proper and Warrant Affirmance.

The district court concluded that St. Jude's IFUs do not disclose this step on four independent grounds. Each is correct, and NLC has not and cannot establish that the district court erred as to any, let alone all four.

First, NLC attempted to rely on an out-of-context quotation from St. Jude's technical expert, Dr. Benditt, stating that it was "desirable" to insert the inner catheter into the branch vein. The court rightfully found, however, that his testimony does not establish that *St. Jude* "encouraged

or recommended doing so in a manner that infringes Claim 11 of the '268 Patent." Appx264. There was no clear error with this factual finding.

Second, the court concluded that the St. Jude IFUs upon which NLC relied do not "describe advancing an inner catheter (1) out of the front end of an outer catheter, (2) along a guidewire, or (3) into a branch vein, all of which are required by step three of the patented method." Appx264; Appx2314. Instead, the IFUs describe advancing the inner catheter into a branch vein *before* the *optional* insertion of a guidewire. Appx264. Likewise, St. Jude's IFUs optionally describe advancing the outer catheter over the inner catheter into the branch vein. *Id.* (fn. 5). Moreover, the court found "St. Jude's instructions clearly involve advancing 'the outer catheter' into the branch vein, *not* advancing the inner catheter into the branch vein as required by the third step of Claim 11." Appx264-265 (emphasis in original). This is an accurate recitation of St. Jude's IFUs and in no way erroneous.

Third, the court recognized that "St. Jude's instructions preface both the insertion of a guidewire *and* the advancement of the outer catheter into the branch vein with the phrase '[i]f desired.'" Appx264. As such, the court found that "even if St. Jude's instructions correctly

described the patented method (which they do not), these steps are neither encouraged nor recommended by St. Jude." *Id.* The court appropriately viewed this language as merely describing "steps that St. Jude's products are capable of performing" and noted that this "type of circumstantial evidence is insufficient to prove infringement." *Id.* (citing *Toshiba Corp.*, 681 F.3d at 1365).

Fourth, the district court further considered NLC's allegations with respect to the allegedly "only reason" to use a specific sized guidewire, *e.g.*, a 0.035-inch guidewire. As an initial matter, the court found that St. Jude's instructions *do not recommend* use of a .035-inch guidewire because the language states that "*if* a guidewire is used, the guidewire can be 'up to 0.035 inch (0.089 cm) diameter' in size." Appx265 (fn. 6). As the court found, "even if it is true that a physician *could* interpret St. Jude's instructions in this manner, St. Jude's instructions for the use of its products do not describe, recommend, or encourage such an interpretation." *Id.* Indeed, the court relied on precedent from this Court recognizing that "'instructions that require one to look outside the label to understand the alleged implicit encouragement [to infringe] do not, without more, induce infringement.'" *Id.* (quoting *Eli Lilly & Co. v.*

Teva Parenteral Meds., Inc., 845 F.3d 1357, 1369 (Fed. Cir. 2017)). Here, neither NLC nor its expert had any additional evidence outside of St. Jude's IFUs. Appx628 (118:12-24).

NLC cannot meet the heavy burden of establishing that all of these conclusions were clearly erroneous—especially because both NLC's expert and the IFUs' plain language support them.

b) The District Court Did Not Construe "Advancing" During Summary Judgment and NLC Waived Any Argument Thereto.

Again, NLC's arguments on appeal with respect to Step 3 rest almost exclusively on construing, for the first time on appeal, "advancing." This is improper. NLC never proposed its brand-new construction for Step 3 below, *i.e.*, "*moving* the inner catheter *further* into the branch vein along the guide wire." Br. at 34. The Court should reject NLC's belated and improper do-over attempt. *Interactive Gift Express*, 256 F.3d at 1344-46.

Regardless, NLC's belated construction contradicts the intrinsic evidence and claim construction principles. Indeed, NLC's attempt to rewrite the claim—by adding the word "*further*" into this limitation—redefines the scope of the claim as a POSA would understand it. The

plain language of this limitation requires "advancing the inner catheter *out of a front end opening* of the outer catheter along the guidewire into the branch vein." Appx292 (8:3-5). NLC's attempt to eliminate the antecedent limitation "out of a front end opening" highlights its improper attempt to rewrite the claim. Likewise, NLC's addition of the word "*further*" into the limitation presupposes, without any antecedence, that the inner catheter itself has already been advanced into the lateral branch vein. NLC's position therefore contravenes both claim construction principles and the claim's plain language.

