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

Appeal from the United States District Court for the District of Minnesota in Case No. 17-CV-5096,

Judge Wilhelmina M. Wright

CORRECTED BRIEF OF PLAINTIFF-APPELLANT

Michael T. Griggs
Adam L. Brookman
Timothy E. Newholm
Marriam Lin
Boyle Fredrickson, S.C.
840 N. Plankinton Avenue
Milwaukee, WI 53203
(414) 225-9755

Attorneys for Plaintiff-Appellant
Niazi Licensing Corporation

June 21, 2021

CLAIMS AT ISSUE

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.

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.

13. An outer catheter configured for use with an inner, pliable catheter which can be 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, the outer catheter comprising a resilient tube having shape memory and sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus, and having a hook-shaped distal end wherein a first bend adjoining a straight, proximal portion of the outer catheter is in the range of 130° to 180°, a second, intermediate bend is in the range of 75° to 100° in a direction opposite the first bend, and a third bend nearest the distal end of the outer catheter in the same direction as the second bend is in the range of to 130° to 175°.

18. A double catheter, comprising:

an outer catheter comprising a resilient tube having shape memory and sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus, and having a hook-shaped distal end wherein a first bend adjoining a straight, proximal portion of the outer catheter is in the range of 130° to 180°, a second, intermediate bend is in the range of 75° to 100° in a direction opposite the first bend, and a third bend nearest the distal end of the outer catheter in the same direction as the second bend is in the range of to 130° to 175°, and

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, wherein the inner catheter has an internal lumen suitable for the introduction of a fluid therethrough and a hemostatic valve at a proximal end thereof that prevents leakage of blood when a pacing lead is introduced through the inner catheter into the coronary system.

24. A method for placing a electrical lead in a lateral branch of a coronary sinus vein using a double catheter including an outer catheter comprising a resilient tube having shape memory and sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus, and having a hook-shaped distal end, and 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 method 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.

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.

5. None.

6. None.

June 21, 2021

/s/Michael T. Griggs
Michael T. Griggs
Attorney for Plaintiff-Appellant

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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.

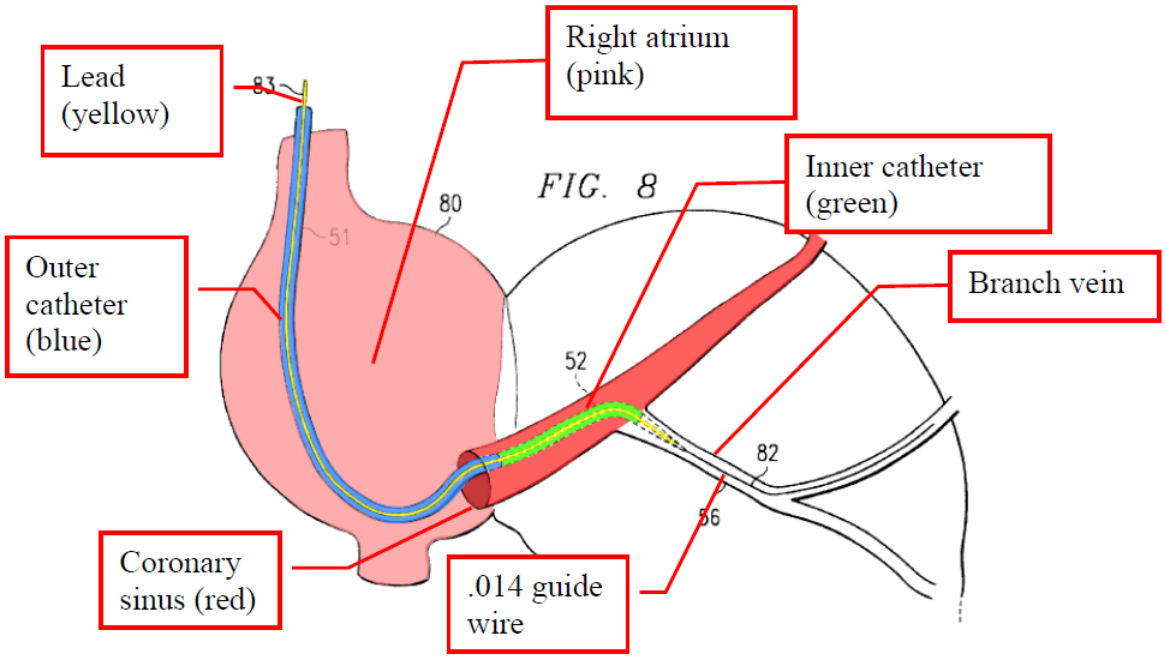


FIG. 8

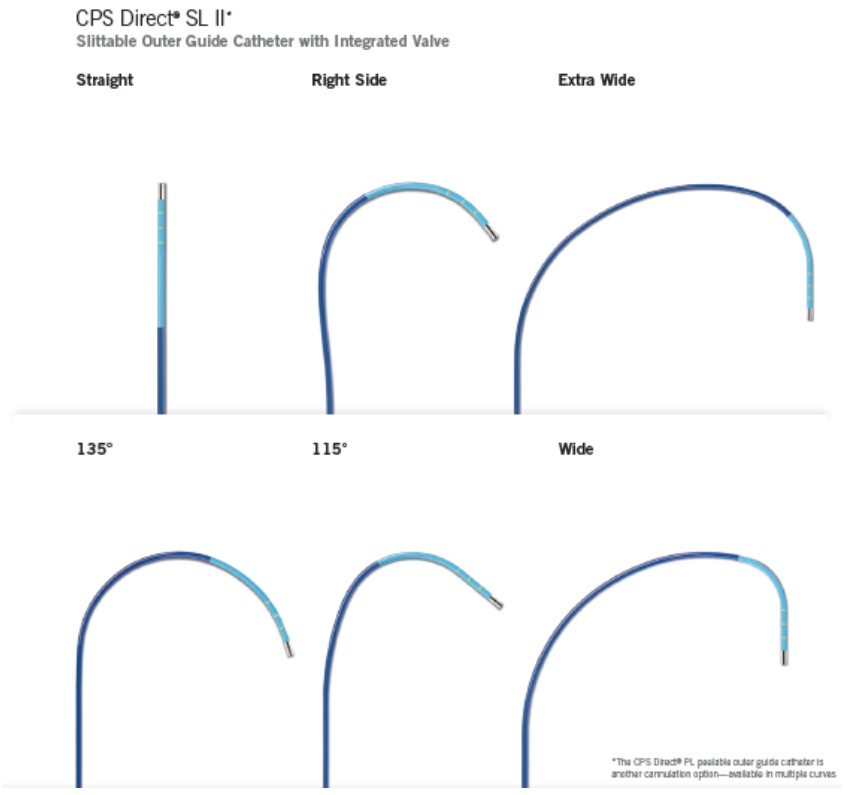
Once the coronary sinus has been cannulated, the inner catheter (green) is advanced into a lateral branch vein to support and guide a pacing lead (yellow) for implantation in the lateral branch vein. The lead and catheters are typically advanced along a guide wire because the typical lead is an over-the-wire 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

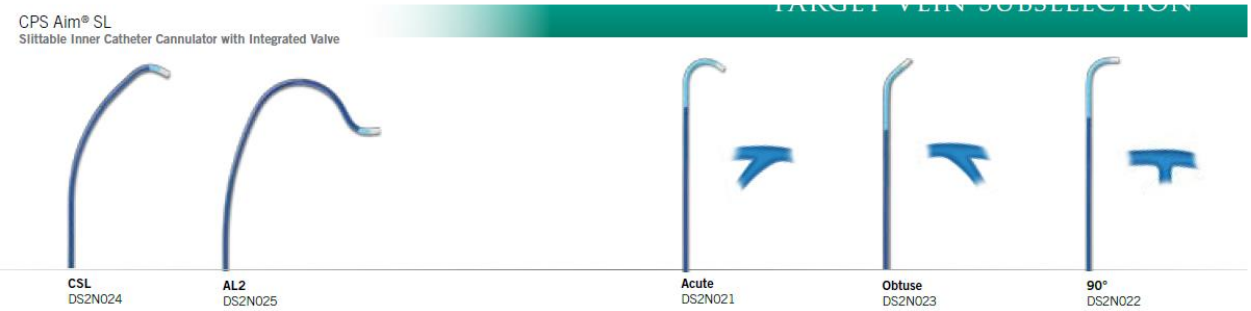
during the procedure to facilitate cannulation of the coronary sinus. Further, the flexible inner catheter is able to access a lateral branch vein to help guide the lead to a desired location.

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

WHEREFORE, 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
Michael T. Griggs
Adam L. Brookman
Timothy E. Newholm
Marriam Lin
Boyle Fredrickson, S.C.
840 N. Plankinton Avenue
Milwaukee, WI 53203
(414) 225-9755

Attorneys for Plaintiff-Appellant Niazi Licensing Corporation

Addendum

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Niazi Licensing Corporation,

Plaintiff,

v.

Boston Scientific Corp.,

Defendant.

Case No. 17-cv-5094 (WMW/BRT)

ORDER

Niazi Licensing Corporation,

Plaintiff,

v.

St. Jude Medical S.C., Inc.,

Defendant.

Case No. 17-cv-5096 (WMW/BRT)

ORDER

Plaintiff Niazi Licensing Corporation (Niazi) commenced these patent-infringement actions against Defendants Boston Scientific Corp. (Boston Scientific) and St. Jude Medical S.C., Inc. (St. Jude), alleging that Defendants have infringed claims in United States Patent No. 6,638,268 (the '268 Patent), titled "Catheter to Cannulate the Coronary Sinus." Pending before the Court are St. Jude's motion to strike Niazi's infringement contentions, Boston Scientific's motion to exclude evidence, and the parties' requests for the construction of disputed claim terms in the '268 Patent. (Case No. 17-cv-5094, Dkts. 56, 83; Case No. 17-cv-5096, Dkts. 67, 78.) For the reasons addressed below, the Court

denies the motion to strike and the motion to exclude evidence and resolves the claim construction disputes as described herein.

BACKGROUND

Niazi, a Washington corporation with its principal place of business in Wisconsin, owns the '268 Patent at issue here. Both Boston Scientific and St. Jude manufacture and sell medical devices. Boston Scientific is a Delaware corporation with its principal place of business in Massachusetts. St. Jude is a Minnesota corporation with its principal place of business in Texas.

The '268 Patent, issued on October 28, 2003, pertains to a catheter system that can be inserted into the coronary sinus of the heart. This catheter system allows medical professionals to administer fluids and introduce pacing leads to the coronary sinus. Although the use of catheters in general was well established by 2003, the '268 Patent describes an invention that, based on its structure and shape, purportedly is better suited for "use in the coronary sinus, especially in patients suffering from congestive heart failure." As relevant here, the '268 Patent claims a double catheter system with an "outer, resilient catheter having shape memory and a hook shaped distal end" and an "inner, pliable catheter slidably disposed in the outer catheter." The '268 Patent also claims methods of using the catheter system.

Niazi initiated these patent-infringement lawsuits against Boston Scientific and St. Jude on November 13, 2017. Niazi alleges that both Boston Scientific and St. Jude have infringed—either literally or through the doctrine of equivalents—the '268 Patent. Niazi alleges that Boston Scientific and St. Jude have directly infringed the '268 Patent by

using, manufacturing, selling, or offering to sell infringing catheter systems. Niazi also alleges that both Defendants have indirectly infringed the '268 Patent by inducing its customers—namely, medical professionals—to infringe the '268 Patent.

The '268 Patent includes 27 claims, some of which are directed to configurations of the catheters and others that are directed to the method of using the catheter system. Niazi alleges that Boston Scientific infringes 11 claims in the '268 Patent: independent Claims 1, 11, 13, 18, and 24 and dependent Claims 10, 14, 19, 23, 25, and 26. Niazi also alleges that St. Jude infringes those same claims, as well as dependent Claims 15 and 27.

ANALYSIS

Before the Court are St. Jude's motion to strike Niazi's infringement contentions, Boston Scientific's motion to exclude evidence, and the parties' requests for claim construction. The Court addresses each, in turn.

I. St. Jude's Motion to Strike

Pursuant to Local Rule 26.1 and the February 22, 2019 Scheduling Order, (Case No. 17-cv-5096, Dkt. 65), Niazi submitted infringement contentions in advance of the claim-construction hearing. St. Jude moves to strike these infringement contentions, arguing that Niazi fails to identify an act of direct or indirect infringement.[1]

[1] St. Jude also alleges that Niazi is arbitrarily applying claim language to force infringement. Specifically, St. Jude argues that the word "bend" in the '268 Patent is indefinite. An argument of this nature—that a term is indefinite—is an argument for claim construction. *See Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1311 (Fed. Cir. 2012). The Court's claim-construction analysis is in Part II of this Order.

A motion to strike generally is brought under Rule 12(f), Fed. R. Civ. P., which provides that a "court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Here, St. Jude is not moving to strike *pleadings*, but rather infringement contentions. In support of its motion, St. Jude relies on Federal Rules of Civil Procedure 16(f) and 41. When a party "fails to obey a scheduling or other pretrial order," a district court may issue sanctions. Fed. R. Civ. P. 16(f); *accord O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1363 (Fed. Cir. 2006) (holding that a federal district court "may impose any just sanction for the failure to obey a scheduling order" (internal quotation marks omitted)). Similarly, when a plaintiff fails to comply with the Federal Rules of Civil Procedure or a court order, "a defendant may move to dismiss the action or any claim against it." Fed. R. Civ. P. 41(b).

St. Jude contends that Niazi's infringement contentions violate the February 22, 2019 Scheduling Order. St. Jude does not argue that Niazi's infringement contentions are untimely, but instead argues that the infringement contentions are *substantively* deficient. Nothing in Rule 16(f), Rule 41(b), or any case to which St. Jude cites contemplates that such a deficiency is a violation of a *scheduling* order. Moreover, the authority on which St. Jude relies provides, at most, that a district court has the *discretion* to impose sanctions if it determines that the infringement contentions violate a court order. Under the circumstances presented here, the Court declines to strike Niazi's allegedly deficient infringement contentions.

Accordingly, St. Jude's motion to strike is denied.

II. Claim Construction

Niazi alleges that St. Jude and Boston Scientific have infringed the '268 Patent. The parties request construction of 21 terms or phrases that are found within the claims at issue.

A patent is infringed by "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a). Courts employ a two-step analysis when making an infringement determination. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must construe the asserted claims of the patent to ascertain their meaning and scope. *See id.* Second, the fact finder must compare the construed claims with the accused product. *See id.* at 976. Only the first step of this analysis—claim construction—presently is at issue.

A district court's duty when performing claim construction is "to resolve a dispute about claim scope that has been raised by the parties." *Eon Corp. IP Holdings v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1319 (Fed. Cir. 2016). This duty resides with the court because "the ultimate question of construction [is] a legal question." *Id.* at 1318 (alternation in original) (quoting *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 842 (2015)).

It also is appropriate at this stage for a district court to determine whether a disputed claim complies with the definiteness requirement of Title 35, United States Code, Section 112(b). *See Noah Sys.*, 675 F.3d at 1311 (holding that a determination of indefiniteness is "a matter of claim construction"). Section 112(b) provides that patent claims must "particularly point[ ] out and distinctly claim[ ] the subject matter which the inventor . . .

regards as the invention." 35 U.S.C. § 112(b). A party asserting that a claim is indefinite must show by clear and convincing evidence that the claim is indefinite. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017). An indefiniteness ruling renders a claim invalid as a matter of law. *See, e.g.*, *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 906 (2014); *Maurice Mitchell Innovations, L.P. v. Intel Corp.*, 249 F. App'x 184, 186 (Fed. Cir. 2007).

When engaging in claim construction, a district court must construe the claims "independent of the accused product, in light of the specification, the prosecution history, and the prior art." *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000) (per curiam) (internal quotation marks omitted). Although it is appropriate for a court to consider the accused device when determining *which* aspects of the patent claim should be construed, the claim itself "is construed in the light of the claim language . . . *not* in light of the accused device." *Exigent Tech., Inc. v. Atrana Sols., Inc.*, 442 F.3d 1301, 1309 n.10 (Fed. Cir. 2006) (internal quotation marks omitted). Claim construction merely elaborates the normally terse claim language "in order to understand and explain, but not to change, the scope of the claims." *Embrex*, 216 F.3d at 1347 (internal quotation marks omitted).

A district court's claim-construction analysis begins by focusing on the words of the claims. "It is a bedrock principle of patent law that the claims of the patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). A construction that gives meaning to all claim terms is preferred. *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005). Because claim terms often are used "consistently

throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Phillips*, 415 F.3d at 1314. And the doctrine of claim differentiation creates a presumption that the use of different terms in a patent claim connotes that those terms should be ascribed different meanings. *See Chi. Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1369 (Fed. Cir. 2012).

