CASE NO. 2021-1864

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

NIAZI LICENSING CORPORATION,

Plaintiff-Appellant,

v.

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

Defendant- Appellee

BRIEF OF PLAINTIFF-APPELLANT

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June 21, 2021

CERTIFICATE OF INTEREST FOR APPELLANT

The undersigned counsel for the Plaintiff-Appellant Niazi Licensing Corporation certifies the following:

1. The full name of every party represented by me is:

   Niazi Licensing Corporation

2. The appellant named in the caption is the real party in interest.

3. No publicly held corporation owns 10% or more of Niazi Licensing Corporation.

4. The names of all law firms and the partners or associates that appeared for the plaintiff-appellant in the district court proceeding or are expected to appear for them in this court are:

   Michael T. Griggs, Adam L. Brookman, Timothy E. Newholm, and Marriam Lin of Boyle Fredrickson, S.C.

June 21, 2021

/s/Michael T. Griggs
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Statement of Related Cases

Pursuant to Federal Circuit Rule 47.5, Plaintiff-Appellant Niazi Licensing Corporation states as follows:

(a) There have been no previous appeals in this proceeding.

(b) There are no cases currently pending that may be directly affected by the outcome of this appeal.

Jurisdictional Statement

The district court had jurisdiction under 28 U.S.C. §§ 1331 and 1338. This Court has jurisdiction under 28 U.S.C. § 1292(c). The district court entered final judgment on March 24, 2021.

Statement of the Issues on Appeal

1. Whether the district court erred in finding that the term "pliable" is indefinite, rendering Claims 1-3 and 13-27 of U.S. Patent 6,638,268 ("the '268 patent") invalid under 35 U.S.C. § 112.
2. Whether the district court erred in finding that the term "resilient" is indefinite, rendering claims 1-3 and 13-27 of the '268 patent invalid under 35 U.S.C. § 112.
3. Whether the district court erred in granting summary judgment that claim 11 is not infringed.
4. Whether the district court abused its discretion in precluding Plaintiff-Appellant's damages expert from relying upon various third-party licenses in support of his opinions on damages.
5. Whether the district court abused its discretion in precluding Plaintiff-Appellant's technical expert from presenting testimony on the issue of direct infringement.

6. Whether the district court abused its discretion when it sanctioned Plaintiff-Appellant for violating the district court's exclusion order and awarded fees in the amount of $35,985.75 to Defendant-Appellee.

7. Whether the district court abused its discretion in precluding Plaintiff-Appellant's damages expert from opining as to which products should be included in the royalty base.

Statement of the Case

I. The catheter system and implantation method of the '268 patent

In treating congestive heart failure, among other conditions, it has been shown that providing a pacemaker with various lead wires implanted in the heart can have tremendous therapeutic benefit. The pacemaker delivers electric current to the heart via the various leads, which helps to regulate the heartbeat. However, placing the leads within the heart poses significant challenges, as the electrophysiologist must guide the lead through tortuous arteries and veins. The procedure is further complicated given the fact that each patient's anatomical structures are different, and that the patient's particular anatomy is not known until the procedure has begun.

Around the time Dr. Imran Niazi invented the subject matter disclosed and claimed in the '268 patent, a select group of electrophysiologists were conducting clinical trials relating to biventricular pacing, a new procedure that involved pacing

both sides of the heart as opposed to just one, which had been the convention at the time. Appx361. Biventricular pacing required access to the left ventricle, a procedure that was not known or performed at the time. *Id*.

The move toward biventricular pacing posed new challenges to electrophysiologists. Implanting a lead in the left ventricle requires access or "cannulation" of the coronary sinus, i.e., "accessing" the coronary sinus, a procedure that was not routinely performed. Appx289, 1:19-27. The coronary sinus is a vein at the back of the heart that is typically three to four centimeters in length and one centimeter in diameter, *id*., 1:11-12, and the size and location of the coronary sinus presents challenges to an electrophysiologist who is attempting to guide a lead through the coronary sinus and into the left ventricle for implantation, particularly for patients with congestive heart failure, who are the majority of patients who receive biventricular pacing systems.

Once the coronary sinus has been cannulated, the electrophysiologist may face additional difficulties when attempting to place the lead in a vein that branches off the coronary sinus, commonly known as "a lateral branch vein." For example, the lateral branch vein may branch off at an acute angle, requiring the lead to advance through a sharp turn.

Dr. Niazi, the inventor of the technology and methods disclosed in the '268 patent, was and is a leader in the field of electrophysiology. At the time Dr. Niazi

developed his invention, electrophysiologists were using a single catheter system when attempting to cannulate the coronary sinus and implant a lead into a branch vein. Appx362. Through careful study and research, Dr. Niazi recognized the difficulties presented by the anatomical abnormalities in the coronary sinuses of patients with congestive heart failure, as well as the difficulties posed by attempting to access a lateral branch vein through the coronary sinus. Appx2124. Such difficulties were not generally known because biventricular pacing – and the need to access the coronary sinus – was not widespread or conventional at the time. Dr. Niazi was the first to undertake such a study.

Dr. Niazi designed the catheter system and implantation methods disclosed and claimed in the '268 patent to address the challenges presented by accessing the coronary sinus of a patient with congestive heart failure. One embodiment of the invention is shown below, which has been annotated to highlight the basic components of the system. Generally speaking, the system includes a curved outer catheter (blue) and an inner catheter (green) that work together in a telescoping fashion. Advancement of the inner catheter through the outer catheter causes the outer catheter to change shape to assist the electrophysiologist in cannulating the coronary sinus. In other words, the electrophysiologist can use the inner catheter to adjust the shape of the outer catheter as needed to accommodate anatomical abnormalities and variances that are specific to each patient.