Additionally, NLC cites the '268 patent's specification to suggest that the inner catheter can be "advanced as far as it will go into the coronary sinus." Br. at 34. But even under this inaccurate reading, importing this language from the specification into the claims violates black-letter patent law and claim 11's plain language. *See Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1354 (Fed. Cir. 2012) ("a claim construction must not import limitations from the specification into the claims.").

Moreover, that construction cannot be correct. If NLC's interpretation of the specification is accepted, the patentee knew how to

describe such a step but failed to limit its claim accordingly. This Court should not rewrite NLC's claim nearly two-decades after the fact, the plain language of which the public relied upon. *See, e.g.*, *In re Rambus*, 694 F.3d 42, 47 (Fed. Cir. 2012) (rejecting proposed claim construction because to the extent the patentee wanted to limit its claim, "it could have expressly done so. It did not, and this court will not do so here.").

4. Step 5 — "Withdrawing the [double] catheter"

Finally, at Step 5, the district court again compared the construed limitation against St. Jude's IFUs. Appx266. In other words, the court viewed Step 5 as requiring "withdrawing the [double] catheter leaving the lead in the branch vein." *Id.* And, as the court noted, "[b]ecause this Court previously construed 'the catheter' to mean 'the double catheter' (*i.e.*, both the inner and outer catheter), this step of Claim 11 requires the inner and outer catheters to be withdrawn simultaneously." *Id.*

However, the court found that St. Jude's written instructions "describe *only* the removal of the inner catheter" and noted that "NLC cites no evidence that St. Jude instructs, encourages, or recommends removing both the inner and the outer catheter simultaneously." *Id.* (emphasis in original). The court further noted that "the record includes

the following testimony from St. Jude's technical expert, Dr. Benditt, about removing the inner and out catheter simultaneously: '[N]obody does that. Well, nobody that I know of does that. Too hazardous to remove them in one step.'" *Id.* (fn. 7).

Thus, after reviewing NLC's best proffered evidence and arguments, the court concluded that St. Jude's IFUs do not track the claimed method, and therefore the record lacked sufficient evidence of direct infringement to support NLC's induced infringement claim. Appx267. The court noted the factual parallels of this case to *E-Pass*. Appx267. In *E-Pass*, the district court granted summary judgment of non-infringement based on the lack of instruction or teaching of the claimed method in accused product manuals along with the lack of evidence of direct infringement. *E-Pass Techs. Inc. v. Com Corp.*, 473 F.3d 1213, 1217 (Fed. Cir. 2007). On appeal, this Court affirmed the district court's finding because, as here, the alleged infringer's instruction manuals do not "teach all of the steps of the claimed method together, much less in the required order." *Id.* at 1222; Appx267. Therefore, this Court affirmed summary judgment because the alleged evidence "requires too speculative a leap to conclude that any customers

actually performed the claimed method." *Id.* As the district court found in this case, "[s]uch is the case here." Appx267; *Mirror Worlds, LLC v. Apple Inc.*, 692 F.3d 1351, 1361 (Fed. Cir. 2012) (affirming summary judgment of no induced infringement because instructions "alone cannot support infringement" if they do not teach "all of the steps of the claimed method together").

The district court appropriately compared the construed claim to NLC's best cited evidence. The district court found that St. Jude's instructions do not teach the method in claim 11 in order "*or otherwise*." Appx267. And, as NLC failed to identify any clear error with the district court's factual findings as to any one step, let alone all five, the Court should affirm the grant of summary judgment of non-infringement.

III. The District Court Did Not Abuse Its Discretion By Excluding Untimely Disclosed Evidence.

NLC's challenges to the district court's evidentiary determinations also fail. NLC challenges three such decisions. Each challenge has already failed once, as the district judge affirmed the magistrate judge's decisions to exclude evidence. NLC offers nothing new in rehashing on appeal these failed challenges. (Of course, if the Court agrees with Parts I. and II. above, it need not address these evidentiary disputes.)