Courts generally give the words in a patent claim their ordinary and customary meaning at the time of the invention. *Phillips*, 415 F.3d at 1313. The ordinary and customary meaning of a claim term is the meaning that would have been understood by a person of ordinary skill in the field of technology in question. *Id.* As the Federal Circuit has explained:

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention—the inventor's lexicography—must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, *viz.*, the patent specification and the prosecution history.

Id. (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). "In some cases, the ordinary meaning of claim language . . . may be readily apparent even to lay judges, and claim construction in such cases involves little more than application of the widely accepted meaning of commonly understood words." *Id.* at 1314. Courts are mindful that "a sound claim construction need not always purge every shred of ambiguity. The resolution of some line-drawing problems—especially easy ones . . . —is

properly left to the trier of fact." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007).

The patent specification, the written description of the invention, must be "clear and complete enough to enable those of ordinary skill in the art to make and use" the invention. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The "specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted). When the specification indicates "a special definition given to a claim term by the patentee that differs from the meaning [the claim term] would otherwise possess," the inventor's lexicography governs. *Id.* at 1316. But a court may not import limitations from the written description into the claims. *Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1347 (Fed. Cir. 1998). For this reason, the disclosure of a particular embodiment of the claimed invention in the specification does not narrow the patent claims. *Id.* at 1347-48.

As with the specification, the patent's prosecution history may be used to understand the claim terms, but this history cannot enlarge, diminish, or vary the claim limitations. *Markman*, 52 F.3d at 980. Similarly, extrinsic evidence may be consulted when necessary to resolve an ambiguity that cannot be resolved by consulting the intrinsic evidence. *See Vitronics*, 90 F.3d at 1583. But extrinsic evidence cannot be used to vary or contradict the terms of the claims. *Markman*, 52 F.3d at 981.

With these legal standards in mind, the Court addresses the disputed claim terms.[2]

A. Inner, Pliable Catheter

Independent Claims 1, 13, 18, and 24 of the '268 Patent contain the phrase "inner, pliable catheter." For example, Claim 1 recites:

> 1. A double catheter, comprising:
>
> . . .
>
> 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 . . .

(Emphasis added.) St. Jude and Boston Scientific argue that the phrase "inner, pliable catheter" renders Claims 1, 13, 18, and 24, and the claims that depend on them, invalid as

[2] Boston Scientific moves to exclude two pieces of evidence with respect to the claim-construction proceedings: the Patent Trial and Appeal Board's Decision on Institution of *Inter Partes* Review in a related case involving Medtronic, Inc., and a declaration of Dr. Imran Niazi. Boston Scientific first argues that Dr. Niazi disclosed the evidence in an untimely manner. A party may not rely on evidence that was disclosed in an untimely manner unless the failure to disclose "was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). Assuming without deciding that the evidence was untimely, the disclosure nonetheless is harmless. The record establishes that Boston Scientific was aware or should have been aware of the underlying substance of both pieces of evidence at the outset of claim-construction briefing. Boston Scientific also argues in favor of excluding Dr. Niazi's declaration, alleging that Dr. Niazi is a biased witness. Mindful that an inventor's testimony "as to the inventor's subjective intent is irrelevant to the issue of claim construction," *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1347 (Fed. Cir. 2008), the Court considers Dr. Niazi's declaration only to the extent that the declaration addresses the state of the art and other objective matters. Finally, Boston Scientific argues that Dr. Niazi's declaration is unsigned. But the record does not support this allegation. For these reasons, Boston Scientific's motion to exclude evidence is denied.

indefinite as a matter of law.[3] Niazi counters that this phrase is definite and proposes that this phrase be construed to mean "a catheter that is easily bent, flexible."

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 572 U.S. at 901. This legal standard arises from the requirement of public notice. "[A] patent must be precise enough to afford clear notice of what is claimed, thereby appris[ing] the public of what is still open" to the public. *Id.* at 909 (alteration in original) (internal quotation marks omitted). Failure to do so would create a "zone of uncertainty" that would discourage further innovation. *Id.* at 911 (internal quotation marks omitted).

Although a claim need not rise to the level of "absolute or mathematical precision," the claim must delineate "objective boundaries for those of skill in the art" when read in light of the specification and the prosecution history. *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370-71 (Fed. Cir. 2014). "Even if a claim term's definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008).

The Court of Appeals for the Federal Circuit recently clarified the distinction between definite and indefinite terms. In *Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, the Federal Circuit held that the term "visually negligible" was definite because the patent specification

[3] Alternatively, Boston Scientific contends that, if this phrase is amenable to construction, it should be construed as an "inner catheter that lacks braiding."

included a general design of a visually negligible indicator, two specific examples of such indicators, and objective requirements for one of skill in the art to measure negligibility. *See* 844 F.3d 1370, 1378 (Fed. Cir. 2017). In contrast, the Federal Circuit held the terms "aesthetically pleasing" and "in an unobtrusive manner that does not distract a user" to be indefinite because those terms turned on an individual's subjective opinion. *See id.* at 1378-79 (distinguishing the facts of *Sonix* from *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342 (Fed. Cir. 2005) and *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364 (Fed. Cir. 2014)). Moreover, the respective patent specifications for those indefinite terms lacked detailed examples and did not provide objective factors on which a person of skill in the art could rely. *See id.*

Here, the disputed claim term, "inner, pliable catheter," does not provide a "meaningfully precise claim scope" on its face. *See Halliburton Energy*, 514 F.3d at 1251. As such, the Court looks to the specification to determine whether the '268 Patent establishes objective boundaries for this disputed term. The specification describes the inner catheter as being "made of a soft, pliable material such as silicone" and as "extremely flexible." Elsewhere, the specification states that the inner catheter "preferably ha[s] a predetermined shape and a *certain degree of stiff[n]ess* to maintain such shape during manipulation in the heart, *but still flexible enough to bend when required*." (Emphasis added.)

These descriptors do not establish objective boundaries as to the range of pliability being claimed. Instead, the specification creates a "zone of uncertainty." *See Nautilus*, 572 U.S. at 911. The inner catheter is both "extremely flexible" and preferably has "a

certain degree of stiff[n]ess." Although 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."

Niazi maintains that "inner, pliable catheter" is a definite term, relying on *McCreary v. United States*, 35 Fed. Cl. 533, 556-57 (1996). Setting aside *McCreary*'s lack of precedential value, the reasoning applied in *McCreary* undermines Niazi's argument. In *McCreary*, the court construed the disputed term "flexible." After observing that the plain meaning of "flexible" is "pliable," the *McCreary* court concluded that the definition was "not particularly helpful because the dispute between the parties is over *how* flexible or pliable the [claimed invention] must be." *Id.* at 556. The court then considered the specification for further guidance and ultimately determined a construction of the term. Here, as in *McCreary*, the amount of pliability is at issue. But, for the reasons addressed above, the specification of the '268 Patent fails to provide objective boundaries or other sufficient guidance for the scope of the term.

The record contains clear and convincing evidence that the term "inner, pliable catheter" renders the claims in which it is found invalid as indefinite.

B. Outer, Resilient Catheter and Resilient Tube

Independent Claims 1, 13, 18, and 24 include the term "resilient" in the context of an "outer, resilient catheter" or a "resilient tube." For example, Claim 1 recites:

> 1. A double catheter, comprising:
>
> an **outer, resilient catheter** having shape memory and a hood shaped distal end configured for cannulation of the coronary sinus with at least one curved bend . . .

(Emphasis added.) St. Jude and Boston Scientific argue that the term "resilient" also renders independent Claims 1, 13, 18, and 24, and their dependent claims, invalid as indefinite.[4] Niazi contends that the Court should give "resilient" its plain and ordinary meaning, namely, "able to return to its original shape when undistorted."

As with "pliable," the term "resilient" does not, on its face, provide clear notice of the scope of the claim. Because indefiniteness is determined by looking to the claims in light of the specification, the Court once again turns to the specification of the '268 Patent. *See Nautilus*, 572 U.S. at 901.

The specification explains that the outer catheter (or tube) is "relatively stiff," has a "braided design," and is "made of a braided silastic or similar material to allow torque control and stiffness." The specification then provides that the outer catheter "preferably ha[s] a predetermined shape and a certain degree of stiff[n]ess to maintain such shape during manipulation in the heart, but still flexible enough to bend when required." The specification fails to provide objective criteria for measuring resilience. And the example of a "braided silastic or similar material" does not provide meaningful notice to the public as to what the '268 Patent claims as the scope of its invention.

[4] Alternatively, Boston Scientific argues that, if the term "resilient" can be construed, it should be defined as "braided."

Accordingly, the record establishes by clear and convincing evidence that "resilient"—as used in the terms "outer, resilient catheter" and "resilient tube"—renders the claims in which it is found indefinite.[5]

In light of the Court's conclusions, "pliable" and "resilient" render Claims 1, 13, 18, and 24 invalid as indefinite. Because Claims 14, 15, 19, 23, 25, 26, and 27 depend on Claims 1, 13, 18, and 24, these dependent claims also are indefinite. *See Soverain Software LLC v. Newegg Inc.*, 728 F.3d 1332, 1335-36 (Fed. Cir. 2013) (per curiam) (explaining presumption that, unless parties specifically present a basis for distinguishing a dependent claim from its corresponding independent claim, the claims "rise or fall together"). Having determined that the claims are indefinite on the foregoing grounds, the Court need not address the merits of Defendants' remaining claim-construction arguments with respect to these claims. *See Noah Sys.*, 675 F.3d at 1307 n.3 (declining to reach the merits of party's alternative grounds for indefiniteness of claims).

C. The Catheter

In light of the above analysis, only Claim 11 remains as asserted against St. Jude and Boston Scientific. The parties dispute the construction of the term "the catheter," as found in Claim 11, which provides:

[5] In support of its argument that "resilient" is a definite term, Niazi contends that this term has been used in other patents. *See, e.g.*, *Cablz, Inc. v. Chums, Inc.*, 708 F. App'x 1006, 1010 (Fed. Cir. 2017). That the term may be found in other patents, however, is not determinative here. The Court does not hold that the term "resilient" is indefinite *per se*. Rather, the '268 Patent does not contain clear, objective parameters that put the public on notice of what is being claimed as "resilient."

> 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.

(Emphasis added.) St. Jude contends that the term "the catheter" renders Claim 11 invalid as indefinite because "the catheter" lacks an antecedent basis.[6] Niazi contends that "the catheter" means "the double catheter."

As addressed above, a patent claim must "inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 572 U.S. at 901. A claim may be indefinite when one of its terms lacks an antecedent basis. *See* Manual of Patent Examining Procedure § 2173.05(e) (providing an example of indefiniteness if a claim refers to "the lever" without any earlier reference to a lever but acknowledging that the mere lack of an antecedent basis is not a *per se* basis for indefiniteness). And although an indefinite claim cannot stand, a court's adopted construction "need not always purge every shred of ambiguity." *Acumed LLC*, 483 F.3d at 806.

The term "the catheter" creates a degree of ambiguity within Claim 11. For example, because the preamble of Claim 11 discusses a double catheter with an outer catheter and an inner catheter, the reference to "*the* catheter" in Step 1 of Claim 11 arguably

[6] Boston Scientific does not argue that "the catheter" is indefinite.

may refer to the double, outer, or inner catheter. (Emphasis added.) But the Court does not consider disputed claim terms in isolation, *see Nautilus*, 572 U.S. at 901, and the remainder of Claim 11 is instructive. When Claim 11 refers to the double catheter's *component* parts in Steps 3 and 4, the claim specifies an *inner* catheter or an *outer* catheter. In this context, a person with ordinary skill in the art would understand that Claim 11's reference to "the catheter" describes the double catheter system.

Accordingly, the Court construes "the catheter" in Claim 11 to mean "the double catheter."

D. Order of Method Steps

The parties also dispute whether the steps recited in Claim 11 must be performed in the order listed to constitute infringement. The parties agree that, logically, the first step *must* be "inserting the catheter into the coronary sinus" and the last step *must* be "withdrawing the catheter." But the parties dispute whether the guide wire must be advanced (Step 2) before the inner catheter is advanced (Step 3).

Generally, a method claim does not require a particular order to the recited steps. *Mformation Techs., Inc. v. Research in Motion Ltd.*, 764 F.3d 1392, 1398 (Fed. Cir. 2014). But when "the claim language, as a matter of logic or grammar, requires that the steps be performed in the order written, or the specification directly or implicitly requires an order of steps," the claim requires the recited order. *Id.* at 1398-99 (internal quotation marks omitted).

Step 3 of Claim 11 describes the act of "advancing the inner catheter out of a front end opening of the outer catheter *along the guide wire into the branch vein*." (Emphasis

added.) Logic 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.[7]

Because logic requires the steps of Claim 11 to be performed in the order listed, the Court concludes that Claim 11 is infringed only when the steps are performed in the order listed.

ORDER

Based on the foregoing analysis and all of the files, records and proceedings herein, **IT IS HEREBY ORDERED**:

1. Defendant St. Jude Medical S.C., Inc.'s motion to strike, (Case No. 17-cv-5096, Dkt. 67), is **DENIED**.

2. Defendant Boston Scientific Corp.'s motion to exclude evidence, (Case No. 17-cv-5094, Dkt. 83), is **DENIED**.

3. The disputed claim terms of United States Patent No. 6,638,268 are construed as addressed herein.

Dated: October 21, 2019

s/Wilhelmina M. Wright
Wilhelmina M. Wright
United States District Judge

[7] Niazi advances no argument that Step 4, "inserting the lead through the outer and inner catheters to a target location in the branch vein," can be performed out of order.

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Niazi Licensing Corporation, Plaintiff, vs. Boston Scientific Corporation, Defendant.	)	File No. 17-CV-5094 17-CV-5096 (WMW/BRT) St. Paul, Minnesota December 2, 2019 8:59 a.m. - 10:46 a.m. 1:34 p.m. - 2:04 p.m. **DIGITAL RECORDING**

Niazi Licensing Corporation,

Plaintiff,

vs.

St. Jude Medical S.C., Inc.,

Defendant.

BEFORE THE HONORABLE BECKY R. THORSON
UNITED STATES DISTRICT COURT MAGISTRATE JUDGE
(MOTION HEARING)

Proceedings recorded by digital recording; transcript produced by computer.

APPEARANCES

For the Plaintiff:	Michael T. Griggs, Esq. Boyle Fredrickson, S.C. 840 N. Plankinton Ave Milwaukee, WI 53203
For Defendant Boston Scientific:	Timothy E. Grimsrud, Esq. Doowon R. Chung, Esq. Faegre Baker Daniels, LLP 90 S. 7th Street, Suite 2200 Mpls, MN 55402-3901
For Defendant St. Jude Medical:	Kalpesh Shal, Esq. Benesch, Friedlander, Coplan & Aronoff, LLP 333 W. Wacker Drive Suite 1900 Chicago, IL 60606
Transcriber:	Lynne M. Krenz, RMR, CRR, CRC Suite 146 316 North Robert Street St. Paul, Minnesota 55101

P R O C E E D I N G S

IN OPEN COURT

THE COURT: This is United States District Court for the District of Minnesota and we are here on two motions in two related cases.

The first is Niazi Licensing Corporation versus St. Jude Medical. And that case is numbered 17-CV-5096 WMW/BRT.

And then the related case is Niazi Licensing Corporation versus Boston Scientific. And that is case 17-CV-5094 WMW and BRT.

Let's get appearances of Counsel, starting with the Plaintiff's side.

MR. GRIGGS: Good morning, Your Honor. Michael Griggs on behalf of Plaintiff.

THE COURT: Good morning. And for St. Jude?

MR. SHAH: Good morning, Judge. Kal Shah on behalf of St. Jude.

THE COURT: Good morning.

MR. GRIMSRUD: Good morning, Your Honor. Timothy Grimsrud from Faegre Baker Daniels on behalf of Boston Scientific.

THE COURT: Good morning.

MR. CHUNG: Good morning, Your Honor, Doowon Chung also on behalf of Boston Scientific.

THE COURT: Good morning.

Thank you everyone for being here. And I know the weather has finally cleared, but I know that it may have taken some effort to get here last night if you were coming in from out of town. So I appreciate that you are here and here on time.

Well, I have reviewed all the materials, and you know that I'm fairly familiar with the case.

We have a related motions and St. Jude filed first and then Boston Scientific joined and has a little bit of a different argument, the response is a little bit different.

My suggestion would be that we start off with St. Jude and that St. Jude argues first.

It might make sense to have the Plaintiff hear both St. Jude and Boston Scientific and then respond to both to avoid repetition, but I'll leave it to Plaintiff.

Would you like the opportunity to respond directly to St. Jude and then we'd move on to Boston Scientific, Mr. Griggs?