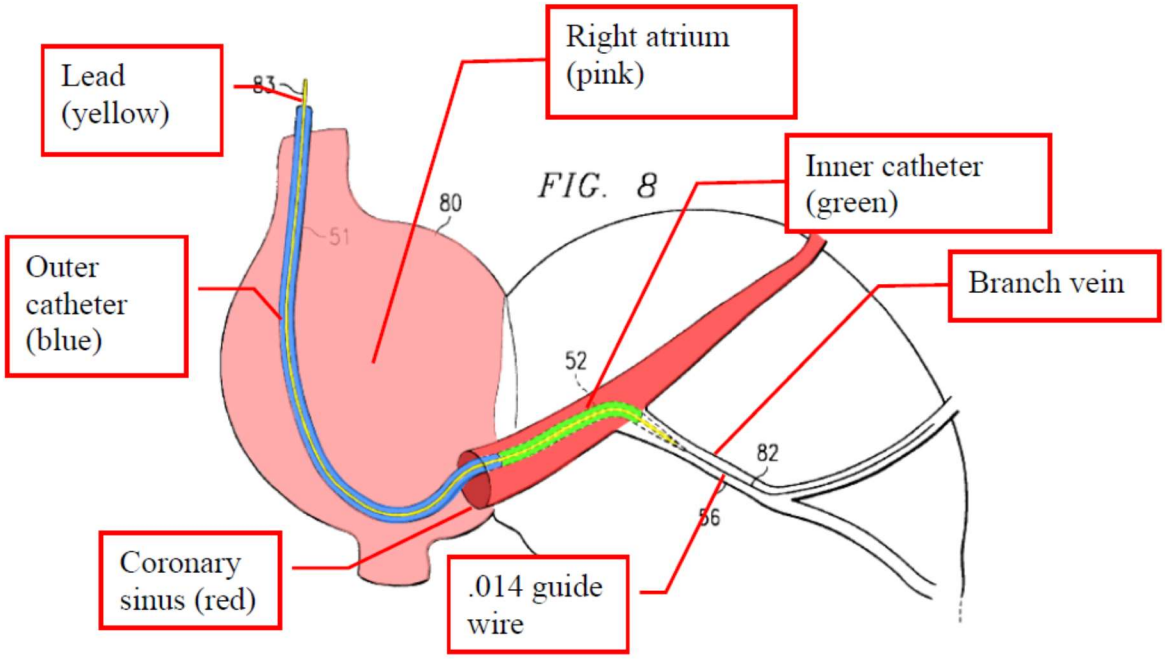


FIG. 8

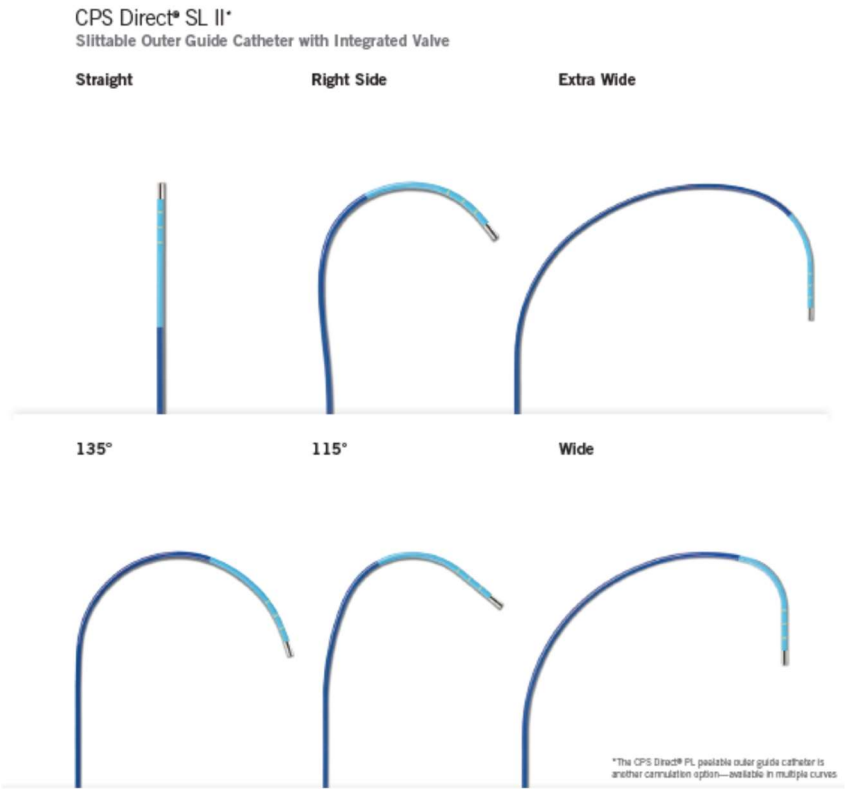
Once the coronary sinus has been cannulated, the inner catheter (green) is advanced into a lateral branch vein to support and guide a pacing lead (yellow) for implantation in the lateral branch vein. The lead and catheters are typically advanced along a guide wire because the typical lead is an over-the-wire lead, meaning that the lead is tubular in shape to accommodate a guide wire that passes through the body of the lead. After the lead has been successfully implanted, the catheters are withdrawn one-at-a-time, leaving the lead in place.

Dr. Niazi's design improved over the existing system and method, which involved using a single catheter to cannulate the coronary sinus and implant the lead in a lateral branch vein. Appx362. For example, Dr. Niazi's telescoping system allows the electrophysiologist to change the shape of the outer catheter

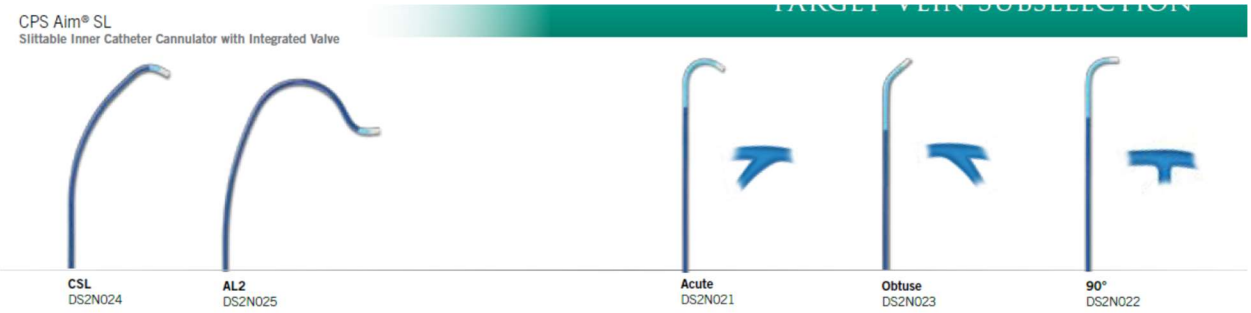
during the procedure to facilitate cannulation of the coronary sinus. Further, the flexible inner catheter is able to access a lateral branch vein to help guide the lead to a desired location.

II. St. Jude's Accused Products and Method

St. Jude sells outer catheters (CPS Direct catheters), inner catheters (CPS Aim catheters), and over-the-wire leads (which come with a guide wire) that are implanted through the inner catheters (Quartet, QuickSite, and Quick Flex leads). Appx1246. An example of one family of outer catheters is shown below. *Id.* In addition to the CPS Direct SL, St. Jude sells the CPS Direct Universal line, and the CPS Direct MediGuide line. *Id.*



An example of one family of inner catheters is shown below. Appx1427. In addition to the CPS Aim SL, St. Jude sells the CPS Aim Universal line, and the CPS Aim MediGuide line. *Id*.



St. Jude provides instructions for use for each family of Aim inner catheters that it sells. Appx1083-1088. Within the same families, the CPS Direct outer catheters and CPS Aim inner catheters are designed to be used with one another in a telescoping fashion to help electrophysiologists cannulate the coronary sinus and to implant pacing leads in branch veins of the coronary sinus. Appx1337. The catheters come in different shapes to offer electrophysiologists several options when presented with differing anatomical challenges from patient to patient. *Id*.

III. The procedural events leading to this appeal

The scheduling order in the case provided for a claim construction hearing and claim construction order prior to summary judgment briefing. The parties exchanged terms and proposed constructions in advance of the claim construction briefing, then filed parallel claim construction briefs and responses.

A. The indefiniteness ruling

As part of its claim construction briefing, St. Jude moved for summary judgment on its indefiniteness defense as to the terms "pliable" and "resilient." The district court granted this motion, rendering all but one of the asserted claims invalid. Claim 11, a method claim, was the only claim remaining in the case after the district court's ruling on indefiniteness.

B. The exclusion of expert evidence

After the close of fact discovery, NLC submitted two expert reports: a technical report from Dr. Martin Burke and a damages report from Brad Carlson.[1] Mr. Carlson's report identified various third-party licenses that Mr. Carlson had identified by searching two private databases. Dr. Burke's report included a short section addressing direct infringement, including statements that Dr. Burke himself is a direct infringer because he used St. Jude's products in an infringing manner. St. Jude filed a motion to exclude the third-party licenses from Mr. Carlson's report and to exclude testimony from Dr. Burke on the issue of direct infringement. The district court granted this motion.

C. The summary judgment decision

The case proceeded to summary judgment, focusing on the only remaining claim, claim 11. NLC moved for summary judgment on the issues of infringement

[1] These reports issued prior to the district court's ruling on claim construction and, therefore, addressed all claims that had been asserted in the case.

and validity. St. Jude moved for summary judgment on the issue of infringement. The district court granted St. Jude's motion for summary judgment, finding that claim 11 was not infringed.

D. The sanctions order

In support of its summary judgment motion, NLC submitted a declaration from Dr. Burke. St. Jude moved to strike the declaration and for sanctions, arguing that the Burke declaration violated the district court's Exclusion Order. The district court granted St. Jude's motion, excluded certain statements from the Burke declaration, and awarded $35,985.75 in fees to St. Jude.

E. The *Daubert* ruling

Finally, around the same time as the summary judgment briefing, both parties submitted *Daubert* motions. St. Jude's motion sought to exclude both Dr. Burke and Mr. Carlson from presenting any testimony at trial. The district court granted St. Jude's motion in part, holding that Mr. Carlson could not present an opinion as to which of St. Jude's products should be included in the royalty base.

Summary of the Argument

The district court erroneously found the terms "pliable" and "resilient" indefinite under 35 U.S.C. § 112, a determination that this Court reviews *de novo*. The district court improperly imposed an overly strict standard for assessing indefiniteness and also wrongly characterized these terms as terms of degree. The

following statement regarding the term "pliable" illuminates the district court's misapprehension of the claims: "These descriptors do not establish objective boundaries as to ***the range of pliability being claimed***." Appx39 [emphasis added]. But the claims to not claim a "range" of pliability or resilience. They simply claim a "pliable" inner catheter and a "resilient" outer catheter. The district court's indefiniteness determination should be reversed, and the terms "pliable" and "resilient" should be given their plain and ordinary meaning to one of ordinary skill in the art when read in light of the underlying disclosure as required by law.

The district court also erred in granting summary judgment that St. Jude did not induce infringement of the method of claim 11. The district court's decision turned primarily on issues of claim construction. Two of the steps of claim 11 are related, requiring "inserting" the double catheter into the coronary sinus and "withdrawing" the double catheter after the procedure is complete. The district court narrowly interpreted these two steps as requiring "simultaneous" insertion and withdrawal of the outer catheter and inner catheter. However, this interpretation runs counter to the teaching of the '268 patent itself, which discloses sequential insertion of the catheters, i.e., first the outer catheter than the inner catheter. The prior art also shows that sequential insertion and withdrawal was common practice.

Continuing with its overly narrow interpretation of the claims, the district court interpreted the interplay between step 2 of claim 11 (advancing a guide wire through the catheter into a lateral branch vein) and step 3 of claim 11 (advancing the inner catheter along the guide wire into the branch vein) to preclude a situation where the inner catheter is positioned within the opening of the branch vein, a guide wire then is passed into the branch vein, and the inner catheter then is advanced along the guide wire further into the branch vein. Contrary to the district court's interpretation, the specification teaches "advancing" a catheter in exactly that order.

Moreover, the district court erroneously granted summary judgment where the record presented questions of material fact that should have been put to the jury. For example, while St. Jude's instructions explicitly state that a guide wire can be used "if desired," the district court held that such a statement did not constitute recommendation, encouragement, or promotion of the use of a guide wire. Interpreting St. Jude's instructions is a question of fact that should be resolved by the jury.