NLC faces a high hurdle. Governing law grants "wide discretion" to district judges on evidentiary matters, so their decisions cannot be reversed "unless there is a clear and prejudicial abuse of discretion." *Dillion v. Nissan Motor Co.*, 986 F.2d 263, 267 (8th Cir. 1993); *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1301 (Fed. Cir. 1999) (on evidentiary matters, this Court applies law of regional circuit governing district court).

Three orders are at issue here. The magistrate judge decided each in the first instance, Appx46-157; Appx158-226; and Judge Wright later affirmed each, Appx2638; Appx2646. Two orders concern evidence that NLC sought to introduce well past the fact-discovery deadline. A third concerns the district court's decision to enforce a prior order, after NLC ignored it.

The First Evidentiary Ruling: The first order relates to untimely evidence from NLC's technical expert, Dr. Burke. Since the case's inception, St. Jude emphasized NLC's lack of evidence on direct infringement. Appx2872; Appx2947; Appx1435; Appx1439. After fact discovery closed, NLC sought for the first time to introduce such evidence through Dr. Burke. *See, e.g.*, Appx423-424 (Section titled "Evidence of

direct infringement"). Dr. Burke contended that he was a direct infringer, and also averred, based on undisclosed "conversations and experiences with other electrophysiologists," that such use occurred frequently in the field. *See, e.g.*, Appx420-424. In doing so, Dr. Burke became a surprise fact witness—one whom NLC never identified as a such. Appx152 (107:15-17); Appx79 (34:8-12); Appx544 (Hearing Exhibit admitted into evidence); Appx447-448. Due to the obvious prejudice and untimely disclosure of this factual evidence, St. Jude moved to strike these portions of Dr. Burke's report. Appx378.

The magistrate judge properly granted St. Jude's motion, for multiple reasons. First, NLC had retained Dr. Burke and could have obtained this evidence from him before discovery closed, if it had bothered to inquire. Appx145 (100:8-16). Second, NLC's failure to do so caused "unfair surprise" by converting Dr. Burke into a fact witness. Appx152 (107:15-17). Thus, the magistrate judge held "that all of the factual disclosures at issue were untimely produced" and should be excluded. Appx150 (105:15-19); Appx153 (108:18-20). Again, NLC unsuccessfully challenged the magistrate judge's ruling. Appx547; Appx563; Appx2645.

The district court judge properly overruled NLC's objection. The court found that the record confirmed that NLC had not been diligent in discovery because NLC had not sought diligently to discover the evidence. Appx2645. Concluding otherwise, as the court recognized, would invite parties to subvert Rule 26 "by simply waiting to obtain relevant information and then arguing that it was turned over as soon as it was received." *Id.* (citing *Dedmon v. Continental Airlines, Inc.*, No. 13-cv-0005, 2015 WL 4639737, at *4 (D. Colo. Aug. 5, 2015)). Further, the court properly concluded that exclusion was the proper remedy because (1) a continuance could not remedy the prejudice stemming from NLC's tardy disclosures, Appx2644, and (2) in any event, NLC neglected to seek a sanction other than exclusion. Appx2643. For these reasons, the district judge concluded that the magistrate judge's December 2, 2019 Order "is neither clearly erroneous nor contrary to law." Appx2645.

The Second Evidentiary Ruling: The second instance relates to similar untimely evidence in the form of thousands of pages of discovery that NLC's damages expert, Mr. Carlson, sought to rely upon even though NLC had not produced that evidence to St. Jude. St. Jude challenged Mr. Carlson's reliance on these documents because "this

section of his report did not include any supporting citations, footnotes, or exhibits," and "[n]either Plaintiff nor Mr. Carlson provided St. Jude with documentation of these 'license transactions,'" "[n]or is evidence of these transactions publicly available." Appx392. St. Jude, moreover, specifically sought such documents during the fact discovery period. Appx392 (fn. 5). NLC did not produce that evidence—over 5,000 pages—until November 8, 2019, nearly two months after fact discovery closed and nearly a month after serving Mr. Carlson's report.[12] Appx77 (32:15-22).