MR. GRIGGS: I'm fine either way, frankly. So whatever would be easiest with the Court, I'd be happy to oblige.

THE COURT: I think either one would be fine.

I'm just thinking about, you know, whether there are arguments that are going to be duplicative, but why

don't we just check and see after St. Jude argues --

MR. GRIGGS: Sure.

THE COURT: -- if there would be anything that you'd want to respond to or if we should just move to Boston Scientific.

So then let's start off with St. Jude's argument.

MR. SHAH: Good morning, Judge.

THE COURT: Good morning.

MR. SHAH: So let me start with, I mean, given your familiarity with the case and the issues, I'll start with why I believe the briefing kind of leaves us, which is there's no dispute between the parties that there was a production, whether through the expert report, and disclosures of factual issues and documents themselves, all of which were produced well after the close of fact discovery, those facts are not in dispute.

Similarly, there's no dispute between the parties on what rule governs. Both briefs indicate that it's Rule 37 of the federal rules that govern. And that those rules provide that a party that fails to disclose information in a timely manner under Rule 26 here by the discovery cutoff should not be, or shall is the word that's used in the rules, shall not be permitted to use those materials at a trial hearing or on a motion.

And that's precisely what we're seeking, Judge.

Is that with respect to Dr. Burke, his last-minute, after-the-fact claim that he is the factual evidence of direct use of the product, that that should be excluded. And then with respect to Mr. Carlson, his reliance on what appears to be 5,000 pages of documents that were not produced before.

THE COURT: Does the 5,000 documents include copies of the actual licenses?

MR. SHAH: I don't believe they do, Judge. I haven't gone through all of them, but I -- and I don't know if Boston Scientific knows, but I believe that they're not in there. Is that correct?

MR. GRIMSRUD: That's correct.

MR. SHAH: Yeah. That's -- so from our understanding, Judge.

And I think it's also useful to tell you, Judge, that I believe that the entirety of their production prior to that was about 10-to-12,000 pages. So we're talking about almost 50,000 -- you know, 50 percent of the entirety.

But I think whether it's 5 or 5,000, the important component is the rule, which says they shall not be permitted for use at trial, which is what we're heading towards.

And there are two exceptions, Judge. One is unless the failure is harmless. And the other is unless

there's substantial justification. And neither of which has been provided, Judge.

The only response that I gathered from their opposition was that they simply weren't aware of this information prior to the expert discovery deadline.

And frankly, Judge, I don't think that falls into either category as harmless or substantial justification, but it's not.

It's certainly not harmless with respect to Mr. -- Dr. Burke and his claim that he's a direct infringer. That has been an essential component to this case.

And let me, if I may, I made a quick timeline demonstrative I have given to opposing Counsel, I'd like to --

THE COURT: All right. As long as you've given it to opposing Counsel I'll receive it. Thank you.

MR. SHAH: Yeah. So before I go to the timeline, I think one other important component, Judge, and maybe it's just a nuance, but I think details are important, is the entirety of NLC's opposition here rests on an affidavit by Mr. Griggs.

So while they claim in their brief that NLC didn't have certain information, no one on behalf of the company has said that, it's only their counsel who, frankly, unless he's going to be a (inaudible) witness at trial, which he's

not, in my view, that the declaration in and of itself is inadmissible and improper to be before Your Honor on a motion.

But putting that aside, if Your Honor is going to consider the argument that somehow they didn't know about it, I think that timeline is very telling as to Dr. Burke, because you may recall, Judge, that we have filed on behalf of St. Jude numerous motions in this case with respect to dismissal. I have it, so.

In any event, Judge, you may recall we filed several motions in this case with respect to the contentions issue.

So the first, as you'll see they're back in -- when this case started we filed a motion on the complaint because the complaint did not have any issues with respect -- did not have any disclosures with respect to direct infringement.

We then a year later received their infringement contentions. We went back and forth with some letters in 2018 and we filed another motion. And in that motion we made clear that there's no evidence of direct infringement and we moved to strike the infringement contentions.

And I think it's important to note, Judge, that that's not our burden. Plaintiff has the burden of establishing infringement. They're asserting indirect

infringement. Indirect infringement by law has a requirement of direct infringement, which is direct news.

Yet, it wasn't there. Our motion was denied, fair enough. But they knew and should have known at all times that that was evidence that needed to be presented.

We subsequently took the deposition of Dr. Burke. And Dr. Burke had indicated he's been working with them for over a year. And so for some reason either Dr. Burke did not disclose, or Plaintiff did not ask, both of which is not a substantial justification, Judge, with respect to what is -- what is the basis of this direct infringement claim until October 15th, when all of a sudden we hear somehow it is Dr. Burke and he's done it.

THE COURT: When did you first know that Dr. Burke would be Plaintiff's expert?

I know there was a disclosure date of the identity of everyone's experts, but I just want to confirm --

MR. SHAH: Correct, Judge.

I think that was earlier this year. I can look it up if you want. I can look it up on my iPad real quick. I don't have a calendar before me.

THE COURT: Well, maybe it's a simpler question, did the -- all the parties disclose the experts, the identity of the experts?

MR. SHAH: Correct, Judge.

THE COURT: By the deadline in the scheduling order?

MR. SHAH: We did.

THE COURT: All right.

MR. SHAH: We did.

THE COURT: But importantly there, Judge, if Dr. Burke was going to be a fact witness as well -- so there's a difference, right? We're not -- there are other *Daubert* issues that we'll have for Your Honor at the *Daubert* phase.

But with respect to his claim that I am the one who's been implanting these devices in an infringing manner, that is a direct piece of factual evidence that's required and that should have been disclosed.

And so we asked discovery, as was on our brief on that question. We also have the federal rules that require additional disclosures of fact witnesses.

He was not disclosed in that regard and so --

THE COURT: I understand the distinction. And so I'm not -- I'm not merging a fact witness --

MR. SHAH: Okay.

THE COURT: -- with an expert witness, but I was just curious whether the parties had, you know, consistent with the order, identified their expert witnesses.

Now, with respect to the -- your point on discovery, what I take Plaintiff's argument to be there is

that you didn't ask for -- you didn't ask an interrogatory about the use, instead you asked for documents about the use.

What is your response to that argument in Plaintiff's position?

MR. SHAH: Well, my response is two-fold, Judge.

First, I shouldn't need an interrogatory on that particular issue because that's a requirement as part of the infringement contentions.

The basis for your infringement if you're going to assert indirect infringement requires a finding or an assertion of direct infringement.

And so I think it's a little bit of burden shifting improperly that suggests that my client now has to determine their infringement analysis.

They need to present the basis of their infringement in their contentions, and that's precisely why we moved to strike it.

And equally important, they've been on notice of this for a significant time to now just say, well, somehow we would have just asked to Rog that would have been clear. And, of course, Judge, that doesn't mesh with their latest complaint but, I mean, the position which is we didn't even know about this.

So whether one would have asked to Rog or not, I'm

assuming the Rog would have said nothing until, you know, well after the discovery deadline, but I don't think a Rog answers it.

And, frankly, I do think -- and I have to go back and check, Judge -- and I will even, perhaps, I don't want to take the time now, I do think we asked a Rog that may have at least a line with this issue, if not directly asks this issue. But, again, I would rest on the contention issue therein the burden on the Plaintiff with respect to that position.

There may have been one on the damages side now that I think about it but I have to go back and check, Judge.

THE COURT: And it seems like the primary argument is that this is a fact witness and a fact witness needed to be disclosed as part of Rule 26(b) initial disclosures.

And here we have a fact witness who is, in your view, well, working under the cloak of an expert witness.

MR. SHAH: Correct, Judge.

And I think, also, it's that -- the nature of that fact evidence. So it's not just a technicality that somehow they made a mistake and merged these two or didn't know about it. They certainly should have known.

Your Honor may recall, we had that mediation and one of the factors that was part of it. I don't want to --

THE COURT: I don't want to insert anything that was covered in the mediation --

MR. SHAH: Sure.

THE COURT: -- because of the mediation ground rules. And it may not even apply because confidential information is what is covered under the mediation ground rule.

MR. SHAH: That's fair, Judge.

THE COURT: But I don't think we even need to get into that.

MR. SHAH: It was more of a timing issue. At the time of that, the evidence had been closed and we went through that effort, but let me skip that.

More importantly, it is the factual nature of this evidence.

So we did depose Dr. Burke before and he was candid that he has not taken the time or has not preserved these records, there might not even be records, on this alleged use over time.

And in order for us at St. Jude to verify this, we would have to take depositions of hospitals, potentially get HIPAA records of surgical patients to see precisely what steps were used.

You may recall that the method claim at issue here, Judge, has five distinct steps, which has been ruled

in the claim construction order must be done in sequence.

In order to determine that, we now are in the position where either Dr. Burke is just going to say, hey, I did it. And I haven't had the opportunity to take discovery of the hospitals, to take discovery of vendors, to take discovery of patients to either determine whether or not that's factually provable or not provable, whether there's any credibility to it whatsoever. That would be a significant amount of discovery that I have to do.

And the position we're in now is an expert's going to get up on the stand and he's going to say, I did this in an infringing way, and the jury's going to have to either believe him or not because I haven't had the time or the opportunity to take that deposition.

So it's a lot more than just, you know, it came -- he happens to have this statement. It's a pretty significant statement that we have been indicated to the Plaintiff from day one, since the time the complaint was filed, that they lack in as far as evidence.

And to come in October 15th and surprise us with that is completely improper.

THE COURT: Let me ask you about your chart here.

MR. SHAH: Yep.

THE COURT: And I'm looking at in the middle of the page. You have a pink reference to "2018 NLC's expert

concludes he is a direct infringer, but this is not disclosed."

Tell me a little bit about what you understood at this point.

You're talking the deposition in -- just a few days ago, right?

MR. SHAH: Correct. Yes.

THE COURT: And during that deposition then you learned what?

MR. SHAH: I asked him, When did you realize that you were an infringer because you claim to be an infringer of St. Jude's products? And he said, When I read the patent. And I said, When was that? And he said about August 20 -- I think it was August, but 2018.

And then I said, Well, when did you disclose that to your lawyers? And he says, On October 4th or 5th, whatever that date was.

And so, you know, again, I don't think that's -- whether it's a communication gap, which I -- frankly I find hard to believe that you're working with an expert and this is the central issue on infringement and you haven't discussed it.

But, in fact, if that's what it is, it's not St. Jude's problem that you didn't ask that pertinent question, particularly when we filed two motions and you have

contentions that require that disclosure to not have asked that of your expert, who apparently was aware of it as far back as 2018, is really hard to swallow for my client, Judge.

I mean, this is a central issue. We've spent a lot of money briefing it, albeit we've lost, but then to have that notice and to take that time through two motions, through the contentions, through all the back and forth, to be in a position where this is the evidence. You know, we were told at the close of fact discovery Mr. Griggs has adamantly said we don't need direct evidence, we can just use the documents. They say that again in their briefing. Yet, here we all are, you know, months after the close of fact discovery, talking about a medical expert who's going to try to get on the stand and say, I am the factual witness who can tell you that I put these products in an infringing manner. That's problematic.

And just as problematic is 5,000 damages documents that we now have to digest and review in a matter of three weeks, spend an expert's time and money to look at.

I mean, those are things that just should have been thought of and done before.

And that's what it comes down to, fairness and what the purpose of the federal rules and the fact discovery is.

THE COURT: Well, it seems like we have two different issues here relating to the motions that seek to exclude portions of the expert opinions, so this is -- this is not a *Daubert* motion. It's related to discovery.

But with respect to Dr. Burke, it's more about we have a new fact witness.

MR. SHAH: Correct, Judge.

THE COURT: With respect to Mr. Carlson, it's whether there is -- there are facts that the expert relies on that should have been disclosed during fact discovery or whether the rules relating to expert disclosures allow that expert to identify new facts.

So tell me about St. Jude's view on the Plaintiff's view of how the rules operate?

MR. SHAH: Well, Judge, I think there's certainly -- I think the rules operate -- here's St. Jude's position on that.

An expert certainly is able to and should be permitted to rely on those things you would rely in the ordinary course of his expertise.

If you're a physician that may be, you know, you're background and training as a physician.

If you're a damages expert, your background and training as an accountant and maybe standard things you would go to, whether it's a textbook, or an examining manual

or, you know, those types of things.

And if in the course of that whether it is because you're turning to your standard arsenal, if you will, of resources that a physician, or an accountant, or an engineer would typically go to then it's probably fair game because both experts would know, okay, we're going to hit this and this is where we should go to.

That's different than factual evidence that's not unique -- I'm sorry, that's unique to a particular individual in a particular analysis.

And so with respect to Dr. Carlson -- I mean, Mr. Carlson, for example, he has apparently used 5,000-plus documents that are not available publicly, that are not available at St. Jude, that don't necessarily relate, in our view, to the facts. I'm sure they don't, which is why they weren't produced during fact discovery, because if they were related directly then I'm sure Plaintiff would have found them and produced them, but they are not.

And somehow whether it's through his prior roles as an expert or some other relationship he obtained these 5,000 documents.

That's not the type of documentation that the federal rules permit an expert to be able to rely upon without prior disclosure because that is factual evidence that you're relying upon for him to digest and then use his

expertise upon, as opposed to a foundation for his expertise.

And the 5,000 documents is a perfect example, because our expert would not have access to them absent us apparently asking, which I don't think is the rule. I think the rule is if we're going to rely on anything like that you must produce it at the time of the expert report. And if it's limited then, of course, our expert is smart and could handle it.

If it was five documents, Judge, three licenses, something manageable, I don't think we would be here.

We're not here -- again, this is not a technicality. This is the reality of the substantial hardship and burden that's been placed on St. Jude in that 5,000 documents relating to damages issues is a lot for someone to absorb.

And whether admissible or not I think is a red herring because they are going to have to be addressed.

Their expert's going to get on the stand on the damage side and say, this is my royalty number based on documents, you may not try to admit them, but in order to cross-examine him, we're going to have to go through those and explain why they're not applicable, otherwise how else to we attack his credibility?

And so now we're faced with, you know, a three or

four week period, albeit it's a little bit longer but it's still a significant production that then has to be analyzed, addressed, and factored into this calculation. Again, all things that should have been produced prior so that we can understand what and how this analysis is coming from, just like we should be able to understood what the claim for direct infringement is when we're addressing and formulating our defenses.

THE COURT: All right. Anything further?

MR. SHAH: One last thing, Judge.

THE COURT: All right.

MR. SHAH: I think it's important to mention, just, I think it's kind of telling of the mess that's created, for example, by Dr. Burke.

I had to go back -- I did go back with my client and I said, Do we have -- you know, how can we check this? Because Dr. Burke did testify, Judge, and I have his deposition transcript, he also testified that about 20 percent of the time he doesn't use the product with -- in a way that would be capable of qualifying as direct infringement.

So there are other issues with his infringement analysis, but at least 20 percent of the time he mixes and matches products.

So he may use a Boston Scientific product for part

of it, a St. Jude product for part of it, an Aero product, but that -- that's in his testimony.

So now, we have an issue of credibility and qualification on percentage.

But I had to go back and find the customer service rep that worked with Dr. Burke and talked to him about Dr. Burke's testimony on the factual side.

And I just updated our initial disclosures two weeks ago to include him because unfortunately if Dr. Burke is allowed to put this testimony on about him being the direct infringer, I'm going to need to put on a witness who's going to have to say why I don't think that's true.

And, again, I don't have any real way to verify that from either side because I don't have the hospital records, I don't have the patient records in order to be able to precisely pinpoint that.

But we're in this position where if he's allowed to do that testimony, I'm going to have to put on a representative or two from St. Jude who's going to say, I don't think that's accurate. In fact, I've seen him in the surgical OR and he's done it in a different way.

And that's the type of mess that entirely could have been prevented had we had this disclosure in time instead of having an expert who's going to also, you know, focus on factual issues and that I have to have two factual

witnesses say, well, for part of his testimony here's what I'm talking about, but for the expert part of the testimony, there's going to be an expert that's rebutting.

So it's just horribly confusing. It all could have been avoided if Plaintiff had just followed the schedule you had provided and the disclosure requirements under the federal rules.

THE COURT: Thank you.

Why don't we go ahead and get Mr. Griggs' response on this, especially since we now got the chart and I asked a few questions.

MR. GRIGGS: Thank you, Your Honor. And I guess I'd like to start with the Carlson issue.

You just heard Counsel for St. Jude basically saying that the burden is on the volume of the -- of the documents, they're 5,000 pages and, you know, that's very difficult for them to address, and so on, and so forth. And that's the basis for the prejudice or the burden that they're feeling.

Counsel said if it was just a few documents we wouldn't even be here today.

And so what it really gets down to is should these documents should have been produced three weeks earlier with the report and what not?