The district court also abused its discretion when it precluded NLC's damages expert, Brad Carlson, from relying on third-party license agreements in support of his damages opinion, holding that these licenses should have been disclosed during fact discovery (which had closed about a month before the expert

reports were due). Mr. Carlson found these third-party licenses in two private databases that he accessed when he prepared his report after the close of fact discovery. NLC was not aware of these licenses, nor did it have possession of them during the fact discovery period. Despite this, the district court precluded Mr. Carlson from relying on them. Experts can rely upon a wide range of information when forming their opinions, and they are required to disclose that information in their reports. The district court turned the notion of expert disclosure and discovery on its head by essentially ruling that anything an expert relies upon must be disclosed during fact discovery. On the contrary, an expert may rely upon information from any appropriate source so long as that source is disclosed in a report in accordance with the Federal Rules of Civil Procedure.

This district court similarly abused its discretion when it precluded NLC's technical expert, Dr. Martin Burke, from presenting testimony on the issue of direct infringement. Dr. Burke included a small section in his report stating that he had used St. Jude's products in an infringing manner consistent with St. Jude's instructions. This was not only evidence of direct infringement, but also part of Dr. Burke's credentials and a qualifying basis for his expert testimony. The district court abused its discretion when it precluded Dr. Burke from presenting this testimony, holding that such testimony should have been disclosed during fact discovery. However, NLC was not aware of these facts until the expert discovery

phase of the case, NLC timely disclosed them in the expert report about a month after the close of fact discovery, and there was no prejudice to St. Jude since there was no trial date set and St. Jude had every opportunity to examine the statements during the expert discovery phase of the case.

The district court further abused its discretion when it sanctioned NLC and awarded $35,985.75 in attorneys' fees to St. Jude based upon Dr. Burke's summary judgment declaration, which did not contain any testimony on the issue of direct infringement. Instead, St. Jude pointed to other statements in Dr. Burke's declaration (largely background information relating to Dr. Burke's experience and the technology at issue) that were included in Dr. Burke's expert report but were not challenged by St. Jude when it moved to preclude testimony relating to direct infringement. The district court, however, characterized its prior ruling to encompass some of the previously unchallenged statements and sanctioned NLC.

Wholly apart from the issues associated with St. Jude's challenge of statements it had previously ignored, and the district court's overly expansive reading of its prior order, there was no bad faith on the part of NLC to justify an award of attorneys' fees as a sanction. *Stevenson v. Union Pac. R. Co.*, 354 F.3d 739, 751 (8th Cir. 2004). ("A bad faith finding is specifically required in order to assess attorneys' fees."). Indeed, the district court explicitly found there was no bad faith underlying the submission of Dr. Burke's declaration. Appx219-220.

("This does not mean that there was bad faith. I believe Mr. Griggs that he did not intent to practice a fraud upon the Court."). The district court abused its discretion in awarding $35,985.75 in attorneys' fees to St. Jude.

Finally, the district court abused its discretion when it granted St. Jude's *Daubert* motion in part and precluded Mr. Carlson from presenting an opinion as to which of St. Jude's products should be included in the royalty base for purposes of a calculation on damages. In doing so, the district court misapprehended the disclosure of the '268 patent and statements in Mr. Carlson's report. For example, the district court stated that the scope of the '268 patent "does not include leads," despite the fact that claim 11 is directed to a method for implanting "an electrical lead" and that the specification contains detailed disclosure regarding methods for implanting a lead.

In another example, the district court concluded that Mr. Carlson did not attempt to apportion the value of patented features from non-patented features. However, Mr. Carlson relied upon a statement from Dr. Burke that the method of the claim 11 was the "predominant" method for implanting leads. The district court usurped the role of the fact finder by rejecting this premise and holding that Mr. Carlson did not appropriately apply the principle of apportionment.

Argument

I. The district court erred when it found the terms "pliable" and "resilient" indefinite pursuant to 35 U.S.C. § 112

This Court reviews the district court's indefiniteness determination *de novo*. *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014). Any factual findings made by the district court are reviewed for clear error. *IQASR LLC v. Wendt Corp.*, 825 F. App'x 900, 901 (Fed. Cir. 2020). Here, the district court did not make any factual findings that underly its indefiniteness determination.

The purpose of the definiteness requirement is to ensure that the claim delineates the metes and bounds of the invention with reasonable certainty. Absolute precision is not required and is often impossible, given the ambiguity inherent in the English language. *Sonix Tech. Co. v. Publications Int'l, Ltd.,* 844 F.3d 1370, 1377 (Fed. Cir. 2017). The U.S. Supreme Court articulated the definiteness standard under § 112 as follows:

> To determine the proper office of the definiteness command, therefore, we must reconcile concerns that tug in opposite directions. Cognizant of the competing concerns, we read § 112, ¶ 2 to require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable.

Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 910, 134 S. Ct. 2120, 2129, 189 L. Ed. 2d 37 (2014). Thus, the claims, viewed in light of the specification and prosecution history, must inform those skilled in the art as to the scope of the claims with only "reasonable certainty," not absolute precision.

This Court should reverse the district court's indefiniteness determination and construe the terms "pliable" and "resilient" as having their plain and ordinary meaning to one of ordinary skill in the art when read in light of the underlying disclosure of the '268 patent. While this Court applies a *de novo* standard of review, it is nevertheless important for NLC to address the district court's analysis so that this Court may understand where the district court went astray.

A. The district court erred by characterizing the term "pliable" as a term of degree

The term "pliable" appears in claims 1, 13, 18, and 24. Claim 1 is exemplary. It claims "an inner, pliable catheter." This term should be construed in accordance with its plain and ordinary meaning – ***easily bent, flexible*** – which is consistent with how it is used in the specification. For example, the specification explains that the inner catheter has flexibility so that it can "negotiate tortuous vessels and side branches." Appx291, 5:20-24. A person having ordinary skill in the art could readily determine what materials are and are not sufficiently bendable for this purpose.

The district court, however, did not attempt to construe this term. Rather, the district court erred by characterizing "pliable" as a term of degree. Appx39. Any modifier, be it an adjective or adverb, lacks absolute precision when read in isolation. That is its very purpose. Terms of degree have been recognized as a special class of modifier that inherently introduce some level of subjectivity into the patent claim. This Court has explained that a term of degree "necessarily calls for a comparison against some baseline." *Liberty Ammunition, Inc. v. United States*, 835 F.3d 1388, 1395 (Fed. Cir. 2016). ("We begin our analysis by recognizing that the term 'reduced area of contact' is one of degree, as it necessarily calls for a comparison against some baseline."); *see also Advanced Aerospace Techs., Inc. v. United States*, 124 Fed. Cl. 282, 292 (2015) (considering whether terms of degree such as "near the point of engagement," "reasonably secure," and "substantially arrested" were indefinite.). Unlike the terms at issue in *Liberty Ammunition* and *Aerospace Techs.*, the term "pliable" does not require a comparison against some baseline. It simply is an adjective meaning "***easily bent, flexible***," and the district court should have construed it accordingly.

The district court's misapprehension is further illustrated by the following statement in the claim construction order: "These descriptors do not establish objective boundaries as to ***the range of pliability being claimed***." Appx39 [emphasis added]. However, the claims do not claim a "range of pliability" – they

merely recite a "pliable" inner catheter. When a claim includes an adjective such as "pliable" – or other commonly used adjectives such as rigid, flexible, soft, hard, porous, solid – the definiteness requirements of *Nautilus* do not require the patent to disclose, let alone claim, a specific quantitative range so that the district court can answer the question of exactly "how pliable?" or "how rigid?" or "how soft?" etc. One of ordinary skill in the art, armed with common sense, their knowledge of the technology, and the underlying disclosure, need not have reference to a specific quantitative range of values to understand what is and is not pliable, rigid, or soft with reasonable certainty – in full compliance with 35 U.S.C. § 112 as interpreted by *Nautilus*.

Following its erroneous characterization of "pliable" as a term of degree, the district court further erred when it failed to recognize that the specification discloses objective criteria as to the meaning of "pliable" that would enable a person having ordinary skill in the art to understand what is meant by a "pliable" inner catheter.

The '268 patent provides exemplary materials and dimensions for an inner catheter that is pliable. Appx290, 3:13-23 ("An inner catheter 12, which slides in and out of outer catheter 11, is constructed of a more pliable, soft material such as silicone."); Appx291 5:20-24 ("[The inner catheter's] flexibility allows it to negotiate tortuous vessels and side branches that originate from the coronary sinus

at an acute angle, yet it still possesses the radial strength needed to prevent it from collapsing when obturator 53 is withdrawn."); Appx291, 5:14-28 (providing dimensions and describing other characteristics of one embodiment of the inner catheter).

Thus, the '268 patent provides an exemplary material – silicone – from which a pliable inner catheter may be made, as well as exemplary dimensions. A person having ordinary skill in the art could construct a pliable catheter in accordance with this disclosure to further understand its qualities and characteristics. Moreover, the '268 patent describes various functional characteristics, e.g., that the inner catheter slides within the outer catheter to change the shape of the outer catheter; that the inner catheter can navigate tortuous vessels and lateral branch veins; and that the inner catheter will not collapse down upon itself during the procedure. *See United States v. Telectronics, Inc.,* 857 F.2d 778, 786 (Fed. Cir. 1988) (rejecting an argument regarding the need to determine a current range, holding that "[a]djusting current so as to minimize fibrous tissue formation in other parts of the living being reasonably apprises those skilled in the art of the bounds of the claimed invention and is as precise as the subject matter permits.") A person having ordinary skill in the art would understand that if the inner catheter functions in this manner, it is "pliable" within the context of the '268 patent.