The magistrate judge properly excluded the information that Mr. Carlson referenced but NLC had failed to disclose. For one thing, that nondisclosure was not a mere oversight because, as the magistrate judge recognized, the information "was directly responsive to Defendant's discovery requests." Appx147 (102:21-24). For another thing, that nondisclosure prejudiced St. Jude because the late disclosure precluded St. Jude from timely submitting a rebuttal report. Appx77 (32:5-7);

[12] Fact discovery closed on September 13, 2019. Appx2923. Mr. Carlson's report was provided on October 15, 2019. Appx452.

Appx149 (104:20-24) (quoting *Ravo v. Covidien*, 55 F. Supp. 3d 766 (W.D. Penn. 2014)).

The district court judge then properly rejected NLC's challenge to the magistrate judge's decision. The district court affirmed because "ignorance, without diligence, is not a viable excuse" and found the "record supports the magistrate judge's finding that NLC was not diligent in discovery … as to the royalty evidence on which Carlson relied." Appx2643-2644. The district court then concluded that: i) "NLC's failure to disclose facts relied on in the expert reports of … Carlson … was neither substantially justified nor harmless;" ii) the magistrate judge did not "abuse her discretion by excluding such evidence under Rule 37;" and iii) the "December 2, 2019 Order is neither clearly erroneous nor contrary to law." Appx2645.

Out of an abundance of caution, St. Jude addresses NLC's arguments regarding the four-factor test, which the district court recognized applies only to "rulings that *predate* the effective date of Rule 37(c)(1)." Appx2642 (fn. 2) (emphasis in original). The first factor, the importance of the information, weighs in favor of St. Jude as the untimely disclosed information was required for NLC's induced infringement claim

even prior to filing suit. This is especially so in light of St. Jude's repeated requests for NLC to identify a single instance of direct infringement or direct infringer.

On the second factor, the reason for exclusion, NLC's argument misses the mark. NLC alleges that it "did not become aware of these facts until it started working with its experts." Br. at 42. NLC rightly recognizes the evidence as "facts" and its argument highlights its lack of diligence to uncover factual evidence central to its induced infringement claim, and which was directly responsive to St. Jude's discovery requests. Indeed, as the district court noted, NLC's reason was that "we were busy … so we put off talking to Dr. Burke until we wrapped up, you know, what we were working on at the time," which does not demonstrate diligence. Appx2639; Appx2644. Thus, this factor weighs in favor of St. Jude.

The third factor, potential prejudice to St. Jude, also weighs in favor of exclusion. NLC wholly fails to capture the situation at that time accurately. NLC alleges that "St. Jude had every opportunity to probe these facts during depositions." Br. at 43. Not so. At Dr. Burke's deposition, he did not have a specific recollection of any allegedly

infringing procedures, which were allegedly performed in the "late 2000s." Appx1447 (101:2-24). Dr. Burke further stated that such medical records are "probably in some archive somewhere." *Id.* Thus, St. Jude was deprived of the opportunity to seek discovery in the form of medical and patient records relating to such alleged procedures from the various hospitals Dr. Burke worked at—all of which would require third-party subpoena discovery, which was not possible as fact discovery closed. Likewise, the court credited the magistrate judge's finding that reopening fact discovery "would involve a significant expense" that "could involve hundreds of thousands of dollars." Appx2640 (fn. 1).

Lastly, the fourth factor, the availability of a continuance, weighs in favor of St. Jude. NLC mischaracterizes the situation as "not an issue of additional expense" but one of "possible delay." Br. at 44. NLC's contention is wrong—it is a question of unfair surprise and violation of the court's scheduling order, coupled with the additional time and expense. And under those facts, the magistrate judge properly found that "a continuance will not cure the problem created by Plaintiff's own doing." Appx152 (107:18-19). Indeed, the district court affirmed because "NLC's failure to timely produce such discovery evidence is not harmless simply

because any prejudice can be remedied by a continuance and additional depositions." Appx2644.

Thus, all four of the factors weigh in favor of exclusion and NLC's arguments do not demonstrate any abuse of discretion with the court's findings. This Court should affirm.