THE COURT: No. I think the question -- that

comment doesn't change the argument, and I think this is an argument on both sides, that damages-related documents needed to be disclosed earlier as part of fact discovery.

And sometimes there will be additional documents that might be referenced and, you know, disclosed a little bit later, but not this type of thing.

But let's go back, you know, let's start with the damages and go back. Because there are, as I look at it, you have an obligation to disclose your computation of damages and all the documents that you rely on as part of 26(a).

And you also have an obligation to respond to discovery requests.

Now I understand your argument about was there a request that with precision asked the fact discovery that Dr. Burke is orally providing.

However, no question that damages-related documents were requested as part of discovery.

And so I think you need to deal with initial disclosures and the requirement to produce documents with initial disclosures. And then why you didn't respond to document requests. And then why you didn't produce. Because the report requirement isn't that you just get to mention a document, it needs to be -- you know, the rule, I think, is pretty clear that the report must contain. And

contained means include facts, and it didn't, and it still doesn't because the license agreements aren't in there.

So that's -- if you want to start out with Mr. Carlson, I think you need to address all of the multiple failures to produce the license agreements that are relied upon here.

MR. GRIGGS: Sure, Your Honor. Thank you.

Well, first, as we set forth in the brief, we didn't have these documents during the fact discovery period.

THE COURT: What about the three agreements related to the patents?

MR. GRIGGS: Those -- the settlement agreements?

THE COURT: Yeah.

MR. GRIGGS: Yeah. Those were produced during discovery.

I think there are three separate agreements that aren't related to the patents.

THE COURT: Okay.

MR. GRIGGS: That Mr. Carlson also identified.

THE COURT: All right.

MR. GRIGGS: And so the timing of this is we did fact discovery. Fact discovery closed.

THE COURT: Uh-huh.

MR. GRIGGS: We started working with our expert.

Our expert decided to use these license databases to search for similar licenses. Ran the searches in the two databases. Retrieved the data. And then I don't want to get too much into attorney/client or work product, provided a draft report to Counsel.

THE COURT: When?

MR. GRIGGS: It was probably about five or six days before the expert report deadline.

THE COURT: When did you know your expert was trying to obtain additional licenses for purposes of the expert report?

MR. GRIGGS: Your Honor, I'd have to go back and look at my records, but I'm fairly certain all of these conversations took place after the close of fact discovery because that's when we pivoted over to the expert phase of the case.

So, again, it's not as if NLC had these documents and were sitting on them during fact discovery. We engaged, you know, an outside expert to do the work and do the damages analysis and this was one component of that.

And so --

THE COURT: It seems pretty clear that what the experts do is work with the facts. And they don't generate the facts. And they don't -- we don't end up with a new fact discovery period on an expert's new investigation of

the -- of facts that should be part of, at least, you know, your efforts to come up with your own -- own facts to support the case.

And I -- it just seems like we are in -- on different planes here with respect to what facts -- what experts do, they opine on the facts.

And there's got -- are you saying that your expert just started fresh and worked on all of these after the close of discovery?

MR. GRIGGS: Your Honor, and I'd have to dis -- I mean, it's not based on just the facts in the case.

For example, you know, if you have trademark cases, you can have survey experts. And they will go out and they will conduct a survey, and they will poll people, and generate survey questions, and so on, and so forth.

Now the expert may generate an opinion based on that survey, but that underlying survey evidence isn't entered into evidence.

And that's generated after the fact, that's what the expert is saying.

THE COURT: But that's generating survey evidence. It's not finding existing facts and relying on them.

MR. GRIGGS: I guess I somewhat disagree with that here because what the expert has done is he's, you know, gathered a number of other licenses that he believes are

similar technology, similar devices, looked at the royalty rates. And then out of those, you know, based -- sort of taken almost a survey of that, and then evaluated that, and then consolidated that, and then used that as part of his analysis. And it is included in his summary chart attached to his report, so. And I think --

THE COURT: But a summary has -- and this is what's -- I guess, the bottom line is we don't have the licenses.

MR. GRIGGS: And, Your Honor, I think we're going to the weight of the evidence at this point, which may be challenged on a *Daubert* motion or a motion in limine later. But just to simply say you're excluded at this stage of the case is quite an extreme remedy.

And, you know, again, if they want to challenge that the documents aren't there, or that they're not going to be submitted into evidence, or whatever other substantive attacks they want to make, you know, that's for later in the case.

THE COURT: But the -- this is not excluding the expert, it's excluding evidence that hasn't been produced.

And so even if I -- if I agree with you all along, there still are no licenses. The licenses aren't produced.

And so if -- if it still hasn't been produced, the license agreements, how can the other side actually look at

the evidence and offer some different analysis if it is a summary analysis? I don't think the case law supports that.

MR. GRIGGS: Okay. Maybe there's a bit of a disconnect here.

I believe what is generated out of these databases is basically abstracts and so it abstracts certain information. It does not contain the actual underlying license documents.

THE COURT: That's my point.

MR. GRIGGS: And the abstracts have been produced.

THE COURT: I'm talking about the license agreements.

If the license agreements are being relied upon by your expert, I think there are cases that say the licenses themselves need to be supported because how would they ever get to cross-examine maybe an incorrect abstract, or summary, or look at whether or not it's comparable really if you don't have the actual document?

So what's your reason for not hunting down the actual licenses?

MR. GRIGGS: Again, Your Honor, our expert does not have the licenses. And those are not provided by those services.

THE COURT: Okay.

MR. GRIGGS: So -- so that's -- I mean, that's

just the fact of why they were not produced.

And like I said, I think we're starting to wander into the weight of the evidence. And, you know, if they want to attack that he's only relying on abstracts and not the documents -- you know, not the underlying documents themselves, like I said, that's an argument for a different day.

What we're -- we're talking about here is we provided what was relied on and we provided it three weeks after the initial deadline.

THE COURT: Why isn't that too late?

MR. GRIGGS: Because, I believe -- and this gets back into Rule 26, and we did cite a number of cases and there are many more that there isn't a production requirement, these are expert disclosures with the report.

THE COURT: What does the word contain mean to you?

MR. GRIGGS: It talks about containing the facts in the data, which we've got other cases that clarify that that just -- it means listing what you are relying on.

And I cited just two exemplary cases, there are many more. I cited the *Bazarian* case, which also simply says you just need to list the expert's experience and the documents and whatever else is being relied on.

I cited the *Fidelity* case, which is out of the

Seventh Circuit which talks about requiring an expert to retain the materials that were considered so that -- you know they could be produced later on in the discovery process, if necessary.

You know, a lot of the cases cited by the Defendants here are about Rule 45 subpoenas being issued to experts for documents that were not included with the initial expert report.

So I think, based on my research, and my reading of it -- and I haven't seen a single case cited by any of the Defendants here saying that there was a production requirement under Rule 26. I mean, Rule 26 talks about expert disclosures, a disclosure requirement.

THE COURT: Yes. And the disclosure must contain the facts.

MR. GRIGGS: Which -- which it does. It identifies these documents.

THE COURT: Okay.

MR. GRIGGS: And then, you know, if they want to see them, they can ask for --

THE COURT: But that's not the facts. That's not the facts. That's saying there's a place for the facts somewhere else.

MR. GRIGGS: But, Your Honor, I understand, but I have not seen a case saying -- supporting what you are

saying. I've seen cases supporting what I am saying. They have not cited any cases supporting that interpretation.

THE COURT: All right. All right.

MR. GRIGGS: So, you know, I --

THE COURT: Don't a lot of your expert disclosures include lists that reference Bates numbers?

MR. GRIGGS: Yes. And that's for the documents that are -- that are in the case.

You know, as I mentioned, they could have a conversation with another expert, or somebody else, or someone not involved in the case at all, and they could list that conversation, and then you can probe that conversation during expert discovery.

But simply identifying that conversation satisfies the rules, Rule 26(a)2(B).

THE COURT: Okay.

MR. GRIGGS: And, you know, again, this dovetails a little bit with Rule 703 which talks about, you know, experts can form their opinions based on anything that other experts would reasonably rely upon here.

And so that says that they can rely on facts and other information that are not part of the record in the case, and they don't need to be admitted into the record in order for the opinion to be admissible.

THE COURT: Right. But the experts have to have

an opportunity -- the parties and the experts have to have an opportunity to digest the facts so that they can prepare their, you know, corresponding evidence and then prepare their experts.

How would it be possible for a rebuttal report to meet the deadline based upon your three-week production of 5,000 documents?

MR. GRIGGS: Well the -- again, we produced them when we had them.

And the three weeks -- we've already extended the deadline.

THE COURT: I'm not talking -- I'm talking about the current deadlines that this Court had in place. I'm not talking about what the Court had to do, only what happened.

I'm talking about we had a deadline for opening reports and then rebuttal reports. And by producing 5,000 documents, how do you think that's fair for the other side?

MR. GRIGGS: Well, Your Honor, again, we're talking about the volume -- I mean, if those had been produced on the day of -- I mean, we're talking about the three-week delay. And, again, there's a fundamental disagreement here as to what is required under Rule 26.

And, you know, this is not a hiding the ball -- I mean, we identified it in pretty substantive and substantial summary charts and an exhibit attached.

But this is not --

THE COURT: But summary charts, you have to make the underlying information available --

MR. GRIGGS: And we --

THE COURT: -- under the rule. Under Rule 1006 you have to -- if you prepare a summary chart, the underlying information has to be immediately available.

MR. GRIGGS: Yeah. And it is. But what happened was --

THE COURT: The licenses aren't.

MR. GRIGGS: We, you know, we just jumped straight to a motion to exclude. If they would have asked it the day they got the reports, we would have turned it over.

THE COURT: Okay. All right.

MR. GRIGGS: So.

THE COURT: I think I understand Carlson.

What did Dr. Burke? Because that is a little bit different in that here you have the burden to produce evidence to support infringement.

The gap, alleged gap, you may not agree that there was a gap, was identified.

In the motion to strike that was rendered moot, the response that you had to that motion was that, We don't have to do anything with the evidence at the time of our infringement contentions. That's just for theories. We

produced the evidence later in discovery.

And you didn't produce that evidence later in discovery. And I have a few questions about that.

MR. GRIGGS: Sure.

THE COURT: What you did was you presented an expert report and you inserted as if this was expert material facts about the experts.

So explain what your thought process -- and if this was a new fact witness, why you didn't identify this person as a fact witness and supplement -- and immediately supplement your initial disclosures and identify this as a fact witness, this person as a fact witness.

And, you know, deal with what, by your declaration, is a big problem, in that, whoops, we found some new facts that we didn't discover earlier. And we're -- we need to be able to present those.

Why did you, and I'll use the word cloak them, in an expert report?

MR. GRIGGS: Well, Your Honor, again, I'd just like to start out that Rule 23(e) provides for supplementation of prior disclosures which --

THE COURT: But not in an expert -- buried in an expert report.

MR. GRIGGS: Well, no, that's not true.

I mean, it says that it just needs to be in

writing. It can be in a letter, it can be in an e-mail, it needs to be in writing. And so this is disclosure in writing.

THE COURT: Okay.

MR. GRIGGS: You don't necessarily need to go back and revise the initial disclosures or interrogatory answers, it just needs to be communicated in writing. And that's what Rule 26(e) requires.

As far as the timing goes, maybe it is unfortunate that it was not learned of Dr. -- that NLC did not learn of Dr. Burke's infringement until after the close of fact discovery.

THE COURT: Why not? You had -- when did you start working with this expert?

MR. GRIGGS: We started in -- we started working with him via the IPR, which was focused on invalidity.

So there were no conversations of infringement back then and that was focused on Medtronic because St. Jude and Boston Scientific, you know, were not involved in that.

And so I believe when you go back and look at the transcript, it was just sort of a general question that was posed to him.

And, you know, it wasn't further developed under the context of what he was thinking, but I believe that's what Dr. Burke meant when he said, That's when I first sort

of started, you know, realizing that I might be a direct infringer, was in the context of that IPR.

And then, frankly, we really didn't engage Dr. Burke until after the close of fact discovery again when we started talking specifically about the question of infringement with respect to St. Jude and Boston Scientific.

THE COURT: But this gap in this evidence that St. Jude alleged was flagged for you.

Don't you think you have some obligation to be diligent in pursuing the fact discovery you want to pursue to prove your case and here you've got an expert right in front of your nose?

MR. GRIGGS: Yep, Your Honor. And, again, perhaps we could have done things differently. But again that, I guess, would go to the substantial justification as to -- you know, I haven't seen any case law about, well, you have to diligent -- you know, diligently go out and try and gather all the evidence within the fact discovery period, which, you know, I believe we were trying to do here.

THE COURT: You don't think you have an obligation to be diligent to look to -- as a Plaintiff when you have claims to discover the evidence needed to prove your case?

MR. GRIGGS: Sure. Your Honor, and we were -- I'm not saying that we were not diligent, maybe we were looking in different areas, but, you know, I can't go back and

change how it unfolded.

And, you know, frankly, I believe we timely disclosed this shortly after we learned about it. We did it in compliance with Rule 26(e).

And, you know, if the Court is going to consider that there is some sort of disclosure violation here, we've cited the cases with respect to harmlessness of this, particularly where expert discovery's still ongoing.

You know, St. Jude has already disclosed --

THE COURT: What about fact discovery?

You're forgetting that fact discovery was closed a long time ago. And this late-breaking disclosure of a fact witness on a gap that you had in facts would require fact discovery to be reopened.

MR. GRIGGS: Well, Your Honor, and we could get into that a little bit because Dr. Burke -- you heard St. Jude's Counsel talking about, well, we need to go and subpoena hospitals, and so on, and so forth.

Well, Dr. Burke explained during his deposition -- Dr. Niazi also explained this during his deposition, but the records that are made with respect to these patients during these procedures, they do not lay out step-by-step what is going on.

So it's neither going to disprove nor corroborate what Dr. Burke is saying.

What Dr. Burke said is, you know, the records that would exist would be records of the equipment that was used and only the equipment.

So it's not going to be a detailed step-by-step of the procedure.

And he said -- and Dr. Burke does not have these records, they are in the possession of the hospitals because they would be associated with patient files.

Dr. Burke also said he thought that St. Jude, since they sold these devices, would also have similar records as to which devices were sold --

THE COURT: You know under the law that's not an excuse for you producing the records.

And that just underscores the need that St. Jude or Boston Scientific, if it's relevant to Boston Scientific, would have to be able to go to those third parties to, you know, have you identify the third parties that Dr. Burke talked to.

I don't see any way around, in light of this late, very late disclosure of information, you absolutely knew that it was the doctors who would know about the use. You wanted St. Jude to disclose the doctors who used the product.

Here you have an expert, your expert, who you know uses the product and you didn't ask the question.

St. Jude, if -- if this was allowed, if this late disclosure of discovery was allowed, and I haven't made that decision yet, St. Jude would absolutely have the right to reopen discovery and find other evidence that contradicts the evidence that you want to present and use to support your case.

They don't just get to look at the facts that that you've produced late.

MR. GRIGGS: Your Honor, and -- I am not saying that they -- we would certainly not object to allow them to take whatever discovery they felt necessary.

My only point was that we believe that they would be in possession of records, as well. And I'm not saying that's an excuse or that they should not be able to pursue whatever additional discovery they would want and we wouldn't object to that.

THE COURT: But this was your burden. This discovery was your burden to go get. Why didn't you do this earlier?

MR. GRIGGS: Well, Your Honor, frankly, the -- you know, like I said -- and I don't want to get too far into what we were doing, but we were going down other avenues. And, yeah, I guess Dr. Burke was sitting right in front of us, but, you know, we were busy with -- and I don't -- you know, we were busy with the claim construction, you know,

there were a lot of fact depositions that were happening at a single time and so we put off talking to Dr. Burke until we wrapped up, you know, what we were working on at the time.

And, you know, when he disclosed that to us, we promptly put it in the expert report and we disclosed it to the other side.

And just further note, Boston Scientific is not challenging this. This is -- St. Jude is the only one that's making a challenge to Dr. Burke's testimony in these motions here.

You know, and, again, I've got a number of cases that talk about, you know, look, if you get an opportunity to depose this person, then the harm is alleviated.

THE COURT: It's not just this person. It's that the whole topic of direct infringement has been opened up on. Because prior to this witness appearing at the two last pages in an expert report, there was no disclosure of a fact witness who would testify about his direct infringement using the method of patent.

MR. GRIGGS: And, Your Honor, again, you know, if we could have disclosed him earlier, if we had known about it, we certainly would. This is not as if we're trying to hide the ball or anything.

You know, my reading of these cases is that

exclusion is an extreme remedy and Court's are loathed to exclude evidence.

And I've cited a number of cases where disclosures have been far later in the case and the courts say, We will provide an opportunity to depose or take whatever followup discovery you need and that alleviates any prejudice.