This Court has held that disclosure such as this overcomes an indefiniteness challenge to a term of degree:

> Accordingly, we have held that the clause "not interfering substantially" did not render a claim invalid as indefinite. In that case, we reasoned that the intrinsic evidence provided guidance as to the scope of the claims, including, *inter alia*, examples of noninterfering structures and criteria for their selection. This guidance allowed a skilled artisan to compare a potentially infringing product with the examples in the specification to determine whether interference is substantial.

Sonix, 844 F.3d at 1377 [citations and quotations omitted].

Finally, the district court erred by failing to address the level of ordinary skill in the art and their attendant knowledge base, which is significant because "[t]he person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art." *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). NLC submitted prior art patents relied upon by St. Jude in its invalidity contentions that describe various catheters as "pliable," which demonstrate that term would be well known and understood by a person having ordinary skill in the art.

Below is an excerpt from U.S. Patent 6,277,107 to Lurie, discussing pliability (Appx353, 7:23-33):

> The guiding introducer may be made of any biocompatible material suitable for use in humans which has a memory or permits distortion from and substantial return to the desired three dimensional shape, such as polyethylene or polyurethane. In a preferred embodiment, the distal tip of the guiding introducer may be made of a more pliable, more compressible material, than the remaining length of the coronary sinus guiding introducer to prevent damage to the vasculature and the coronary sinus when in use. Also, preferably, the distal tip is made radiopaque.

Another example is U.S. Patent 5,488,960 to Toner (another prior art reference identified by and relied upon by St. Jude), which describes the introducer as having a "pliable tip" (Appx327, Abstract):

> A coronary sinus catheter introducer system in which an introducer is installed in the right atrium of the cardiovascular system of a patient for delivery of a coronary sinus catheter into the coronary sinus. A bend near the distal end of the introducer enables placement of the end of the introducer into the coronary sinus opening and within the coronary sinus. A soft pliable tip end provided on the introducer minimizes abrasion of the coronary sinus and its opening by the introducer.

Thus, not only does the '268 patent provide exemplary characteristics of a "pliable" inner catheter, St. Jude's own cited prior art provides additional examples of "pliable" catheters and demonstrates that the term "pliable" is commonly used

to describe elements of catheters.[2] The district court erred in failing to address the level of ordinary skill in the art and the pertinent prior art in rendering its indefiniteness determination.

In summary, the district court's erroneous indefiniteness determination should be overturned. This Court should construe the term "pliable" in accordance with its plain and ordinary meaning – ***flexible, easily bent***.

B. The district court erred by characterizing the term "resilient" as a term of degree

The term "resilient" appears in claims 1, 13, 18, and 24. Claim 1 is exemplary, which claims "… an outer, resilient catheter having shape memory…" The specification provides ample support as to what is meant by a "resilient" outer catheter having shape memory. In the same manner as it did with respect to "pliable," the district court erred by characterizing "resilient" as a term of degree. Appx40-42. For example, in support of its indefiniteness determination, the district court stated that "[t]he specification fails to provide objective criteria for measuring resilience." Appx41. But the claims do not require a particular range of resilience, as the district court incorrectly suggests – they simply require a "resilient" outer catheter.

[2] The term "pliable" appears in the claims of more than 8,750 patents. Appx370. This is a commonly used term that should be attributed its plain and ordinary meaning in the context of the '268 patent.

Just as with "pliable," "resilient" should be given its plain and ordinary meaning: ***able to return to its original shape when undistorted***. Thus, in the context of the claim, a person having ordinary skill in the art would understand that an "outer, resilient catheter having shape memory" is a catheter that is able to return to its original shape when undistorted. Indeed, the claims themselves describe the resilient outer catheter as having "shape memory."

The district court erred when analyzing the specification, which provides ample description and explanation to inform a person having ordinary skill in the art what is meant by a "resilient" outer catheter. First and foremost, the '268 patent explicitly recites the plain and ordinary meaning of the term "resilient" in the specification: the outer catheter "has sufficient shape memory to return to its original shape when undistorted." Appx290, 4:21-23. To a person having ordinary skill in the art, a "resilient" outer catheter having shape memory is one that will return to its original shape after being deformed.

Moreover, the specification explains that the outer catheter "has sufficient shape memory to return to its original shape when undistorted," Appx290, 4:21-23, and that the angle of the outer catheter "can be changed by inserting or withdrawing the inner guide." Appx291, 6:6-8. A person having ordinary skill in the art would understand that a "resilient" outer catheter in the context of the '268

patent is one that may be distorted by the insertion of an inner catheter and, upon withdrawal of the inner catheter, will return to its original shape.

The specification offers additional disclosure regarding the functionality and characteristics of a "resilient" outer catheter. For example, one embodiment of the outer catheter "is made of braided silastic or similar material to allow torque control and stiffness." Appx290, 3:10-12. The specification further explains that this stiffness permits the outer catheter "to be manipulated in the right atrium to allow cannulation of the coronary sinus," *Id*., 3:39-41, and that the stiffness "lends support to the pacing lead as it is introduced into the distal coronary sinus." *Id*., 3:41-43.

Still further, the specification describes another embodiment of an outer catheter, stating that the preferred dimensions are "2.9 mm in outer diameter" and "2.6 mm inner diameter." Appx291, 5:3-5. The outer catheter "is relatively stiff and has a braided design, which lends support for one-for-one torque control." *Id*., 5:4-6. "In this respect, it can resemble an angioplasty guiding catheter," *Id*., 5:6-7, an existing catheter that would have been known to a person having ordinary skill in the art. In another embodiment, the outer catheter is "9 French in diameter" and is "60 cm" long. *Id*., 6:32-33. Thus, the specification provides exemplary materials and dimensions, including the thickness and length, of the outer catheter. *See Sonix Tech.*, 844 F.3d at 1377 (finding that the term "visually negligible"

satisfied the definiteness requirements of *Nautilus* where the specification provided examples of noninterfering structures and the criteria for their selection).

Still further, this Court has on numerous occasions addressed claims where the term "resilient" is used consistently with how that term is used in the context of the '268 patent. For example, the claim at issue in *Transtex Inc. v. Laydon Composites Ltd.*, No. 2020-1576, 2021 WL 1115435 (Fed. Cir. Mar. 24, 2021) involved a "resilient strut" that sustained elastic deformation when subjected to a load and then returned to its original shape after the load was removed. This Court did not find "resilient" indefinite. In another example, this Court did not find fault with a claim related to eyeglasses that required temple retainers connected by a "resilient member," which the United States Patent Trial and Appeal Board had interpreted as "having sufficient stiffness to maintain its shape and to return to its original form after being bent." *Cablz, Inc. v. Chums, Inc.*, 708 F. App'x 1006, 1010 (Fed. Cir. 2017). *See also Rawlplug Co. v. Illinois Tool Works, Inc.*, 11 F.3d 1036, 1037 (Fed. Cir. 1993) (describing a claimed shank made of "resilient material" as follows: "This metal shank has a memory such that, when forcibly deformed—e.g., pounded into a hole—it seeks to recover its original bent shape.")

This is just a small sampling of claims involving the term "resilient." A simple search of the USPTO patent database shows that the term "resilient" appears in the claims of over 144,000 patents. Appx370. This term is ubiquitous

in the context of patent claim drafting, and, as the above cited cases and the '268 patent demonstrate, the plain and ordinary meaning of the term "resilient" is well known and definite, i.e., that the object will return to its original shape after deformation. Indeed, the '268 patent explicitly describes the outer catheter in such a manner: the outer catheter "has sufficient shape memory to return to its original shape when undistorted." Appx290, 4:21-23. *See Advanced Aerospace Techs., Inc. v. United States*, 124 Fed. Cl. 282, 294 (2015) ("A patent claim is definite, where a claim term has an objective meaning in the art and the patent uses the term consistently with that meaning.").

In summary, the district court's erroneous indefiniteness determination relating to the term "resilient" should be reversed. This Court should construe the term "resilient" consistent with its plain and ordinary meaning: ***able to return to its original shape when undistorted***. Allowing the district court's approach to stand would cast serious doubt on the validity of any patent that does not disclose a specific numerical range for every modifier used in the claims, potentially invalidating tens of thousands, if not hundreds of thousands, of patents, with respect to the use of "resilient" alone.

II. The district court erred when it granted summary judgment of non-infringement with respect to claim 11

After the district court's determination of indefiniteness with respect to the terms "pliable" and "resilient," which invalidated most claims in the '268 patent,[3] claim 11 was the only claim remaining that NLC had asserted against St. Jude. NLC moved for summary judgment on the issues of infringement and validity. St. Jude moved for summary judgment on the issue of infringement. The district court granted St. Jude's motion, denied NLC's motion as to infringement, and denied NLC's motion as to validity moot in view of the determination of non-infringement.