The Third Evidentiary Ruling: The district court's third at-issue evidentiary ruling enforced the first. Even though the district court excluded portions of Dr. Burke's testimony, NLC relied upon those claims to support its summary judgment motion. *See, e.g.*, Appx1744 (¶¶ 12, 13, 26, 36). St. Jude therefore had to enforce the prior ruling by moving to strike the offending portions of the summary judgment motion. Appx3395.

The magistrate judge granted that motion, properly recognizing NLC's summary judgment motion as a willful violation of the prior discovery order. Appx219 (62:12-24). To remedy that violation, the magistrate judge ordered that the tardy-disclosed facts from Dr. Burke be stricken from the summary judgment record and awarded NLC to pay St. Jude's fees and costs incurred in seeking to exclude that evidence again. Appx220 (63:15-19, 63:23-64:3).

Again, NLC challenged the magistrate judge's order, and again, the district court judge properly affirmed. The court emphasized that NLC failed to challenge the facts central to the magistrate judge's ruling:

- NLC did not dispute that it failed to "disclose Dr. Burke as a fact witness before the close of fact discovery and that Dr. Burke's expert report contained facts that were not disclosed before the close of fact discovery." Appx2647.
- NLC tacitly admitted it failed to properly instruct Dr. Burke regarding the prior exclusion. Appx2647 (recognizing that NLC conceded to the magistrate judge that "we were busy … so we put off talking to Dr. Burke until we wrapped up, you know, what we were working on at the time.").
- "*NLC does not dispute that it violated the magistrate judge's December 2, 2019 Order.*" Appx2649.

Thus, the district court recognized that the magistrate judge's imposition of nondispositive sanctions was not clearly erroneous; it was correct. Appx2650.

NLC's Arguments On Appeal: NLC now challenges each of these rulings on the same bases as below. Judge Wright already considered NLC's arguments and confirmed that the magistrate judge did not abuse her discretion. NLC presents no new arguments but instead seeks a third bite at the apple. This is improper.

In each instance, NLC has failed to show error, much less an abuse of discretion. *See SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278,

1292 (Fed. Cir. 2005) (finding no abuse of discretion in excluding undisclosed evidence pertaining to infringement); *O2 Micro Int'l, Ltd. v. Monolithic Power Sys.*, 467 F.3d 1355, 1369 (Fed. Cir. 2006) (finding no abuse of discretion "given the significance of the omitted material and O2 Micro's lack of diligence"). Here, NLC does not dispute that it violated the scheduling order by untimely disclosing this evidence. Its explanation — that it "did not know" of these facts until it started working with its experts — does not demonstrate clear error. Indeed, such an explanation fails to demonstrate that NLC was diligent in discovery or in supplementing its discovery responses. And, importantly, NLC does not challenge that it violated the exclusion order by reincorporating facts previously stricken. Thus, the district court did not abuse its discretion in either excluding NLC's belatedly disclosed evidence or enforcing that exclusion order. NLC offered nothing to suggest that its belated disclosures were either substantially justified or harmless. The court thus properly concluded that NLC's delay was "inexcusable." Appx146 (101:5-6). This Court should affirm.

IV. The District Court Did Not Abuse Its Discretion By Excluding NLC's Damages Expert's Royalty Base Testimony.

Finally, the district court did not abuse its discretion in excluding NLC's damages expert's opinion and testimony regarding the royalty base used to calculate damages. Appx244. The district court excluded Mr. Carlson's royalty base calculation because it did "not comport with settled principles of apportionment." Appx251.

To overturn that conclusion, NLC needs to show that the district court abused its discretion. *SSL Servs., LLC v. Citrix Sys.*, 769 F.3d 1073, 1082 (Fed. Cir. 2014) (this Court reviews evidentiary decisions under the law of the regional circuit); *Wing Enters. v. Tricam Indus.*, 829 Fed. Appx. 508, 512 (Fed. Cir. 2020) ("The Eighth Circuit reviews a district court's exclusion of expert testimony for abuse of discretion."); *see also Excel Corp. v. Bosley*, 165 F.3d 635, 640 (8th Cir. 1999) (court will not reverse evidentiary decision "unless the ruling is manifestly erroneous").