And so here, you know, again, we've got a lot of -- a fair amount of time left in this case.

And, you know, unfortunately we didn't disclose it.

THE COURT: We don't have a lot of time left in the case. Dispositive motions are due February. How can you say that?

I mean, I'm a pretty even keel here, but to tell me on December 2nd that we've got a lot of time left in this case is simply not true. How can you say that?

MR. GRIGGS: I guess two months to me seems like we -- probably two-and-a-half months before dispositive motions, in my mind, that is enough time to conduct third-party discovery of hospitals, take whatever depositions we need.

If they want to depose Dr. Burke again, you know, Dr. Burke can be made available for another deposition before dispositive motions. And I think that's what -- you know, that's what would need to be done. And I think

there's certainly enough time to do that in advance of the dispositive motion deadline.

THE COURT: All right. One last question before we move on to Boston Scientific.

I think the rule for supplementation is not that you can just wait and look later for things you could have found before, but that it has to be something that was incorrect or had you been diligent you wouldn't have found before.

And so how do you think that 26(e) is -- is going to salvage the late disclosure when had you been diligent during the discovery period you would have found it?

MR. GRIGGS: Well, again, and I don't want to get too far into what we were doing, but it's not as if we were not being diligent. I believe we were pursuing other avenues and ultimately decided we did not want to go down that path and -- so it's not like we were just ignoring the issue, we were trying, but ultimately we decided we did not want to pursue that path.

I wish I could offer a little bit more detail and the reason behind it, but, you know, so the issue of diligence is broader than just, well, why didn't you find Burke sooner? It's because, you know, we were looking in a different place and, you know, that -- we decided not to go down that path.

And then, you know, when we came back around during expert discovery, we -- Dr. Burke informed us that, you know, what's -- what's set forth in his reports. And so we included it in his report and disclosed it in a timely manner with respect to when we learned of it. You know, I understand the question of diligence but, you know, sometimes you're asking the wrong questions and --

THE COURT: Why didn't you put him on a witness list for 26(a)? Why didn't you supplement your initial disclosures?

MR. GRIGGS: When we did his report?

THE COURT: Yeah.

MR. GRIGGS: Well, because I did do some research on this and there are cases that say you don't -- as long as you disclose it in writing you satisfy 26(e), you do not need to go back and amend -- amend those other documents. I can do that.

But the spirit of Rule 26(e) is you communicate the information. And, you know, the Courts say it's a little bit of an elevation of form over substance if, you know, for example, we disclosed it and then someone came back around later and said, well, you didn't update your initial witness and so you need to exclude this where, you know, the information had been communicated in writing.

And so I'd gladly do that and I can do that if the

Court believes that would be helpful.

But, you know, based on my research, communicating this information in writing, whatever form, satisfies the supplementation requirements of 26(e).

THE COURT: What about 26(g) when you have an initial disclosure that identified your fact witnesses? Under 26(g) don't have you have to fix your 26(a) disclosure?

MR. GRIGGS: So it's -- you're referencing signing disclosures and discovery requests?

THE COURT: Right. So you sign a disclosure, it's not complete or accurate anymore. So don't you have to do something?

MR. GRIGGS: Yeah, perhaps, Your Honor. And frankly I've not researched 26(g), and nobody's raised a 26(g) issue, or frankly argued that our, you know, that the initial disclosures are inaccurate or incomplete at this point.

You know, I agree, Dr. Burke, you know, he has some factual testimony and he should be listed as a fact witness.

So, again, if that renders our original initial disclosures incorrect under 26(g), like I said, I believe that's an easy fix and --

THE COURT: I'm talking about what has happened up

to this point of the hearing, not what we do after.

Because if we do anything after other than exclude the portions of the report that were not disclosed or deal with the fact discovery issues, then fact discovery will be reopened.

MR. GRIGGS: Sure.

And I'm looking at 26(g) and what it says is -- under a, it says that it's, you know, accurate with respect to a disclosure it is complete and correct as of the time it's made.

And so I think the signature on the initial disclosures is -- it complies with 26(g) because the disclosure was correct and accurate at the time it was made.

THE COURT: Uh-huh.

MR. GRIGGS: So, again, I think that dumps you back into 26(e) supplementation which does not necessarily require issuing an amended initial disclosure, so.

THE COURT: Okay. I -- I don't know what your research was to kind of think that you, wow, I have a new fact witness and I'm going to, you know, disclose a new fact witness in my expert report and not amend your other -- other discovery. I'm not sure what your research was on that.

I -- I don't know. You know, I may look at that during the break but, anyway, I think I've covered what --

what my concerns were with you and to give you a chance to respond.

MR. GRIGGS: Okay. Thank you, Your Honor.

THE COURT: Thank you. Let's hear from Boston Scientific.

UNIDENTIFIED SPEAKER: Did you want me to reply to all of them. I mean, I'm happy to. I have a couple points but I --

THE COURT: Why don't we go ahead and hear from Boston Scientific. And I don't have any time pressure here today, so I will let everybody make whatever points they'll make. And my -- my plan here is that I will take a break. I'm not sure how long of a break I'll need, and I will be issuing my decision from the bench here today.

MR. GRIMSRUD: Thank you, Your Honor.

From Boston Scientific's perspective, just to be clear, there's all sorts of problems that we think exist with both expert reports, Carlson and Burke. And we -- as far as there's a comment about Boston Scientific not challenging Dr. Burke, I mean, that's not accurate, we are very much challenging Dr. Burke and think his opinion is just rife with problems, and lack and foundation and all sorts of issues.

One issue is -- we've been dealing with, too, is when to raise all these issues. There's, you know, if

appropriate, there would be *Daubert* motions, potentially other motions to exclude. There's all sorts of things going on.

What we are most concerned about, though, with -- with both of these reports is as flawed as they are in our view is we don't want supplementation of them. We don't want document productions coming on the fly.

Our damages expert, Mr. Grosky, had been analyzing Mr. Carlson's report. And then, basically, you know, was -- we were trying to get it done because the initial deadline, I believe, was before Thanksgiving even, and then I think got moved to the 26th of November, or something.

But we were on the verge of having Mr. Grosky finish it up when all of a sudden we get this 5,000-page document dump. And that's a big deal. I mean, talking about analyzing complex data and 5,000 documents, that's certainly not harmless, it's highly prejudicial to us.

We're coming to, you know, think about, you know -- Mr. Grosky hasn't actually analyzed this stuff yet either because it's not properly in the case, but if he were to do that, it would be very, very prejudicial, more time, more money, and it's just not the way litigation's supposed to work.

We're having to scramble to deal with this untimely kind of chaotic production from the Plaintiff's

side.

It's also not substantially justified. There is no way on earth this production is substantially justified.

And this is on Page 7 of NLC's brief in our case, Your Honor.

And there's footnote here, forgive me -- there's a footnote here that says -- this is their explanation for why they did this 5,000-page document dump.

They say that "St. Jude moved to strike various portions of Mr. Carlson's expert report without ever asking Mr. Carlson to produce the documents. As a result of NLC's meet and confer with St. Jude, NLC reached out to Mr. Carlson without formal request from either St. Jude or BSC" that's not correct, "and Mr. Carlson agreed to provide the documents at issue in this motion to NLC. NLC subsequently produced the documents to St. Jude and BSC."

So what I want to be clear about is this is not a situation where NLC was scrambling to get the documents produced from the get-go and, you know, got this report from Mr. Carlson and thought to themselves, oh, jeez, we've got to get these documents produced. And they're, you know, working hard to get it done and then produced it, you know, a couple days late or something. That's not the situation we're in at all.

We're in a situation where they served this expert

report. They knew it had this Royalty Source, KT Mine analyses in it, which were not available to Boston Scientific or St. Jude.

They're based on compilations of data that these two entities did that we have no way of knowing what -- what in the world they did.

And then they sat on it. And then in response to St. Jude's motion, apparently, they decided to, oh, maybe we should go collect the documents and produce them.

That's not a substantial justification at all. If St. Jude hadn't brought this motion, I don't think they would have produced the documents. I mean, from the characterizations they have here, it's that St. Jude brought the motion and then they decided to produce the documents. And that's not a substantial justification and it's very harmful to both Boston Scientific and St. Jude for them to have done that.

And so under Rule 37, this is clearly a case where the remedy is automatic exclusion, the sanction, it's automatic exclusion. That it's untimely production. The case -- the *Johnson* case we cite says likewise -- I mean this is what -- this is this is a Minnesota case saying, "Likewise," this is the *Johnson* case, "Likewise, pursuant to Federal Civil Procedure 26(a)2(B) experts must produce facts and data considered by the expert in formulating her

opinion."

Must produce it. And of course they have to. If they're relying on it, they have to produce this information.

We have no way -- our expert has no possible way of analyzing the KT Mine and Royalty Source information without the reports that we received from them, so.

THE COURT: In your request what you were planning to do is to move to strike the references to the opinions based on the unproduced material? What was Boston Scientific planning to do?

MR. GRIMSRUD: Before we brought this motion?

THE COURT: Before you -- before the documents were produced?

MR. GRIMSRUD: Yeah. Sure.

Before the documents were produced, I mean, there's -- there's many problems with these reports, this isn't one of them and so we were, you know, going to depose Mr. Carlson. And ultimately whether it would have been as a *Daubert* or a motion to strike, maybe -- potentially a motion to exclude, too, there's no rule that you have to bring a motion to exclude now.

I mean, sometimes we bring those at summary judgment, even, which is another option for some of the problems, as well.

So there were a lot of ways that we were going to deal with it. And whether it would be a *Daubert* motion, motion to strike, or it's just another motion to exclude, I'm not -- I'm not positive, but it would probably have been in one of those flavors.

THE COURT: Uh-huh.

MR. GRIMSRUD: But, you know, it would have been after the depositions when we were initially planning to do it.

And part of the discovery process -- you know, we have to do our rebuttal reports, which is what we were most focused on.

And so then having them serve basically what are supplemental expert reports.

I mean, it's a 5,000-plus documents that are apparently central to this -- Mr. Carlson's preparation of Exhibits 1 through 5, I think it is, you know, it's essentially supplemental to expert reports.

So it's at that time that we say, well, if they're producing all this information in the middle of our expert discovery period while we're preparing rebuttal reports, we -- I mean, now they've forced us to bring a motion to exclude.

THE COURT: What -- if you could clarify your arguments on the, you know, reasons that this should have

been produced earlier, if you do think it should have been produced earlier.

I note, you know, obviously there's the computation of damages as part of Rule 26(a) disclosures.

I do see, based upon the Defendant's submissions, that there were discovery requests for documents relating to any related licenses. And I -- I take it you didn't get the licenses that were later disclosed by the expert. And then you didn't get these immediately with the expert reports.

So please talk about your views about when these types of materials should be produced in a case, starting with 26(a), and then moving to fact discovery, and then moving to expert disclosures.

MR. GRIMSRUD: Yes.

Your Honor, with 26(a) with the initial disclosures, obviously if they have the information they need to identify it and produce it, so that's clear.

As part of discovery, both sides clearly during a case are gathering information and learning facts. That is typical in a discovery case.

But during fact discovery it should have been produced, Request Number 27 is our document request that asks for documents that NLC may rely on to support its claim for damages in this litigation. Their response, No objection. NLC will produce documents in support of its

claim and damages. And these are clearly in that category and it should have been produced during fact discovery.

Then, at a minimum, by the time you do your opening expert report, you know, if your expert has some information that they somehow discovered, absolutely would have to be produced at that time with the opening expert report.

THE COURT: And what is your position on -- and none of the parties really focused on this, but when I looked at the cases, it was certainly the focus that if a party is going to rely on license agreements, then the license agreements need to be produced.

Here it appears the 5,000 documents are some compilation or summary of license agreements, but you don't have the license agreements. Is that an issue?

MR. GRIMSRUD: Yeah. That's absolutely an issue.

Yes. The license agreements -- if NLC's going to actually try to pursue this theory that Mr. Carlson is pursuing they would have had to have produced the license agreements. And that -- I would put that in the category of there's all sorts of problems in these reports and there's just going to be more motion practice on that, I'm sure and one -- and, you know, depending on how things shake out.

But one of them would be that there's -- there's a lack of the actual license agreements as well. And so those

absolutely would have had to have been produced.

And, you know, whether that falls in -- since they don't have them apparently, whether that falls in the category of a motion to strike or exclude or a *Daubert* motion is probably another question.

But in order to successfully rely on this information, they would have had to get the license agreements, produce the license agreements, you know, presumably these reports, these 5,000-plus pages of documents, they would have had to produce those as well, but the license agreements absolutely would have had to have been produced.

And since they weren't produced, that is a glaring *Daubert* motion to strike issue with Mr. Carlson's report for sure.

THE COURT: All right.

MR. GRIMSRUD: That -- the issue -- the issue that we've brought up today, just as far as, you know, what's kind of the most timely issue right now while we're in the middle of expert discovery is that these 5,000 pages of reports, or whatever it is, from Royalty Source and KT Mine need to be excluded from the case.

That what we're worried about is kind of periodic supplementations to try to cure problems in the reports, because the problems are full of -- or the reports are full

of problems. And, you know, the first attempt now has been to produce the 5,000-plus pages, which you can't do, that should be excluded.

If you read Mr. Griggs' declaration closely, he lets the Court know that he's now produced, I believe it was right before Thanksgiving, didn't produce the license agreements, the three license agreements that we have a problem with, too. He didn't produce those, but he produced documents about them.

So there's, you know, there's -- I haven't even have a chance to look at them but I think there's some court orders or opinions from some other case or something that's been produced, so they're trying to produce more and more information to take care of these problems. And that's what we absolutely don't want to happen, is we don't want to be in a situation where we're having to, you know, respond to untimely productions and bring more motions to exclude things.

And so with the 5,000-plus documents, we're bringing this motion now because we don't -- it's not appropriate for them to be basically supplementing the extra report --

THE COURT: All right.

MR. GRIMSRUD: -- in discovery.

THE COURT: So your motion is a little bit

different.

You're seeking to exclude the 5,000 documents and you're saving for later the challenge to the expert report based upon a lack of support?

MR. GRIMSRUD: Well, we have brought up now -- in our motion we brought up the issue with Mr. Carlson's report that -- basically joining St. Jude's motion on that, that the Court should strike the portions of the report that we're relying on these documents just because it seems like now we've -- we've, you know, this issue's been brought up and it's before the Court.

And so there is -- and our position on that is once the 5,000 pages are out, there's just -- there's nothing in his report. The exhibits -- the exhibits to this report -- to Mr. Carlson's report are basically apparently summaries of these 5,000-plus documents.

And so, if those documents are out, which NLC's saying they're not going to use at trial anyway but, again, that's sort of a misnomer, because we don't want Mr. Carlson talking about the documents even if they're not in evidence.

So that's why now we have brought this issue to the Court of joining St. Jude's motion to just strike -- to strike Mr. Carlson's opinion on these because there's just nothing there anymore.

THE COURT: And I -- I want to get both parties'

views on this so I know what the scope -- bless you -- what the scope of my ruling should be. But both parties are moving to strike only a portion of the Carlson report that points to -- bless you -- the 5,000 documents, or the 5,000 documents, and they have disclosed three documents. I'm not sure if I completely understand if there's an overlap there.

Why can't the Court rule -- and this is probably one I need both of you to speak on, since this is about discovery and what hasn't been produced in discovery, and what hasn't been produced as facts in support of the reports, why can't I make that ruling based on the fact that the license agreements themselves weren't produced?

Why does that need to wait for a dispositive motion?

MR. GRIMSRUD: It does not need to wait. Your Honor could -- from Boston Scientific's perspective, Your Honor, absolutely could strike the portion --

THE COURT: Isn't that the same issue --

MR. GRIMSRUD: Yes.

THE COURT: -- that they haven't been produced?

MR. GRIMSRUD: Yes.

THE COURT: And so since they haven't been produced, then that portion -- I'm just not sure I understand why there would be a distinction.

MR. GRIMSRUD: Between the 5,000-plus documents

and the failure to produce the licenses?

THE COURT: Right.

MR. GRIMSRUD: Yeah. Absolutely, Your Honor.

I mean, that would be the efficient way to handle it, is that's basically what I would say cutting to the chase of the effect of there not being anything in there to support these licenses means the report should be stricken on those issues.

THE COURT: Not the whole report?

MR. GRIMSRUD: Those portions.

THE COURT: But in the -- you know, the summary --

MR. GRIMSRUD: Yeah.

THE COURT: -- of the documents weren't produced that support the summary, but also there's no license agreements that support the -- that statement.

MR. GRIMSRUD: Right.

THE COURT: I just need to get a handle. And, of course, Mr. Griggs can address that point because I'm grappling with that a little bit.

MR. GRIMSRUD: You're right, Your Honor.