This Court applies the law of the regional circuit when reviewing a summary judgment decision. The Eighth Circuit reviews *de novo* a grant of summary judgment. *Torgerson v. City of Rochester*, 643 F.3d 1031, 1042 (8th Cir. 2011). On a motion for summary judgment, facts must be viewed in the light most favorable to the nonmoving party only if there is a genuine dispute as to those facts. *Id*. Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge. *Id*.

[3] NLC sought leave to file a motion for reconsideration with respect to the district court's indefiniteness determination, which the district court denied.

The district court's summary judgment decision is premised largely on claim construction issues involving the intrinsic record, which this Court reviews *de novo*. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331, 135 S. Ct. 831, 840–41, 190 L. Ed. 2d 719 (2015). Claim 11 has five steps and is reproduced in its entirety below:

> 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:
>
> [1] inserting the catheter into the coronary sinus;
>
> [2] advancing a guide wire through the catheter into a coronary sinus lateral branch vein;
>
> [3] advancing the inner catheter out of a front end opening of the outer catheter along the guide wire into the branch vein;
>
> [4] inserting the lead through the outer and inner catheters to a target location in the branch vein; and
>
> [5] withdrawing the catheter leaving the lead in the branch vein.

[numbers added here for convenience and reference].

In its summary judgment decision, the district court erroneously construed steps 1, 3, and 5. St. Jude neither identified these claim terms during the parties' exchange of claim construction disclosures, nor asked the district court to construe these terms during claim construction briefing. Instead, in a violation of the

district court's scheduling order regarding the identification of terms for construction by the court, St. Jude presented new claim constructions at the summary judgment stage, as well as new noninfringement arguments based upon those constructions.[4] NLC moved to strike St. Jude's untimely request for these untimely claim constructions arguing that St. Jude had waived them, but the district court, by adopting these constructions, implicitly denied NLC's motion.

The district court abused its discretion by allowing St. Jude to present untimely claim construction arguments at the summary judgment stage and then additionally erred by granting summary judgment based upon those waived arguments. In doing so, it read non-existent limitations into the claim without any basis for doing so. These limitations exclude specific embodiments disclosed in the '268 patent and also ignore common practices in the field.

A. Step 1 (inserting the catheter into the coronary sinus)

Step 1 of claim 11 requires "inserting the catheter into the coronary sinus." The district court previously construed the term "catheter" as the "double catheter" that is recited in the preamble, i.e., the outer catheter and the inner catheter. The

[4] In its non-infringement contentions, St. Jude did not contest that its instructions included Steps 1, 2, 3, and 5. Appx1067. Rather, St. Jude argued that NLC had not identified an instance of direct infringement. Thus, St. Jude waived its new non-infringement positions and new claim construction positions that it first presented at summary judgment. The district court abused its discretion by allowing St. Jude to present these untimely arguments.

"inserting" step should be given its plain and ordinary meaning: ***positioning the outer catheter and inner catheter in the coronary sinus***, whether by sequential insertion (e.g., first inserting the outer catheter and then the inner catheter) or by simultaneous insertion (e.g., inserting the outer catheter and inner catheter together).

The district court, however, adopted a far narrower construction, requiring ***simultaneous*** insertion of the outer catheter and inner catheter into the coronary sinus. Appx262. In other words, the district court's construction requires that the inner catheter must first be placed into the outer catheter, and then both catheters are positioned in the coronary sinus at the same time. This construction is too narrow because it ignores disclosure in the '268 patent whereby the outer catheter and inner catheter are inserted into the coronary sinus in a sequential fashion, i.e., the outer catheter is first inserted into the coronary sinus and then the inner catheter is inserted into the coronary sinus through the outer catheter. Appx291, 5:46-50 (describing how the physician first attempts to cannulate the coronary sinus using the outer catheter alone); 6:13-16 (describing how the outer catheter alone can be used to cannulate the coronary sinus before inserting the inner catheter). *See Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1379 (Fed. Cir. 2014) ("A construction that would exclude the preferred embodiment is rarely, if ever, correct and would require highly persuasive evidentiary support.") [citation and quotation

omitted]. NLC's expert, Dr. Burke, also explained that the '268 patent discloses sequential insertion of the outer and inner catheters into the coronary sinus. Appx2397-2398.

Still further, various purported prior art patents recognize the common practice of inserting two sheaths sequentially. For example, U.S. Patent 6,562,049 to Norlander ("Norlander") explains that "… the two introducer sheaths can be introduced simultaneously or one sheath can [be] introduced prior to the other, e.g., the outer introducer being initially placed to facilitate subsequent placement of the second introducer." Appx319-320, 4:58-5:1. In another example, U.S. Patent 5,935,160 to Auricchio ("Auricchio") discloses sequential insertion of catheters into the coronary sinus. Appx304, 3:22-38. *See Eidos Display, LLC v. AU Optronics Corp.*, 779 F.3d 1360, 1365 (Fed. Cir. 2015) (declining to interpret a claim term in a manner inconsistent with industry practice where the specification offered no indication of intent to deviate from the industry practice).

Claim terms should be given their ordinary and customary meaning as used in the field of invention unless it is clear from the specification and prosecution history that some other definition applies. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The ordinary and customary meaning is the meaning a claim term would have to a skilled artisan at the time of invention—the effective

filing date of the patent application. *Phillips*, 415 F.3d at 1313 (*citing Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116) (Fed. Cir. 2004). Here, the specification of the '268 patent, as well as the purported prior art references, confirm that a person having ordinary skill in the art would understand that "inserting" a double catheter into the coronary sinus may be accomplished by sequentially inserting the outer catheter and then the inner catheter, as this was common practice and expressly disclosed in the '268 patent. The district court failed to construe the "inserting" limitation as it would be understood by a person having ordinary skill in the art – indeed, the district court's summary judgment opinion does not even mention the phrase "ordinary skill in the art."

This Court should construe Step 1 as: ***positioning the outer catheter and inner catheter in the coronary sinus***, without limitation as to whether the catheters are inserted sequentially or simultaneously. It should also vacate the district court's entry of summary judgment based upon the district court's overly narrow construction requiring simultaneous insertion of the outer catheter and inner catheter into the coronary sinus.

Even if the district court's narrow construction stands – which it should not – the district court erred in granting summary judgment that no reasonable juror could find that St. Jude's instructions encourage simultaneous insertion of the outer catheter and inner catheter into the coronary sinus under the district court's narrow

interpretation of the limitation. For example, Step 4 in the Cannulating Catheter section of the instructions states: "Insert the inner catheter into the outer guide catheter, using the inner catheter to facilitate positioning in the coronary sinus." Appx1086. Moreover, NLC's expert, Dr. Burke, testified that this instruction satisfies Step 1 of claim 11. Appx2403. Dr. Burke further testified that a statement in St. Jude's marketing materials also encourages simultaneous insertion. Appx2404 ("When used in conjunction with CPS Direct™ Universal outer guide catheters, CPS Aim™ Universal cannulators facilitate coronary sinus cannulation."). Viewed in the light most favorable to NLC, a reasonable juror could find that St. Jude's instructions and marketing materials encourage simultaneous insertion of the outer catheter and inner catheter into the coronary sinus based upon the evidence of record.[5] At a minimum, the evidence presents a question of fact to be resolved by the jury. The district court's determination with respect Step 1 should be vacated.

B. Step 2 (advancing a guide wire through the catheter into a coronary sinus lateral branch vein) and Step 3 (advancing the inner catheter out a front end opening of the outer catheter along the guide wire into the branch vein)

The district court's ruling on Steps 2 and 3 also turned on a claim construction issue, namely, what it means to "advance" the inner catheter along the

[5] St. Jude did not submit a countervailing expert declaration in support of its positions on summary judgment.

wire into a lateral branch vein as recited in Step 3. The "advancing" limitation of Step 3 should be accorded its appropriate scope and construed as follows: ***moving the inner catheter further into the branch vein along the guide wire***. The initial starting point of the inner catheter (i.e., whether the inner catheter is positioned outside or inside the lateral branch vein) is irrelevant so long as the inner catheter is moved further into the lateral branch vein along the guide wire.

This construction is supported by the '268 patent. For example, the specification describes "advancing" the inner catheter into the coronary sinus as follows: "In that case, inner catheter 12 is gradually advanced until the coronary sinus is cannulated. Once the coronary sinus is cannulated, inner catheter 12 ***is advanced*** as far as it will go ***into*** the coronary sinus and/or great cardiac vein." Appx290, 4:51-55 [emphasis added].[6] Thus, the '268 patent uses the term "advance" to describe moving the inner catheter further into a vein once the inner catheter has been positioned within the vein, analogous to advancing down a hallway by walking further down a hallway after entering it.

The '268 patent also describes situations where it may be difficult to insert the guide wire into the lateral branch vein without assistance from the inner

[6] This language mirrors the language of Step 3, which clearly indicates that the patentee intended "advancing" a catheter within a vein to encompass situations where the catheter is already placed within the vein and then moved further into the vein.

catheter and an obturator (which is not a claim 11 element but is another device similar to a catheter that is nested within the inner catheter). For example, the specification refers to Figure 7 as an example of how to position the inner catheter and the obturator within the lateral branch vein so that the guide wire can be inserted. Appx291, 53-58. Once the guide wire is in place, "inner guide 52, with obturator 53 inside, is then passed through the outer guide 52 [sic] over the 0.038" wire into the target side branch 56." *Id*. The district court's construction precludes this methodology, which is explicitly recited in the specification and shown in the figures.