Here, excluding Carlson's royalty base testimony was not an abuse of discretion; it was the correct decision. To be admissible in a patent infringement case, damages opinions must "separate the value of the allegedly infringing features from the value of all other features." *CSIRO*

v. Cisco Sys., 809 F.3d 1295, 1301 (Fed. Cir. 2015). Thus, unless the case implicates the entire-market-value rule, "principles of apportionment apply." *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1326 (Fed. Cir. 2014). NLC does not dispute that apportionment principles apply here. Appx246. Thus, to be admissible, the expert's opinion must "'apportion value between the patented features and the vast number of non-patented features contained in the accused products'" because otherwise, the opinion cannot "'carefully tie proof of damages to the claimed invention's footprint in the marketplace.'" Appx248 (quoting *VirnetX*, 767 F.3d at 1329).

Yet Carlson's proffered royalty base fails for two reasons. First, and most fundamentally, Carlson failed to apportion damages to the value of claim 11's method. Instead, he arbitrarily lumped four components (outer catheter, inner catheter, guidewire, and lead) together and claimed that those four components collectively comprise the "smallest saleable" patent-practicing unit. Appx247; Appx727. That approach, however, does not apportion value to the patented features, and certainly not to the claimed method. Appx247; *see Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1310, 1338 (Fed. Cir. 2009) (observing that expert's

use of "the price of the entire computer as a royalty base" for a method claim was improper, even though a computer was recited in the claim language). Thus, the district court reasonably concluded that "Carlson's royalty base accounts for more than the *method* claimed." Appx248 (emphasis in original); *LaserDynamics, Inc. v. Quanta Comput., Inc.*, 694 F.3d 51, 68 (Fed. Cir. 2012) (rejecting damages award because the patent only covered a method practiced using an optical disc drive, but damages were based on the entire computer).

Second, Carlson's proffered royalty base improperly included electrical pacing leads in the royalty base. That error is obvious: NLC's own technical expert admitted that leads are not "part and parcel of the '268 patent." Appx638 (239:14-24). So even if an expert could calculate a method's value by adding the value of the product's component patented parts (and he cannot), including leads would be inappropriate here. Considering leads in the royalty base fails to distinguish "the patented features" from "the vast number of non-patented features contained in the accused products." *VirnetX*, 767 F.3d at 1329.

NLC cannot dodge this conclusion by asserting that because claim 11 is "not a product claim," "[t]here are no 'patented features' or

'unpatented features' of the four recited components." Br. at 53. NLC's argument proves too much. It confirms that Mr. Carlson did not "carefully tie proof of damages to the claimed invention's footprint in the marketplace." *VirnetX*, 767 F.3d at 1329.

Nor can NLC fix that problem by contending that "Mr. Carlson did consider non-patented aspects or alternatives to the method of claim 11." Br. at 56. For one thing, Carlson himself disputes that contention. He testified that he had "no idea" as to whether "St. Jude's leads have non-patented features." Appx787 (125:2-24). For another thing, it is beyond dispute that St. Jude's catheters and leads have clear and substantial non-infringing uses and non-patented features that in no way relate to the method in claim 11. *See Riles v. Shell Exploration & Prods. Co.*, 298 F.3d 1302, 1312 (Fed. Cir. 2002) ("The economic relationship between the patented method and non-infringing alternative methods, of necessity, would limit the hypothetical negotiation").

Finally, NLC's reliance on *Exmark* for support is misplaced. That case centered on whether an expert can adjust the royalty *rate* as a means to apportion value. *Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp., LLC*, 879 F.3d 1332, 1348 (Fed. Cir. 2018). This Court held that

"[s]o long as Exmark adequately and reliably apportions between the improved and conventional features of the accused mower, using the accused mower as a royalty base and apportioning through the royalty rate is an acceptable methodology." *Id.* That case says nothing about what is at issue here—a damages calculation that fails to discount the value of non-patented features and non-infringing uses.

In sum, the district court did not abuse its discretion in excluding Carlson's royalty-base opinion and testimony. Carlson failed to do what was required (apportion value) and did do what was forbidden (including an unpatented feature—specifically, leads—in the royalty base).

CONCLUSION

For the reasons stated herein, this Court should affirm the district court's rulings.

Dated: August 2, 2021

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FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

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