That is the effect of it, is that since there's no licenses that have been produced the portions of the report that are based on the unproduced licenses should be stricken.

THE COURT: And what are your views in responding

to what Mr. Griggs says is that, you know, you had fact discovery and the parties, you know, exchanged fact discovery, and asked for written interrogatories, and sought documents, and took depositions of fact witnesses and then they completed the fact discovery, didn't -- didn't get license agreements then and -- in response to your requests and so then that point ended.

And then they turned to their expert and their expert collected what would be responses to your requests.

What is your position on whether that is permissible to start, essentially, a new fact discovery period?

MR. GRIMSRUD: That's not permissible.

THE COURT: Why? And they say you haven't cited any cases.

MR. GRIMSRUD: Well, I don't know of a case offhand, but in the fact discovery period, that's when they produce facts.

And so the licenses would be factual information. To the extent they want to rely on licenses, we had requests for documents supporting damages, licenses, those types of things. They needed to go out and get them.

So if that involved going to going to a third-party, KT Mine, Royalty Source, any other party, they needed to do that during fact discovery, get the documents

and produce them so we could analyze them. So we could take fact discovery.

You know, the fact that NLC hasn't obtained any of the licenses, if we had known of one that they were interested in, maybe we would have gone to the third-party to try to get it, who knows.

But that's just to give an example of absolutely they should have done that during fact discovery. And if they're using an expert witness, Mr. Carlson to help them, that's fine, but he needs to help them during fact discovery to get the licenses produced.

He can then subsequently give an opinion on the licenses during expert discovery, but we -- we would have needed to get the licenses during expert discovery, that would have been the proper time to do it.

THE COURT: Right. Why don't I give Mr. Griggs an opportunity to respond to Boston Scientific's argument.

And I think I've teed up a couple of things for you to respond to, as well, Mr. Griggs.

MR. GRIGGS: Sure.

First, that *Johnson* case that Counsel put up, there is a distinction there that does not say that you need to produce documents along with a report.

If you look through that case, what that case is about is a Rule 45 subpoena that's issued to an expert

seeking to -- for production of documents that were considered but maybe not relied upon in the report or just considered.

So what the Court is saying is, yes, if it's considered it has to be produced. In this instance it's produced in response to a Rule 45 subpoena. It's not produced along with your initial expert report in rule -- according to Rule 26. So that case does not say that an expert has to produce every single document that's considered along with the report.

And, again, Your Honor, we've cited a number of cases, and there are many more out there that talk about listing information in reports that is what meant and required by Rule 26. That's what Mr. Carlson did here.

And then you can continue the expert discovery phase to seek to discover those documents.

Your Honor, of all --

THE COURT: I don't think the expert discovery phase is -- there's -- the expert discovery phase has discovery being depositions.

Were you ever intending to produce the documents that were relied on voluntarily or was Counsel correct in that they were only produced because you produced them when St. Jude demanded?

MR. GRIGGS: Well, Your Honor, again, we disclosed

them and if they want to see them, certainly we'll produce them --

THE COURT: All right.

MR. GRIGGS: -- so they can go back.

THE COURT: So your view is that you can put the list together but you don't have to produce them unless there's requests.

MR. GRIGGS: Sure.

I mean, for example, there's a -- and this is a different part of the rule, but we list all of Dr. Burke's publications. We didn't produce all of those. You know, if they wanted to see one or two of those and question him --

THE COURT: But doesn't that say a list?

MR. GRIGGS: It does, Your Honor.

THE COURT: So that doesn't help you.

MR. GRIGGS: But I'm just saying that, you know, this is about disclosing information. It is not about producing every -- every document that is relied upon, for example, like treatises, or other texts, or, you know, whatever else may fall into that category, those don't need to be produced.

If the expert happens to have possession and it is asked for, you know, then we can produce that as part of the expert discovery phase.

THE COURT: Okay.

MR. GRIGGS: And so --

THE COURT: And your view -- just to make sure I know, your view was that you could deliver the report, provide a list of things that were relied on that weren't available to the other side because you haven't produced them in discovery, or they weren't publicly available, and then you only needed to produce them if they were requested?

MR. GRIGGS: Sure.

THE COURT: Okay.

MR. GRIGGS: And that's --

THE COURT: That's what I want.

MR. GRIGGS: And there are cases that support that position.

THE COURT: Okay.

MR. GRIGGS: And that's the course of expert discovery. That's, you know, that's the way it's intended to be implemented.

I did want, while we were sitting there, I was able to pull up one case, and I can give you the case cite about supplementing initial disclosures if you wanted, and I can read the quote here, I think I highlighted it.

It says -- and this case is *Poitra v. School District*, 311 F.R.D. 65 --

THE COURT: Okay. What district is it out of or circuit?

MR. GRIGGS: District of Colorado.

It's 2015, 311 F.R.D. 659. And this quote is at 664. And the quote is, "There is, however, no affirmative duty to supplement initial disclosures when 'if the additional or corrective information' has 'otherwise been made known to the party -- to the other parties during the discovery process or in writing.'" So, and, again, there's a number of other cases that support that.

So the spirit of the rule is as long as you communicated in writing, there's no obligation to formally go and, you know, amend the prior disclosures as long as that information has been communicated.

You know, again, I'm sort of wrestling with this, we should have produced the license agreements, but first of all I'd like to draw a distinction between NLC and Mr. Carlson, because, you know, Mr. Carlson's documents and his work are not NLC's work, just in terms of, you know, document requests issued to NLC. I mean these -- these are things that are in Mr. Carlson's custody and control.

THE COURT: You don't have any control over your expert?

MR. GRIGGS: I can ask. If he said no, I can't -- if I said, please, you know, give me the -- you know, this -- the KT or the data from the Royalty Source and he said, no, we paid money for that, that's ours, you know, I'm not

-- you know, I'm not going to turn that over to you. I have no means to produce -- to get those documents or produce it. So, you know, we have a working relationship and, you know, he -- he responded when asked.

But, you know, I think there is an important distinction here. And there are a lot of cases that involve Rule 45 subpoenas to expert for that very reason. Because a lot of this information is not in the parties' custody and control, the requests should really properly be directed to Mr. Carlson.

THE COURT: Didn't -- aren't those Rule 45 cases, aren't those really no longer that applicable given the whole change in the, you know, the discovery of the, you know, the expert report drafts, and all that?

Aren't the parties objected to produce the information that is contained in the expert report?

MR. GRIGGS: No. I think it -- actually the change in the rule, when it changed from just the facts and data relied upon they changed it to considered and so that has actually opened up this Rule 45 discovery.

Because, you know, there could be information that the expert considered, but perhaps undercut the expert's position.

THE COURT: Right. But here -- my point is here you're relying on licenses. Licenses were asked for.

Licenses are always relevant in patent cases involving reasonable royalty.

It seems like the practice is that parties work with experts all along the way. And all along the way, you know, you might say will we be relying on any other licenses because I'm going to need to produce them in discovery, I've got a discovery request and we don't want to have those excluded.

That didn't enter your mind?

MR. GRIGGS: Well, Your Honor, here, you know, first of all, I don't even know if these licenses -- the license documents themselves are available from KT Mine and Royalty Source.

THE COURT: Well, I'm just talking about generally. When you -- when you know licenses are going to be part of your case.

MR. GRIGGS: Your Honor, and that sort of gets into what type of information acts -- like Rule 703.

For example, if Mr. Carlson were to say, yes, you know, this is how I value -- and IP, and determine royalty rates is I rely on these abstracts from these royalty sources, and they are reliable, and other experts in the field rely upon these.

Then that is a proper basis for his opinion, whether or not the underlying licenses have been produced.

Now, I understand if --

THE COURT: I'm -- I'm going to pause here because discovery of these documents helps the another side to be able to discover information about those documents. They can fully look at the document. They can prepare for cross-examination, they can see if the license is -- is one that they need to do some further discovery.

There's a reason that discovery is produced so that more discovery can be taken. And it's not all produced with the expert. And that's why we have fact discovery followed by expert discovery.

MR. GRIGGS: And, Your Honor, again, NLC does not have licenses other than the ones that were produced during fact discovery. You know, NLC doesn't have subscriptions to these royalty databases or anything else.

And, you know, that's why we rely on the expert who has access to that and an understanding of that to go and, you know, conduct his own analysis of that.

And, you know, if -- again, this seems to be going to the weight of the evidence and the reliability --

THE COURT: I don't think -- it's discovery. It's discovery.

MR. GRIGGS: But, Your Honor, we don't have the licenses. I mean, we can't produce what we don't have. And Mr. Carlson can't produce what he doesn't have.

And, you know, he did produce what he does have, which are the abstracts and other information that were provided from KT Mine and Royalty Source.

And, like I said, under Rule 703, if that is the type of information that experts routinely rely upon, then it is perfectly appropriate for him to base his opinion on that, whether or not those abstracts are admissible into evidence.

And so that is -- is sort of the basis. We may be having a fundamental disagreement among the parties here as to, you know, what is required. But, you know, I have not seen any case law that says that an expert has to produce every document relied upon or considered along with the report.

On the contrary, we've submitted the cases that say you just have to include -- identify the information in the disclosure, which is the report, which is the --

THE COURT: It doesn't say that.

The rule says it has to contain the facts. That means it has to include the facts and data.

MR. GRIGGS: Yes. And I've got cases interpreting that as --

THE COURT: Okay.

MR. GRIGGS: -- disclosing in a list form.

THE COURT: And do you have a case out of the

Eighth Circuit that interprets that? Because nothing else is binding on me. I get to look at the rule.

MR. GRIGGS: Sure, Your Honor.

And, but, again, there's no -- and I can look for an Eighth Circuit case. But, you know, there's nothing on the other side. And that's part of the problem here is --

THE COURT: Right.

MR. GRIGGS: -- you know, they haven't cited any case saying that, well, you need to produce all of this. And, again, that is not generally how the rules are applied throughout the country.

I've got a number of sampling district courts as to how this rule is interpreted. And none of them interpret it as requiring production of documents.

And, again, if there is some violation here, you know, let's -- let's assume there is some violation here, you know, it certainly was unintentional. And I think we're having a disagreement over the interpretation of the rule. You know, the documents were produced three weeks later.

THE COURT: Only because you were caught.

MR. GRIGGS: It's not about -- we weren't withholding anything.

THE COURT: No. But you only produced them --

MR. GRIGGS: When we were asked to.

THE COURT: -- after St. Jude said, We're bringing

a motion.

MR. GRIGGS: Yeah.

THE COURT: That's what triggered your production.

MR. GRIGGS: Yes.

Because typically instead of bringing a motion they would say, Can we see these documents? But they skipped that step. And they just went straight to exclude the evidence, which, you know, again, and we've got the cases, that is an extreme remedy, exclusion of evidence.

And in terms of prejudice and alleviating prejudice, courts across the country say that, you know, if you get an opportunity to depose that witness and conduct whatever further in discovery, then that's alleviated.

You know, I cited that Second Circuit case where a new opinion was disclosed during trial while the expert was on the stand. And the Court said, No, there's no prejudice here because you haven't -- you can cross-examine that expert and you haven't -- I'll give you the opportunity to recall your expert, so.

THE COURT: But here we have new facts. Here we have new facts.

MR. GRIGGS: With respect to the --

THE COURT: Everything.

MR. GRIGGS: The documents?

THE COURT: Yeah. There are new facts disclosed.

You have sought to reopen fact discovery.

MR. GRIGGS: Again, with respect to Carlson, I disagree. I mean those are -- those are the basis of his opinion and, you know, they're facts outside the case.

THE COURT: Are they responsive to Boston Scientific's document requests?

MR. GRIGGS: It may be.

But, again, that goes back to, you know, they were -- when we got the draft report, I mean, that's when we would have supplemented.

THE COURT: And you didn't have any idea that your expert would be relying on other licenses until a few days before the expert report was finalized?

MR. GRIGGS: Well, again, I don't want to get too much into work product, but he explained what he would be doing.

THE COURT: Yeah.

MR. GRIGGS: And then he gave us the results of the work a few days before the report was --

THE COURT: Did you know that he would be locating license agreements?

MR. GRIGGS: I did not know. He just said he was going to survey license -- license information.

THE COURT: All right.

MR. GRIGGS: And so then when we received the

draft report.

THE COURT: When did he say that?

MR. GRIGGS: That was when we -- at the beginning of expert discovery. I, you know, I said, All right. You know, now's the time.

I gave the information that we had and he went off and did what he did. And then he gave us the draft report. And then that's when we disclosed what we disclosed in the initial report, which, like I said, we believe complies with Rule 26.

THE COURT: Uh-huh.

MR. GRIGGS: There's no sandbagging, there's no withholding, there's nothing about being devious or anything here.

You know, we produced it promptly once the issue was raised, because there -- you know, there may be even other information that --

THE COURT: Uh-huh.

MR. GRIGGS: -- you know, that he relied on that there has been no issue with, you know, so.

THE COURT: When you say that you first learned that -- and I'm just asking you for similar things to what's on your declaration.

MR. GRIGGS: Uh-huh.

THE COURT: So I'm just asking. The -- when did

you first have knowledge that your expert would be looking for information about licenses?

MR. GRIGGS: I --

THE COURT: Time/date.

MR. GRIGGS: I tried. It was probably during our initial conversations right at -- toward the beginning of the expert phase. I don't know that I know --

THE COURT: He was identified in August, right?

MR. GRIGGS: Yes.

THE COURT: And so by August you had at least information before the close of fact discovery where you knew that he would be locating -- he would be looking for license agreements, right?

MR. GRIGGS: It's possible.

And, again, looking for license agreements, you know, I don't think it was that specific, you know, I think it just -- he -- they -- I believe it's explained in his report, I mean they value IP. And this is the way they value IP.

THE COURT: Right.

MR. GRIGGS: And so, I don't --

THE COURT: But my question is very specific.

MR. GRIGGS: Yeah. And I don't know that he said I am going to be identifying specific licenses. I think he said I will --

THE COURT: But did you know he'd be looking for licenses?

MR. GRIGGS: Again, I'd have to go back and look at my records and see what, you know --

THE COURT: What do you think?

MR. GRIGGS: -- what was communicated when.

THE COURT: At some point --

MR. GRIGGS: At some point certainly --

THE COURT: -- he has permission.

MR. GRIGGS: At some point he said --

THE COURT: To spend money on third-party reports.

MR. GRIGGS: Sure.

THE COURT: When did he get that permission to start looking at third-party reports?

MR. GRIGGS: Well, again, that -- I mean, that was in sort of the scope of the work --

THE COURT: Yeah.

MR. GRIGGS: -- I believe. But the question is, you know, whether during that initial conversation, August, whether we discussed specifically what he would be doing, or, you know, whether that conversation occurred later when we actually said, Green light. Go. Do it.

THE COURT: At some point he knew that he had permission to spend money on third-party reports, right?

MR. GRIGGS: At some point, certainly.

THE COURT: And was that some point in October?

MR. GRIGGS: It may have been. Again, I -- I know that --

THE COURT: Does that make sense that they have a draft including all that -- I -- it seems to me that he would have to push the button on trying to obtain that information long before his draft was produced to you.

MR. GRIGGS: And, again, I don't know -- and I -- I haven't spoken to Mr. Carlson about his timing.

All I know is, you know, generally when I had conversations with him -- and what I do know is we do not get the draft report until, you know, less than a week before the final deadline. And that's, again, that's when NLC first learned of this information.

THE COURT: But were you -- were you surprised that you -- that it was in there? It was like, Whoa. There's 5,000 documents here.

MR. GRIGGS: Well, I didn't have the documents.

THE COURT: I didn't give him permission to do that.

MR. GRIGGS: I had a summary. So I didn't understand what the underlying documents were.

THE COURT: Okay.

MR. GRIGGS: He had, like, distilled the information into a summary table. And so that's what was

disclosed to NLC.

THE COURT: Uh-huh.

MR. GRIGGS: You know, the first time we saw the documents was in the result of what we're doing here today.

And, you know, again, it seems like there's a fundamental misunderstanding as to what Rule 26 requires. And I believe we've got the case law that supports --

THE COURT: Okay.

MR. GRIGGS: -- that, you know, we did everything in accordance with the rule.

THE COURT: All right. I believe I understand your position. Thank you for responding to my questions.

So now let's hear from St. Jude. And why don't we hear then anything that Boston Scientific wants to respond with, and then I'll give the final word to the Plaintiff's side.

MR. SHAH: Yeah.

And, Judge, I mean, if there's something specific you'd like me to cover, well, I have three points that I thought of as this morning progressed that I'd like to go over with you.

But, first, I have had this dispute on the initial disclosures before in other cases. And so in this case, like all cases since then when I was a young attorney I had that problem, I shouldn't say problem, but we had this

debate on whether the initial disclosures require to be supplemented or not.