The guide wire and the inner catheter work together as a system to advance the inner catheter into the lateral branch vein. NLC's expert, Dr. Burke, explained this telescoping action whereby the electrophysiologist moves the guide wire and the inner catheter in a push-pull fashion to advance the inner catheter along the guide wire into the lateral branch vein. Appx2405-2407. Moreover, Dr. Burke testified that a physician who follows St. Jude's instructions will perform the steps of claim 11 in the order recited. Appx2403. The district court did not view this unrebutted evidence[7] in the light most favorable to NLC.

[7] St. Jude did not submit a declaration from either of its experts to rebut Dr. Burke's testimony at summary judgment.

This interplay between Steps 2 (advancing a guide wire through the inner catheter into a coronary sinus lateral branch vein) and Step 3 (advancing the inner catheter out of a front end opening of the outer catheter along the guide wire into the branch vein) is consistent with and supported by the disclosure of the '268 patent.

When appropriately construed, Step 3 is satisfied by simply moving the inner catheter further into the branch vein along the guide wire. St. Jude's instructions direct advancing the inner catheter along a guide wire into a lateral branch vein. Appx2405-2407 (explaining that steps 4-6 of St. Jude's instructions "Subselection Catheter" section describe a telescoping action that will result in the inner catheter being advanced over the guide wire into the branch vein).

The district court, however, narrowly construed the "advancing" limitation of Step 3 to require the inner catheter to be positioned outside of the lateral branch vein prior to commencement of Step 3.[8] Applying this construction, the district court found that St. Jude's instructions directed "advancing" the inner catheter into the lateral branch vein (as set forth in the sub-selecting step of St. Jude's

[8] The district court seems to have equated the term "advancing" with "inserting," which would mean that the inner catheter must begin in a position outside of the lateral branch vein before it is advanced over a guide wire into the lateral branch vein. One analogous example is that a person can only enter a hallway from outside of the hallway. However, a person who is already in a hallway can advance further down the hallway, which is consistent with NLC's construction and the plain meaning of that term.

instructions) before directing insertion of a guide wire into the lateral branch vein. The district court did not consider subsequent advancement of the inner catheter over the guide wire to fall within the scope of Step 3, despite the fact that the specification discloses this exact methodology. Appx291, 5:50-58.

The district court also erred when it held that no reasonable juror could find that St. Jude's instructions encourage use of a guide wire. Appx263. On the contrary, the instructions explicitly recite the use of a guide wire. Appx1087 ("If desired, insert a guidewire… through the inner catheter lumen into the branch vein."). The district court held that St. Jude's statement that a guide wire could be used "if desired" did not constitute recommendation, encouragement, or promotion of the use of a guide wire.[9] *Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1339 (Fed. Cir. 2019) (The question for inducement is "whether the label encourages, recommends, or promotes infringement."). Given the instructions' explicit recitation of a guide wire, whether such recitation constitutes recommendation, encouragement, or promotion of the use of a guide wire is a question of fact that should go to the jury. For this additional reason, the district

[9] NLC presented testimony from St. Jude's 30(b)(6) witness that the instructions were St. Jude's recommendations for how to use the product. Appx2090-2091; Appx2098-2099. The district court did not view this evidence in the light most favorable to NLC.

court's determination of summary judgment as to Steps 2 and 3 of claim 11 should be vacated.

C. Step 5 (withdrawing the catheter leaving the lead in the branch vein)

Similar to the "inserting" limitation of Step 1, the Court narrowly construed the "withdrawing" limitation of Step 5 to require simultaneous withdrawal of the outer catheter and the inner catheter. As with the "inserting" limitation, this limitation should be given its appropriate scope to encompass sequential withdrawal of first the inner catheter and then the outer catheter. In other words, this limitation should be interpreted as ***removing the outer catheter and the inner catheter***, whether simultaneously or sequentially.

The '268 patent does not specifically describe simultaneous or sequential removal of the inner and outer catheters and, as such, does not impart criticality to any particular sequence of removal. NLC provided expert testimony and third-party prior art to demonstrate that catheters are removed by splitting them, or cutting them, as they are withdrawn. Appx2399. This technique requires sequential removal of the catheters because an electrophysiologist can only split one catheter at time. Thus, the inner catheter is typically removed first, and then the outer catheter is removed. *Id*. Moreover, sequential removal of a double catheter is recognized in several of the asserted prior art patents. Appx321 8:15-43; Appx304, 3:22-38.

A person having ordinary skill in the art would understand that "withdrawing the catheter…" simply means ***removing the outer catheter and the inner catheter***. The sequence of this withdrawal is irrelevant insofar as the claim is concerned. However, in practice, withdrawal of such catheter sets is typically performed in a serial fashion rather than simultaneously. At a minimum, one of ordinary skill in the art, when viewing the claims in light of the underlying specification and armed with their own knowledge of the technology, would not have equated "withdrawal" with "simultaneous removal of the outer and inner catheters." The district court erred in artificially narrowing this claim limitation to preclude serial removal of the catheters, and then by granting summary judgment based upon that narrow construction, making no reference to a person having ordinary skill in the art. This Court should construe Step 5 consist with the plain and ordinary meaning of the term as it would have been understood by a person having ordinary skill in the art, and it should vacate the district court's summary judgment determination relating to Step 5.

III. The district court abused its discretion when it precluded NLC's experts from presenting and relying upon certain evidence

After the close of fact discovery, NLC submitted two expert reports in accordance with Rule 26(a)(2)(B), Fed. R. Civ. P., and in compliance with the deadline set forth in the scheduling order: a technical report from Dr. Martin Burke and a damages report from Brad Carlson.

Mr. Carlson identified various license agreements comparable to the technology at issue in this case upon which he relied in forming his opinion as to a reasonable royalty rate. For example, Mr. Carlson explained in his report that "As a means of testing my assertion [as to a reasonable royalty rate], I contacted two firms, Royalty Source and KTMine both of whom collect information regarding licensing transactions from available public sources including filings with the Securities and Exchange Commission." Appx466. "I combined the 53 licensing transactions obtained from the two royalty data sources as presented on Exhibit 1 to this report." *Id*.

As for Dr. Burke, his report included statements that he had used St. Jude's Accused Products in a manner that infringed claim 11. This established that he had knowledge and expertise relative to the accused products, and that he was a direct infringer for purposes of NLC's induced infringement claim with respect to claim 11. For example: "…on numerous occasions I have personally used St. Jude's catheters, leads, and guide wires in a telescoping manner – consistent with St. Jude's instructions and claim 11 of the '268 patent – to implant leads in a branch vein of a coronary sinus." Appx423. Dr. Burke's statements on knowledge of the accused devices and direct infringement appeared on pages 25-26 of his report under Section 6, entitled "Evidence of direct infringement." *Id*.

With respect Mr. Carlson's report, St. Jude moved to preclude him from relying upon the license agreements he identified in the third-party databases, arguing that those agreements should have been disclosed during the fact discovery period. St. Jude similarly moved to preclude Dr. Burke from offering testimony regarding his knowledge and use of the accused devices, arguing that Dr. Burke's this information should have been disclosed during fact discovery. NLC pointed out that it was not aware of these facts during the fact discovery period and could not disclose what it did not know. Appx541-542. Despite this, the district court granted St. Jude's motion and precluded Mr. Carlson from relying upon various license agreements he had identified and Dr. Burke from testifying regarding his knowledge of the accused devices direct infringement of claim 11.

A district court's decision to sanction a litigant under Rule 37 is reviewed for abuse of discretion. *Alexsam, Inc. v. IDT Corp.*, 715 F.3d 1336, 1342 (Fed. Cir. 2013). This Court applies the regional law of the circuit to the issue, which in this instance is the Eighth Circuit. *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002).

In the Eighth Circuit, there are four factors to consider when deciding whether to exclude material that was not disclosed in a timely manner pursuant to Rule 37, Fed. R. Civ. P.: (1) the importance of the excluded material; (2) the explanation for failing to comply with the disclosure rules; (3) potential prejudice

from allowing the material to be used at trial; and (4) the availability of a continuance to cure such prejudice. *See Citizens Bank of Batesville, Arkansas v. Ford Motor Co.*, 16 F.3d 965, 966 (8th Cir. 1994). The district court abused its discretion when it applied these factors and precluded Mr. Carlson from relying upon various license agreements in forming his opinion and Dr. Burke from testifying regarding his direct infringement.

With respect to the first factor, the district court considered the importance of the information as neutral. However, evidence of direct infringement is required to prove inducement, so this factor should weigh against preclusion. The licenses identified by Mr. Carlson supported his royalty analysis, which should also weigh against preclusion.