And so since then my practice has been, as it is in this case, that my first interrogatory always is to identify any witnesses you will be calling at trial or any hearing in this case.

Interrogatory 1, you had asked me about interrogatories before, Interrogatory Number 1 that I asked says exactly that. "Identify the name of any person you intend to call at any hearing or trial in or related to this matter."

NLC identified three fact witnesses, Dr. Niazi, Mr. Stawicki, and then a representative from St. Jude.

To this day, today, standing here, Judge, that interrogatory has not been amended to identify Dr. Burke. And we know now know that Dr. Burke has been a fact witness at least since October.

There's no excuse for not supplementing that.

I do not believe there's case law, and I'd love to see if that says you don't have to respond to discovery like an interrogatory if you provide it in writing in some other format. That's the purpose of this interrogatory is so that we may be able to be able to rely upon it.

We are now months after the close of discovery. Dr. Burke's not listed.

That's the problem that we're dealing with here is that he is a surprise fact witness.

And kind of dovetailing to my second point is, you know, I don't think willful ignorance is a substantial justification.

We've heard time and time again for them to say, well, we just didn't know or didn't ask. But infringement has been at the forefront of this case.

They should have had a good faith basis to establish indirect infringement against St. Jude before they even brought this case.

And so it's a little troubling to hear that they were dealing with Dr. Burke on the IPR issue but infringement wasn't on their mind because it should have been the reverse. Infringement should have always been on their mind.

And Dr. Burke's kind of summary testimony that, I am the infringer, just as Mr. Carlson's report that I'm realizing that -- I mean, frankly, I don't think I understand the full scope of the problem that it's summaries relating to licenses until today, that is significantly problematic, Judge, because as you pointed out, we should be provided the opportunity to find and take evidence that would contradict, undermine, maybe not until we have to come up with a different strategy, all of that discovery, both as

to Dr. Burke and as to Mr. Carlson. We don't have that opportunity. I now would have to open discovery up. We would have to take hospital discovery, we'd have to take third-party discovery on the damages.

To the extent that it's true that there's no record and it's just going to be oral testimony, we may have to take a survey. Right? We may have to take a survey of other doctors to say, Well, is this consistent with your practice? Because I'm going to have someone on the stand saying this is my practice.

There's just a floodgate of discovery that have to be taken here.

And so -- and it's very troubling that after discovery I'm hearing that these are all just summaries. That's completely improper and we should have had before.

And then the last part I want to make is just on the law.

I mean, there's cases today that are claimed that I have not heard of, but the two cases that NLC cited in their brief in response to our motion are both distinguishable.

There's the first case which is out of Iowa, the *Estate of Thompson*. That case dealt with demonstrative exhibits. We're not talking about demonstratives here, Judge, we're talking about late, central burdensome, factual

issues that would require opening up of discovery well after discovery's closed.

And then the other case that they mentioned was this *Downeast Ventures*, where, yes, in fact, there was new -- a new theory allowed at trial.

But the key distinction in that case, Judge, was first, it was a consistent theory that had been presented before.

And, second, the witness was a prior 30(b)(6) corporate witness who was espousing his new theory, which was consistent with the prior damages theory.

So it was not an instance of new discovery being added, it was just simply how it was being presented.

That's not what we have here. What we have here is in line with the cases we cited.

And so I'll start -- let me start with the District of Minnesota case, which is *Lisdahl*, which is cited at Page 16 of our brief. It's 698 F. Supp. 2d 1081. But this case is almost exactly in line, although it's more in the *Daubert* context, but the court says that they conclude that, "The doctor at issue was properly excluded from testifying as to a certain topic because the effort to admit his testimony was a subversion of the disclosure requirements imposed upon all litigants."

I mean, here he is not provided -- he's not

permitted to testify because he is trying to subvert the fact discovery rules. That's exactly what happened here.

Whether it was unintentional or was intentional, it is not justified. And where we are now is that Dr. Burke had not been asked about these questions. Dr.(sic) Carlson had not been asked about these licenses and we're faced with that.

There's another case that I think is also very telling. It's not from this circuit, it's a Fifth Circuit case, but we cited it at Page 12 of our brief, which is the *Geiserman* case, 893 F.2d 787. And there the Court finds that, "The reasons offered by the Plaintiff for their failure to identify are weak at best."

It says, "As a result of their failure -- I'll just read the quote, "Regardless of *Geiserman*'s intentions or inattention which led to the flouting of discovery deadlines, such delays are a particularly abhorrent -- are a particularly abhorrent feature of today's trial practice. They increase the cost of litigation to the detriment of the parties immeshed in it. They are one factor causing disrespectful lawyers in a judicial process."

Now, maybe that's a little extreme but that's precisely what's happened here, Judge. We have -- you know, it's been two years, almost three. We're at close of fact discovery and it's like we're starting again. And that's

just not something that we should be doing on an issue that St. Jude has raised upon motion, upon motion which is their initial burden in which they knew about it.

So, again, as to both of these issues, you know, maybe one last point to make is that Plaintiff has suggested in its briefing that these aren't important issues, or central issues. They're not dispositive, they're just factual issues that they came upon but it clearly is a problem for Boston Scientific and St. Jude. And so that -- maybe that's just another reason that weighs in favor of striking these components of those expert reports.

THE COURT: What about a final comment on what Mr. Griggs is saying is that this is exclusion as both parties are requesting is an extreme result and that, you know, that discovery -- opening up discovery, they wouldn't be opposed to and, you know, there's time?

MR. SHAH: Well, a couple things.

I agree with Your Honor, I don't think there's time. And discovery was done -- we had interrogatories and discovery in a way that we should have had all this information before.

So to come to answer that latter part, I would be loathed to agree to opening discovery again and incurring those costs. It is expensive. My client is already upset about the budget.

I certainly wouldn't want to do that unless, I mean, if the Plaintiff wants to pick up the costs, that's one thing, but we are where we are.

THE COURT: What do you think the costs would be?

MR. SHAH: To open up third-party discovery? I mean, I would --

THE COURT: And then do additional expert disclosures based upon new discovery.

MR. SHAH: Yeah. I mean, damages experts are expensive. And if there's surveys involved, I mean, Judge, we're looking at $200,000, $300,000, all in. I mean, you have an expert on two sides that we'll be needing to survey.

Right. I mean, if it's correct that this can't verified that Dr. Burke, in fact, uses it in an infringing way, then we'd have to take a survey of doctors to see whether or not that's consistent with his testimony. That's probably 50 to 100 grand right there.

We'd have to do the same thing potentially on the damages side, because if these are just summaries of licenses, who knows what methodology was used for those summaries, and so other summaries would need to be created, or analysis would need to be created based on these 5,000 documents.

My guess is -- I mean, knowing how much these

experts costs on the damages side, they're pretty expensive, that's probably another $100,000. And then, of course, there's all the attorney time in between. It is an expensive proposition in between.

And then, of course, there would be the third-party discovery to start all that, which we would have to subpoena hospitals. Hospitals have requirements. And so there's timing and we may need court orders. I mean, there's all the legal process in there.

It's not just as simple as saying, take the depos, shoot out a Rule 45 subpoena to somebody. It is, I think, quite intense. It would require a lot of work.

And then, you know, maybe because I'm answering in the reverse, as to the extremeness of it, and I disagree, but certainly whether it's extreme or not, I mean, let's say it is extreme. I think this is the type of case that warrants it. I mean, infringement is the only reason we are here in the first place.

From day one they've been asserting that St. Jude's indirectly infringed. If they didn't think about that, they didn't think to ask their expert about that for a year and a half after he realized he was the infringer, I think it warrants that type of extremist, particularly since they're saying in their brief they don't even really even need that. That's just the cherry on top for them. Well,

that's a problem for us. That's significant.

And so if that's extreme, they knew the rules. This is their case. We have asked time and time again through motions. I don't know if we can see how we can give them more notice that direct infringement is the significant, as we see it, hole to allow them now after the close of fact discovery to come in and add a physician who's going to just say that without getting us adequate disclosures in the interrogatories we asked, the document requests we asked, or in the adequate period. I think that warrants that type of extreme measure.

But certainly, to the extent that Your Honor wants to do it the other way, I would suggest then the ruling should, you know -- humbly I would suggest that the -- what we would have is that discovery open and Plaintiff pay for the rest of discovery and we'll take that discovery.

I really don't want to do that but we're excited about getting to dispositive motions in this case because I think we'll be able to wrap this up, frankly, deal with some of the other issues that my colleagues -- that Boston Scientific alluded to.

But if Your Honor believed that it's too extreme, that striking these issues is too extreme and that something else should happen like discovery, then I would ask that whether there's some sort of way to address with the

additional burden, because it is significant on St. Jude, and I believe Boston Scientific would agree that it's going to be pretty expensive to go ahead and proceed on these late filed discovery issues.

THE COURT: Thank you.

Let's hear from Boston Scientific. And then again, Mr. Griggs, you'll have the last word.

MR. GRIMSRUD: Thank you, Your Honor. I'll be brief.

Yeah. On the -- on these points that have been raised, you have Dr. Burke and his opinion, for example, Boston Scientific, as I was saying, thinks there's all sorts of problems with it.

And, you know, we have the same issues in our case, as far as, we served the interrogatory asking for specifically for, Tell us who the direct infringers are. No response. I mean, there's just -- no one's identified, so we have all these same issues.

As far as when -- I think we had --

THE COURT: You just, you have the same issue, but you decided to not raise it now, but to raise it with a *Daubert* motion?

MR. GRIMSRUD: Yeah. We had been -- we had been planning to raise it later, as far as a case management, I just wanted to just flag that for the Court, though, because

as far as case management goes, if it's more efficient, you know, we'd be happy to accelerate that process, as well as far as dealing with Dr. Burke.

I just want the Court to be aware that we think that all of the same issues apply in our case. It's more of -- the question is more of when we were going to raise it.

THE COURT: Okay.

MR. GRIMSRUD: And so -- but as far as, you know, the sanctions that you were talking about with, you know, exclusion versus reopening discovery.

Reopening discovery, you know, obviously if it's going to be reopened, it would be reopened in both cases. And we're talking then about damages issues, infringement issues, expert discovery, but also depositions of hospitals, probably the hospital that Dr. Burke works at, potentially people at the hospital, getting documents from those hospitals.

Then there's, you know, the KT Mine, the Royalty Source, potentially depositions of them, potentially subpoenas for documents.

I mean, between the two cases, it's easily, hundreds of thousands of dollars.

And so if we're reopening discovery, certainly NLC should be paying for all that discovery. That would be a huge burden to impose on us. It would be very expensive.

Now, stepping back though, we don't -- we think the appropriate remedy is exclusion here for sure. That is not an extreme sanction, it's spelled out in Rule 37 that if information is not produced timely, and there's not a substantial justification, or it's not harmless, the automatic rule is exclusion, the District of Minnesota is clear on that.

There's many cases that talk about how it's a -- you know, how it's a self-invoking sanction, basically, automatic exclusion, so it's not a partial remedy.

But -- but I agree exactly with what St. Jude was saying is perfectly called for here where there's all this information, factual information, that was not produced during fact discovery, wasn't produced at the opening expert report, and then was produced late. And it should be -- it definitely should be excluded.

If NLC wanted to rely on this information, NLC should have gone out and had an obligation to go out and get that information during fact discovery. That's what fact discovery's there for. It's for the parties to go out and get what they think they need factually to -- for their case and NLC didn't do that.

And this is just very untimely and it should be excluded.

THE COURT: Thank you.

And so, Mr. Griggs, I will allow you, and I won't pepper you with questions, I'll just allow you to summarize your response and to address any points that you feel that you haven't had an opportunity to address.

MR. GRIGGS: Sure, Your Honor.

And I did -- I was doing a little bit of research and I found a case out of the District of Nebraska. It talks about, again, listing documents and then subsequently providing those documents in advance in the expert deposition.

It's *E3 Biofuels v. Biothane,* the citation is 2013 WL 5729537. And it's a 2013 case. Again, that was just very quick research that I was --

THE COURT: Can you repeat the Westlaw citation?

MR. GRIGGS: Sure. It's --

THE COURT: 2013 WL 57 --

MR. GRIGGS: 29537.

THE COURT: Great.

MR. GRIGGS: And I can just read a couple of the sentences. "Having considered these factors, the court finds that plaintiff's reported failure to provide an exhaustive list of information that its experts considered in reaching their opinions does not justify exclusion of its experts testimony. Plaintiff's expert report provide -- reports provide extensive lists of the facts or data

considered by each expert. The retained expert's alleged failures to provide all encompassing lists is harmless, as Defendants have not been prejudiced by any such omission. They have had to be deposed in this case." And so on and so forth. And so --

THE COURT: And that was for the exclusion of the expert, right?

MR. GRIGGS: Yes, I believe so. Again, I'd have to -- but, yes, I believe they're trying to exclude expert testimony similar to what's going on here.

THE COURT: The whole report, right?

MR. GRIGGS: What was that?

THE COURT: The whole report based upon --

MR. GRIGGS: Yeah. It's either the whole report or it's a portion of the report.

THE COURT: Okay.

MR. GRIGGS: They say the testimony should be excluded because they don't comply with 26(a)(2), which requires to contain the facts and data.

And, you know, the court said it contains a list. They'll get the experts filed before the deposition and then so there's no prejudice or harm or anything there.

THE COURT: Okay.

MR. GRIGGS: So, again, that just dispute was not about whether they needed to produce the documents, it was

whether the list was complete enough.

So, again, I -- I have not seen any case law that says you need to turn over the entire expert file or every piece of paper that the expert looked at in considering the report. You have to list that out. And if the other party wants it then, you know, they get it prior to the deposition.

And, again, I believe that's how things should have progressed here but, you know, they did not --

THE COURT: With respect to Carlson.

MR. GRIGGS: With respect to Carlson, yes.

And, again, I want to circle back to this, you know, this -- this prejudice. And, you know, it's talking about the expense and the -- all of this. You know, they would have had to have borne that had this been, for example, if we had a conversation with Burke and disclosed him during fact discovery.

So just the sheer volume that's been -- and expense associated with this, it's more of a time shifting thing, because that would have been incurred had this been timely -- you know, timely disclosed.

And so the fact that they have -- they may have to do the work, you know, they would have had to have done that before if that was -- if that was, you know, timely disclosed in the event that the Court finds, that, you know,

we should have, so.

So the, you know, the amount of work that needs to be done in response to this is -- is not prejudiced, you know, that's just work that's associated with the case.

You know, the real question is are they prejudiced in their ability to defend against this information? Which as I've cited a number of cases, including the one that I've just, you know, cited to you, is they're afforded the time to basically focus on depositions and allowing their experts to respond to this, then there is no harm.

And, you know, the rules are about, you know, giving -- making rulings based on the facts and the -- you know, the full record in front.

And, you know, in this instance they were disclosed, you know, a few days after NLC learned of this information.

And I understand there's been some attacks on how NLC may have, you know, conducted the litigation during fact discovery but, you know, that's not part of the record.

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.

And, you know, so then Dr. Burke offered this, we

disclosed it and, you know, that's where we are here today.

With respect to Mr. Carlson, you know, again, this is -- this is not information that NLC had or provided to him. This information that he generated on his own as, you know, a lot of experts will do. They will go and they will use their resources, generate their opinions and then, you know, the basis for those opinions, the facts and the data were disclosed in his report.

And when there was an issue raised as to where is all the underlying data? We promptly disclosed that.

And in advance, Mr. Carlson hasn't been deposed yet. You know, the expert report or the rebuttal expert deadlines that are, you know, still -- we've already extended that deadline. So, you know, we're sort of right in the middle of expert discovery right now.

So, again, I'd go back -- exclusion is -- is an extreme remedy. And, you know, it is prejudicial to NLC to not be able to at least get past this stage of the case, you know.

If there are going to be *Daubert* challenges, sufficiency of the evidence relating to the, you know, not having the underlying license agreements, those are for a later point in the case.

But to cut that off at that stage even before these expert depositions is -- is an extreme remedy and it's

not warranted here.

THE COURT: Thank you.

Anything further? Any final points?

I'm going to be telling you when to come back, because I am going to do some followup work based upon the arguments in the cases that were identified here.

Anything you'd like to add as a last point?

MR. GRIMSRUD: Nothing from Boston Scientific. Thank you, Your Honor.

THE COURT: All right.

MR. SHAH: Nothing from St. Jude.

THE COURT: All right. Then I think you did have the last word.

So what I'm going to do, it's about quarter to 11:00 now, why don't you come back at 1:00 and I will give you my decision.

MR. GRIGGS: Thank you, Judge.

MR. SHAH: Thank you.

(Recess at 10:45 a.m.)

(In open court at 1:34 p.m.)