With respect to the second factor, as the record indicates, NLC did not become aware of these facts until it started working with its experts during the expert phase. Appx541-542. The district court, however, in essence punished NLC for failing to disclose information it did not know and could not have reasonably known at the time. Experts typically rely on a broad range of material when forming their opinions. Damages experts often locate and identify comparable license agreements when determining a reasonable royalty. Here, Mr. Carlson accessed a private license database – to which NLC did not have access – and he identified and disclosed comparable licenses that he relied on in his report.

Applying the district court's approach, an expert would have to write a report before the close of fact discovery so that all facts in the report (including all materials relied upon or consulted) could be disclosed during the fact discovery period. This defies logic and common litigation practice, which typically includes an expert discovery period where parties can request materials relied upon by the expert, which was available to St. Jude in this case. In some district courts, this issue is completely obviated by the practice of closing fact discovery after the deadline for expert reports. Regardless of the actual procedure, NLC was not aware of these facts until after the close of fact discovery, and upon becoming aware of them, disclosed them to St. Jude via expert reports shortly after learning of them. Thus, the second exclusion factor – the reason for the late disclosure – weighs against preclusion as NLC acted reasonably under the circumstances.

With respect to the third factor – potential prejudice to St. Jude – fact discovery closed on September 13, 2019. Appx145. NLC produced its expert reports containing the facts at issue on October 15, 2019, a little more than a month after the close of fact discovery. There was no trial date set at the time. St. Jude had every opportunity to probe these facts during depositions of Dr. Burke (two depositions taken November 12, 2019 and November 19, 2019) and Mr. Carlson (February 5, 2020), precisely the point of the expert discovery phase of the case –

to examine the expert's opinions and the facts relied upon. This factor weighs against preclusion.

Finally, with respect to the fourth factor – the availability of a continuance – there was no trial date scheduled at the time this issue arose. To the extent St. Jude needed to conduct additional third-party discovery to probe the facts disclosed in the reports, there was ample time to do so – and indeed, St. Jude deposed NLC's experts after the disclosure of these facts. The district court noted the expense associated with potential third-party discovery as a basis for precluding the facts, Appx152-153, but St. Jude would have incurred those very same expenses during the fact discovery period had the facts been disclosed before the close of fact discovery. This is not an issue of additional expense. It is an issue of possible delay. But given that the disclosure occurred roughly a month after the close of fact discovery, and given that there was no trial date set, there is no reason that a continuance could not have been available for St. Jude to pursue whatever third-party discovery it believed appropriate.

The district court abused its discretion in precluding Mr. Carlson from relying upon various license agreements that he identified in a private database and Dr. Burke from testifying about his direct infringement of the method claims of the '268 patent. This Court should vacate the district court's order precluding these

facts and allow Mr. Carlson and Dr. Burke to rely upon these facts and present testimony consistent with the full scope of their reports.

IV. The district court abused its discretion when it entered sanctions against NLC based upon Dr. Burke's summary judgment declaration

After the district court entered its December 2, 2019 Exclusion Order, NLC submitted a declaration from Dr. Burke in support of its motion for summary judgment. While Dr. Burke and NLC were mindful of the district court's exclusion order and deliberately avoided making any statements relating to direct infringement, St. Jude nevertheless moved to strike the declaration and requested monetary sanctions. The district court abused its discretion by, after the fact, broadening the scope of the exclusion order to encompass statements from Dr. Burke that were not previously challenged by St. Jude and then sanctioning NLC based upon this broadened scope.

St. Jude's motion to exclude sought ***exclusively*** to preclude statements related to direct infringement by Dr. Burke. Those statements, as identified by St. Jude in its motion, were found in pages 25-26 of Dr. Burke's Report in a section entitled "Evidence of direct infringement." Appx423-424. St. Jude asked the Court to strike "(1) the portions of Dr. Martin Burke's Expert Report ***in which he claims that he is a direct infringer*** of the '268 Patent (Ex. A at 25), and any testimony, opinion, or argument related thereto; (2) the portions of Dr. Martin

Burke's Expert Report referencing undisclosed "interactions," "conversations and experiences with other electrophysiologists" ***as evidence of direct infringement*** of the '268 Patent (Ex. A at 25– 26), and any testimony, opinion, or argument related thereto." Appx394 [emphasis added]. Thus, St. Jude focused only on statements on pages 25 and 26 of Dr. Burke's report.

The district court granted St. Jude's motion in its December 2, 2019 Order and excluded Dr. Burke from presenting such evidence. Despite granting the motion, the district court's oral ruling does not identify any particular statements or sections in Dr. Burke's expert report for exclusion. Nor does the district court's ruling identify any other category of information other than "direct infringement." Thus, the only reasonable interpretation of the district court's order is that the district court granted the relief requested by St. Jude, namely, the preclusion of the identified statements on pages 25-26 of Dr. Burke's report relating to direct infringement.

The district court's ruling explicitly states that it is limited to the issues presented by St. Jude, i.e., precluding Dr. Burke testifying as a fact witness on the issue of direct infringement. For example, the district court stated that "[t]he Court finds that all of the factual disclosures ***at issue*** were untimely produced." Appx150 [emphasis added]. The district court further noted that "had Dr. Burke's ***direct infringement*** been disclosed properly in discovery, St. Jude could and

would have sought documents, communications and testimony related thereto." Appx153 [emphasis added].

In response to the specific scope of St. Jude's motion ("evidence of direct infringement") and the district court's reference only to that issue, NLC and Dr. Burke crafted and submitted a summary judgment declaration that removed the statements relating to direct infringement. Indeed, NLC's summary judgment filing does not present or otherwise rely on Dr. Burke as a fact witness on the issue of direct infringement.

Despite NLC's and Dr. Burke's efforts to comply with the Exclusion Order by removing all references to evidence of direct infringement, St. Jude attacked Dr. Burke's summary judgment declaration with a motion to strike and for sanctions, focusing on statements disclosed in Dr. Burke's expert report that St. Jude ***did not*** challenge in its original motion to strike, i.e., specifically, statements in paragraphs 12, 13, 25, 26, and 28 of Dr. Burke's summary judgment declaration ***that do not relate to direct infringement***.

The district court granted St. Jude's motion for sanctions in its April 30, 2020 Order ("the Sanctions Order"), characterizing its Exclusion Order in terms inconsistent with St. Jude's original motion to strike: "Simply stated, Dr. Burke was precluded from offering testimony of fact in this case because he was not timely disclosed as a fact witness." Appx219. Thus, the district court expanded its

Exclusion Order after-the-fact to go far beyond the issue of direct infringement. In doing so, the district court abused its discretion when it found a "willful" violation – not for submitting the evidence of direct infringement that had been the subject of St. Jude's motion, but for submitting previously unchallenged facts that are little more than background supporting Dr. Burke's qualifications and experience to support his standing as an expert – as required by Rule 26, Fed. R. Civ. P.

In the Eighth Circuit, "[a] bad faith finding is specifically required in order to assess attorneys' fees." *Stevenson*, 354 F.3d at 751. "This bad faith conduct must have practiced a fraud upon the court or defiled 'the temple of justice.'" *Id*. [citation omitted]. The district court made no finding of bad faith on the part of NLC. On the contrary, the district court explicitly found that there was ***no*** bad faith: "This does not mean that there was bad faith. I believe Mr. Griggs that he did not intent to practice a fraud upon the Court." Appx219-220. Despite this, the district court sanctioned NLC in the amount of $35,985.75. This was an abuse of discretion. The district court's order on sanctions and subsequent fee award should be vacated.

Alternatively, the district court abused its discretion by sanctioning NLC for violating an order that was unclear and ambiguous. The district court did not specifically identify which portions of the report were excluded, and St. Jude only asked for statements on pages 25-26 relating to direct infringement to be stricken.

To the extent the district court subsequently interpreted its oral ruling to extend beyond the relief requested by St. Jude – which is precisely how the district court interpreted the ruling when sanctioning NLC – the Exclusion Order is unclear and ambiguous and cannot be the basis for sanctions.

"[A] party commits a willful violation when he or she takes an action that he knew or ... should have known, to be contrary to a court order." *Pyramid Real Estate Servs., LLC v. United States*, 95 Fed. Cl. 613, 623 (2010) [citations and quotations omitted]. However, "[a] district court may punish for disobedience of an order only if the order is clear and unambiguous. *Fonar Corp. v. Deccaid Servs., Inc.*, 983 F.2d 427, 429 (2d Cir. 1993); *see also Pascale v. G. D. Searle & Co.*, 90 F.R.D. 55, 59 (D.R.I. 1981) ("Considering the ambiguous nature of the June 12 order, that part of the November 3 order imposing sanctions is not 'just'; it is therefore contrary to law, and is hereby vacated."); *Joint Stock Co. Channel One Russia Worldwide v. Infomir LLC*, 2017 WL 3671036, at *21 (S.D.N.Y. July 18, 2017), report and recommendation adopted, 2017 WL 4712639 (S.D.N.Y. Sept. 28, 2017) ("Noncompliance with discovery orders is considered willful ***when the court's orders have been clear***, when the party has understood them, and when the party's noncompliance is not due to factors beyond the party's control.") [emphasis added].

St. Jude's original motion to exclude was directed to Dr. Burke's testimony as a fact witness on the issue of direct infringement. In granting St. Jude's motion, the district court's Exclusion Order did not explicitly identify any statements to be stricken from Dr. Burke's report. Rather, it simply granted St. Jude's motion, which sought to strike portions of statements on pages 25-26 of Dr. Burke's report (though St. Jude did not explicitly identify which portions it sought to strike).

Despite this obvious ambiguity, and the district court's subsequent expansion (or expansive interpretation) of its Exclusion Order, NLC was found to have willfully disobeyed the Exclusion Order. Demonstrating the district court's fluid interpretation of its ruling, and NLC and counsel's difficulties in understanding and complying with the district court's order, the district court struck paragraph 20 of Dr. Burke's declaration in its entirety, even though this statement in Dr. Burke's report (Appx418-419) ***was not challenged by St. Jude in either its original motion to strike or in its motion for sanctions***. Nor were the statements in this paragraph identified or seemingly encompassed in either the district court's Exclusion Order or in its Sanctions Order. Why would NLC – or any objective reviewer of the record – believe that Dr. Burke would be precluded from making these previously unchallenged statements? And, more importantly, how can the submission of these statements be considered "willful disobedience"

of the district court's Exclusion Order given that the motion by St. Jude and the district court's prior statements all focused on "evidence of direct infringement?"

The scope of the district court's Exclusion Order became a moving target, having been greatly expanded (or interpreted in a greatly expanded manner) after the fact. Given that, it cannot objectively be characterized as "clear and unambiguous." *See Fonar*, 983 F.2d at 429. The Exclusion Order did not explicitly identify any statements in Dr. Burke's report that were excluded. Moreover, the district court's subsequent interpretation of its Exclusion Order as precluding Dr. Burke from testifying as to ***any*** facts is inconsistent with the issues raised and relief requested by St. Jude. Appx219 ("The Court finds that the insertion of facts into the Burke declaration violates this Court's [Exclusion] order.").

Accordingly, the district court's characterization of the Exclusion Order as "clear" (Appx219), and the resultant sanctions from the ambiguous Exclusion Order, are an abuse of discretion. *See Fonar* (sanctions cannot be predicated on an order that is unclear or ambiguous).

V. The district court abused its discretion when it excluded Mr. Carlson from opining as to the appropriate royalty base

This Court applies the law of the regional circuit when reviewing a district court's decision to exclude expert testimony from trial. *Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1391 (Fed. Cir. 2003). The Eighth Circuit reviews a

district court's determination to exclude expert testimony at trial for an abuse of discretion. *Lauzon v. Senco Prod., Inc.*, 270 F.3d 681, 685 (8th Cir. 2001).

Mr. Carlson offered an opinion on damages for infringement of claim 11 of the '268 patent – a method claim directed to a procedure for implanting a pacing lead into a lateral branch vein through the coronary sinus. He ultimately concluded that a reasonable range for a royalty was 6.0% to 16.63%, with a recommended royalty of 9.9% based upon the analysis contained in his report. Appx728. As for the royalty base, claim 11 recites four components necessary to perform the method – an outer catheter, an inner catheter, a lead, and a guide wire. Mr. Carlson offered an opinion that the royalty base for infringement of claim 11 should include these four components.

St. Jude moved to exclude NLC's damages expert, Mr. Carlson, from presenting any damages opinions at trial. The district court granted the motion in part, ruling that "[Mr.] Carlson's opinions and testimony as to the royalty base [for claim 11] are inadmissible." Appx251. In other words, the district court ruled that Mr. Carlson could not opine that the royalty base for infringement of claim 11 should include the four components recited in the claim: an outer catheter, an inner catheter, a lead, and a guide wire.[10] The district court's exclusion of Mr. Carlson's

[10] The district court denied St. Jude's motion with respect to Mr. Carlson's opinion as to a royalty rate.

opinion is an abuse of discretion because the district court misapplied applicable patent law principles and because its determination is contrary to the plain language of the claim.

The district court's error flowed from its focus on the principle of apportionment, which attempts to separate the value of the patented features from the value of the unpatented features. For example, the district court held that "Carlson did not even attempt to identify, let alone subtract, the value of any unpatented aspects of the four components that comprise his definition of the royalty base." Appx248. But this is not a product claim. It is a method claim directed to a method for implanting a pacing lead. There are no "patented features" or "unpatented features" of the four recited components – they are simply workpieces used to perform a process.

The district court also made the puzzling statement that "although leads are recited in claim 11, the '268 patent does not teach or disclose leads." *Id*. On the contrary, the '268 patent discusses pacing leads throughout the specification, and leads are clearly shown in various figures. Appx290, 3:29-31 ("Valve 14 prevents leakage of blood when a 5 French pacing lead is introduced through the inner catheter 12 into the coronary system."); Appx288 (Fig. 8 showing electrical lead 83), and Appx291, 5:46-64 (referring to Fig. 8 and discussing implantation of a lead).

The district court then concluded that "[t]he entirety of the '268 Patent's scope is limited to a 'double catheter' for use in the 'coronary sinus.'" Appx248. "This scope does not include leads." *Id*. "As such, Carlson's royalty base accounts for more than the *method* claimed." *Id*. [emphasis in original]. The district court's erroneous statements cannot be reconciled with the disclosure in the '268 patent – which includes a detailed description of a method for implanting a pacing lead and a figure directed to the same – and with the plain language of claim 11 itself – which is directed to "[a] method for placing an electrical lead in a lateral branch of a coronary sinus vein…" and recites a lead as a component that is necessary to perform the method.

This Court has held that it is appropriate to include conventional features in a royalty base:

> On appeal, Briggs argues that Exmark's expert should have apportioned or separated the value of the baffle from the other features of the mower through the royalty base rather than the royalty rate. We disagree. We have held that apportionment can be addressed in a variety of ways, including "by careful selection of the royalty base to reflect the value added by the patented feature [or] ... by adjustment of the royalty rate so as to discount the value of a product's non-patented features; or by a combination thereof." Ericsson, 773 F.3d at 1226. So 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. (citing Garretson, 111 U.S. at 121, 4 S.Ct. 291). "The essential requirement is that the ultimate reasonable royalty award must be based on the incremental value that the patented invention adds to the end product." Id.

Exmark Mfg. Co. Inc. v. Briggs & Stratton Power Prod. Grp., LLC, 879 F.3d 1332, 1348 (Fed. Cir. 2018).

Thus, even if the district court was correct in its statement that the scope of the '268 patent "does not include leads," it is not *per se* improper to include leads in the royalty base. However, just as the claim in *Exmark* recited a mower, which was appropriately included in the royalty base, claim 11 at issue here recites a lead, which likewise can permissibly be included in the royalty base.

Moreover, this Court has recognized the common practice of using per-unit royalties as an appropriate measure for the use of a technology:

> This court has noted the common (not universal) economic justifications for using per-unit royalties for measuring the value of use of a technology: doing so ties compensation paid to revealed marketplace success, minimizing under- and over-payment risks from lump-sum payments agreed to in advance.

Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd., 807 F.3d 1283, 1304 (Fed. Cir. 2015).

The district court also took issue with Mr. Carlson's analysis, stating that "Carlson's calculation of the royalty rate expressly does not discount the value of the non-patented features of an inner catheter, outer catheter, guide wire, or lead…" Appx251. However, in his report Mr. Carlson noted his assumption that "NLC's expert will provide testimony explaining that the method claims are infringed when a lead is implanted in accordance with St. Jude's instructions, and that the claimed method is the predominant implantation method that is utilized when implanting leads with a telescoping system." Appx716.

Thus, Mr. Carlson did consider non-patented aspects or alternatives to the method of claim 11 when he relied upon testimony that the claimed method was the "predominant" method employed by electrophysiologists. Mr. Carlson's reliance on NLC's technical expert is not a flaw in his analysis. The district court abused its discretion by playing the role of the fact finder and rejecting the premise that the claimed method is the predominant implantation method. This is a question of fact for the jury to resolve. Moreover, this is precisely why Mr. Carlson offered a range for a reasonable royalty rate – to accommodate the resolution of factual disputes that may move the rate higher or lower.

The district court abused its discretion by ruling that Mr. Carlson could not offer an opinion as to the royalty base for infringement of the method claims. This

Court should reverse the district court and allow Mr. Carlson to offer the opinions disclosed in his report.

Conclusion

WHEREOFRE, Plaintiff-Appellant NLC respectfully requests that this Court:

1. REVERSE the district court's indefiniteness determination with respect to the terms "pliable" and "resilient" and CONSTRUE those terms consistent with their plain and ordinary meaning;
2. VACATE the district's court summary judgment determination and CONSTRUE the "inserting," "advancing," and "withdrawing" steps consistent with their plain and ordinary meaning as would be understood by a person having ordinary skill in the art;
3. REVERSE the district court's order precluding from Mr. Carlson from relying upon the third-party licenses identified in his original report and precluding Dr. Burke from presenting testimony about his use of the accused devices and direct infringement;
4. REVERSE the district court's sanctions order;
5. REVERSE the district court's order precluding Mr. Carlson from presenting an opinion as to which devices should be included in the royalty base; and

6. REMAND the case to the district court to proceed in a manner consistent with this Court's rulings.

Dated: June 21, 2021

s/Michael T. Griggs

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Date: June 21, 2021

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