THE COURT: We are back on the record in the Niazi matters and we were earlier hearing the two motions in case Number 17-CV-5096 WMW/BRT and 17-CV-5094 WMW/BRT.

Why don't we, for the record, go ahead and get appearances, Counsel, who are here after the break.

MR. GRIGGS: On behalf of Plaintiff, Michael Griggs.

THE COURT: Thank you.

MR. SHAH: Good afternoon, Your Honor. Judge, on behalf of St. Jude, Kal Shah.

THE COURT: Thank you.

MR. GRIMSRUD: On behalf of Boston Scientific, Timothy Grimsrud.

MR. CHUNG: Also on behalf Boston Scientific Doowon Chung.

THE COURT: Thank you.

I am now going to be deciding the two motions before the Court.

For the record, St. Jude's motion is to strike facts disclosed in Dr. Burke's expert report that were not disclosed by the fact discovery deadline.

St. Jude also seeks to preclude Dr. Burke from testifying as a fact witness due to late disclosure.

And St. Jude also seeks to strike facts not disclosed during fact discovery relating to the Carlson report and not produced with the report.

Boston Scientific joins in St. Jude's motion and has separately sought to strike the late production of 5,000 documents and to strike any reference to those documents in Carlson's expert report.

Before I go through and walk through my decision and the analysis, I do want to make a record on the Court's jurisdiction to hear the motion.

And these two motions before the Court do not seek to exclude the entire expert opinion pursuant to *Daubert*, which would be dispositive, according to the local rules in this district.

Instead, all of the parties initially when we talked about this motion agreed that the two motions before the Court are nondispositive motions relating to the alleged discovery disputes and sanctions pursuant to Rule 37.

So I want to make clear that I'm not deciding these motions based a *Daubert* analysis and that any *Daubert*-related motions will need to be filed pursuant to the scheduling order on dispositive motions.

So now I'll turn to my ruling on the motions.

The common nondispositive issue before this Court is whether facts and fact witnesses relied on by Plaintiff's experts were disclosed too late.

And if I answer that question affirmatively in that they were disclosed too late, according to the rules, then the Court moves to a Rule 37 analysis as to whether the fact witnesses should be excluded and expert reports, the references to the newly-disclosed facts should be stricken as a sanction.

We'll first discuss the answer to the first question and that is, Was the identification of this material that is at issue and the new fact witness produced too late?

Plaintiff Niazi's primary argument in opposing St. Jude's motion regarding Dr. Burke is that Plaintiff did not withhold the identity of Dr. Burke as a fact witness and Plaintiff did not disclose the facts too late.

And I'll quote from Niazi's brief. "Rather NLC learned of the information at issue during expert phase of the case and timely disclosed it to St. Jude." And that's from the Niazi brief, Document 138 at Page 4.

Plaintiff Niazi further explains that, "NLC did not discover this information until after the close of fact discovery. And upon discovery of this information promptly disclosed it to St. Jude." And, again, that's from Niazi's brief at 30 -- 138.

Counsel filed a declaration declaring that Niazi first learned that Dr. Burke directly infringed Claim 11 of the method patent on October 4th, 2019. And that Niazi disclosed this new factual information on October 15th through the Burke expert report. And I'm referring to the declaration of Mr. Griggs at Document Number 139.

In this case, Plaintiff was alerted to St. Jude's evidentiary challenge regarding direct infringement of the

method claim.

And I looked to a filing on March 21st, 2019, where St. Jude arguing -- argued the following. And this is St. Jude -- this is a document in the St. Jude case, Document Number 69, and I'm going to quote the excerpt.

"Plaintiff's contentions, however, failed to identify a single instance of direct infringement underlying its assertion of indirect infringement do not reference actual St. Jude product and arbitrarily apply claim language to enforce infringement. Plaintiff's contentions in short are substantially hollow and should be stricken."

So that was St. Jude filing a motion back in March alerting Plaintiff to this deficiency. And I'll -- I should mention it's an allegedly deficiency.

Plaintiff responded to that motion and Plaintiff claimed that only theories needed to be disclosed.

So in Plaintiff's view the infringement contentions only needed to disclose theories.

And then Plaintiff went on to say, and I quote, "With the expectations that the parties will conduct discovery relating to the evidence that underlies the Plaintiff's infringement theories." That's document Number 172.

"Plaintiff as the party with the burden to establish infringement should have been diligent to timely

produce evidence to support its theory of infringement.

Plaintiff argues that 26(e) permits supplementation and that it's supplemented in fact discovery obligation by making the new fact witness known in writing as part as an expert report.

Even if the Court agreed that supplementation under Rule 26(e) to identify an important new witness and important new facts could be disclosed within the pages of an expert report, 26(e) does not operate to permit a party to conduct fact discovery after the discovery deadline when that discovery could have easily been conducted within the fact discovery period."

Plaintiff's interpretation would encourage parties to, and I quote, "subvert the very purpose of a Rule 26 by waiting to ask for relevant information and then argue that information was turned -- that the -- that they turned other the information as soon as they received it." See *Dedmon*, D-E-D-M-O-N, *versus Continental Airlines*. This is a case out of the District of Colorado, August 5th, 2015, 215 WL 4639737.

Now Plaintiff's cited *Poitra versus School District Number 1* at 311, F.R.D. 659. And that's another case out of the District of Colorado, December 31st, 2015.

As discussed in *Poitra*, and I quote, "Rule 26(e) creates the duty supplement, not a right, and does not

create a loophole to be exploited by a party to its advantage."

The *Poitra* case also discusses -- discusses that "Supplementation of disclosures must be made in a timely manner and that it must occur in a fashion that will allow the opposing party to conduct meaningful discovery and avoid undue delay in the progress of the case."

Fact discovery closed on September 13th, 2019. Here Plaintiff admits that important facts and these important facts and important fact witnesses, those disclosures as far as Dr. Burke is concerned, could have been inquired about during the fact discovery period had Plaintiff's Counsel asked Dr. Burke for this information.

Plaintiff admits it had ongoing access to Dr. Burke as a potential fact witness long before the fact discovery deadline approached. But Plaintiff does not dispute that they began working with Dr. Burke during the IPR period.

Dr. Burke recently testified and he concluded that he was a direct infringer all the way back in 2018. And now I'm referring to the chart that was submitted, and there was no opposition to the Court receiving that chart, and that will be filed as Exhibit 1 to this hearing.

So as I've already discussed, the alleged gap in Plaintiff's negligence was clearly highlighted for Plaintiff

by St. Jude.

And a fundamental topic of infringement could have been easily explored by Plaintiff with Dr. Burke prior to the September 13th deadline for fact discovery.

Even if Plaintiff's late disclosure was not intended to sandbag, it is in the Court's view inexcusable.

Plaintiffs were in control of obtaining this information and it should have been produced earlier.

The *Poitra* case confirms that a Plaintiff's good faith alone may not be enough and that a party should not be permitted to ignore disclosure obligations throughout the discovery period and then avoid sanctions simply by claiming his deficiencies were not willful.

So now I will turn to the Carlson report.

And before getting into that, I do want to just make a record about how clear the deadlines were in this case and how careful the Court was with respect to working with the parties on the deadlines to make sure that this case proceeded in a way that was efficient and consistent with Rule 1.

This Court set clear deadlines for fact discovery, including the service of third-party subpoenas in its scheduling order.

This Court set deadlines for expert reports following the close of fact discovery.

This Court's scheduling order framework was predicated on the assumption that fact discovery would close and that the parties, along with the experts, would digest the facts and base their opinions on the facts.

Rule 26(a)(2)'s requirement that an expert report contain the facts or data considered by a witness in forming opinions does not trump the fact disclosure obligations in the rules, and that includes Rule 26(a)(1) or the need to timely respond to discovery requests.

The fact that a document is cited by a party's expert and is -- strike that. I'm going to quote from a case entitled *Transamerica Life Insurance Company v. Lincoln,* 255 F.R.D. 645. And that's a Northern District of Iowa, January 29 case, 2009.

And in that case, the court said that "The fact that a document is cited by a party's expert and is publicly available does not excuse that party from timely production of that document if it is the subject of an appropriate discovery request." And that's even for a publicly-available document.

The information referenced in the damages expert report but which was not disclosed until demanded by St. Jude was directly responsive to Defendant's discovery requests.

I'll offer one example. Boston Scientific's

Question Number 27, and I quote. "Documents that NLC may rely on in any way to support its claim for damages."

Plaintiff explains that it did not produce the information because it only needed to produce a list with its expert reports even if those documents were not available through previously-produced discovery.

This reason by Plaintiff ignores that Plaintiff had an obligation to produce this information in discovery. And at the very least to supplement responses to multiple discovery requests. And even if the parties don't believe that supplementation of disclosures under 26(a) needs to be done, the rule does require supplementation at times. And this Court ordered supplementation of initial disclosures to be made in, I believe, February and March of last year.

The Court agrees that a list attached to an expert report may be sufficient, but that list has to identify things produced in discovery if they're not general information.

The Court took a look at the *Bazarian International* case cited by Plaintiff. And this case actually confirms this basic assumption that lists are sometimes sufficient as long as those lists do provide for the disclosure, the content of facts have -- are already available.

And I took a look at the *Bazarian* case and it was

interesting. This case cite is 315 F. Supp. 3d 101, District of Columbia, October 25th, 2018.

And it wasn't totally clear from the case of *Bazarian* on what this list was. But in *Bazarian*, it internally cited to a number of cases about the adequacy of lists.

And in each of the cases that were internally cited, the parenthetical talked about the list, including books and article, review of relevant authority and I quote, "discovery materials."

Another internal citation in the *Bazarian* case included a parenthetical in an internal cite that discussed that a list was appropriate because everything on the list was produced as part of discovery.

The Court takes note of a case that I don't think was cited by any of the parties and it is the *Ravo versus Covidien* case out of the Western District of Pennsylvania, 55 F. Supp. 3d 766, Western District of Pennsylvania, October 24th, 2014.

And the Judge in that case reiterated the basic premise that I believe applies here. And I quote, "An expert cannot offer testimony based on documents not produced in discovery because there is no principle way to test that expert's recollection and opinion."

The Court also reviewed the *E3 Biofuels versus*

Biothane case cited by Plaintiff. And that case is at 2013 WL 5729537, District of Nebraska, October 22nd, 2013.

In that case, the issue wasn't that the judge had decided that the list was okay. For purposes of the decision in that case, the judge assumed that the list was not sufficient and that for purposes of Rule 37 the failure was harmless.

And so this case does not support that Plaintiff's list which disclosed admittedly unavailable licenses or licensing data was permitted under the rule was permitted based upon the document requests that had been made and was permitted based upon the rule for expert disclosure. That includes a requirement that the facts and data needs to be included.

The Court finds that all of the factual disclosures at issue were untimely produced.

Since the Court finds untimely disclosure, the Court now proceeds to the factors for exclusion of the evidence pursuant to Rule 37.

The Eighth Circuit has set forth four factors that the Court considers in determining whether a failure to disclose was justified or harmless.

Factor one is the importance of the excluded material.

Factor two is the explanation for failing to

comply with the disclosure rules.

Factor three is the potential prejudice from allowing the material to be used at trial.

And factor four is the availability of a continuance to cure such prejudice.

And I am referring to the factors, and I believe both parties have cited to this case, it's the *Citizens Bank of Batesville, Arkansas versus Ford Motor*, 16 F.3d 965, 966 Eighth Circuit, 1994.

Regarding the first factor, it appears that the parties agree that the potentially excluded factual material in the Burke report is important.

With respect to the Carlson report, it's -- it's unclear what the level of importance is. The Plaintiff says it will not introduce the underlying data but it would be prejudice if the Court were to exclude the opinion. And so I'll find that the information is important and I will rule that regarding factor number four, the information is important.

I will note, however, that this finding, in my view, does not factor one side or the other.

It's important, and I think that is certainly a factor that points to -- would support either party. So I'll move onto the other factors.

And in factor two, the Court has already discussed

Plaintiff's explanation for failing to comply with discovery as part of the question number one I had to answer, and discovery -- discovery and disclosure obligations.

In the Court's view these raisins -- reasons favor exclusion pursuant to Rule 37.

So now I'll move onto factor three. And under factor three, the Court looks at potential prejudice.

The Court finds that Defendants are prejudiced if the -- if the Court does not exclude the evidence because they should have had the opportunity to take discovery on the factual information in a timely manner.

They should have had opportunity to work with their clients and the experts earlier to digest factual information that is core to Plaintiff's case.

The Court finds that there was unfair surprise as far as the disclosure of Dr. Burke as a fact witness is concerned.

The Court finds that a continuance will not cure the problem created by Plaintiff's own doing.

Reopening fact discovery and opening of new discovery to further examination of these new facts and the impact of a new fact witness on infringement, and then to look at the change in expert analyses will be expensive. And a record, a clear record, was made on the expense that that expense could involve hundreds and thousands of dollars

is significant.

Reopened discovery would likely involve the participation of third parties. As St. Jude notes, had Dr. Burke's direct infringement been disclosed properly in discovery, St. Jude could and would have sought documents, communications and testimony related thereto.

St. Jude also could and would have taken corresponding discovery, including that of hospitals and manufacturers to determine the veracity and nature of Dr. Burke's claims.

The fact that Defendant's experts might be able to address the undisclosed information in their yet unserved expert reports does not cure the prejudice.

Defendants have been denied use of this information during the fact discovery period.

Thus, factor four shows that a continuance is not available to cure the problem.

In sum, the Court's analysis of the factors with respect to the Carlson report and the Burke report clearly supports exclusion of the late disclosed evidence.

I'll conclude with a quote from the *Poitra* case that was identified by Plaintiff here today as a case that supported Plaintiff's position. And I'll quote, "There comes a time when an opposing party is entitled to make informed decisions and to rely on the statements (or

silence) of the other side. If the risk or consequences for indecision should fall on one side or the other, it should be the party with the affirmative disclosure obligation. Any other resolution bodes ill for the just, speedy and inexpensive determination of every action."

And, again, I'm quoting from *Poitras v. School District* 311 F.R.D. And that was cited earlier.

The Court will grant both motions. And this order will just be followed up with a text entry on the docket. And this record will serve as the reasoning and analysis of this Court's decision.

We're off the record.

(Off-the-record.)

(In Open Court at 2:00 p.m.)

THE COURT: We are back on the record.

Off the record we were discussing some of the timing of the remaining deadlines in the case. And what I will do is hear Boston Scientific's request or comment.

And if you could step up to the podium so we get a good record of this.

MR. GRIMSRUD: Yes, Your Honor.

With respect to the Dr. Burke ruling, since that's an issue that St. Jude brought up, but it -- it applied all the same arguments and rationale, I guess, you'd say applies to the Boston Scientific case.

Dr. Burke issued a very, if similar, if not almost identical opinion in the two cases.

And so, with respect to that, there's a number of issues we have with Dr. Burke's report, but that's one of them.

And I think the nondispositive expert deadline is currently for motion practice is in January.

So given in light of the Court's ruling, we were thinking that perhaps it makes sense to accelerate us bringing that issue in front of Court.

It's going to be virtually identical to the issue that was heard today, but we just wanted to raise that issue and get clarity from a case management perspective how best to handle that.

THE COURT: All right.

Let me hear from Plaintiff's Counsel, Mr. Griggs. And let you respond to that issue that was just raised.

MR. GRIGGS: Again, I -- I don't see there's a need to brief this out if the Court's going to rule in a similar fashion.

So, I mean, we're comfortable saying that this ruling applies in the Boston Scientific case as well, just to avoid the, you know, the unnecessary briefing if they truly are doing the same arguments and the same evidence, and the same rationale that the Court just gave.

THE COURT: All right. Do you want to file some sort of stipulations so that you've got an order that would apply to both cases so there's clarity? And I'll start with you, Mr. Griggs?

MR. GRIGGS: Yeah. We can put together a stipulation to file in the Boston Scientific case that just says that the ruling as it relates to the St. Jude's case applies with respect to the Dr. Burke aspect of that motion.

THE COURT: All right.

MR. GRIGGS: I agree that would be the most efficient way to proceed, Your Honor.

THE COURT: All right. So let me go off the record again? Oh -- well, let's hear from St. Jude.

MR. SHAH: Yes. I'm sorry. Just it may be similar in the first, with respect to the -- I mean, it may be kind of a moot point, but since the motion was granted and doctor and Mr. Carlson can't rely or testify about those docs, those 5,000 docs are technically still produced.

I mean, should we do the same thing, submit a similar stipulation that they're not part of the record or that they are stricken? Because I believe that's what your -- the St. Jude case are technically stricken from production, correct? I'm sorry, from Boston Scientific case.

THE COURT: Right. Boston Scientific's motion.

MR. SHAH: Correct. If that's okay with Your Honor. And then maybe Mr. Griggs and I can work out some similar stipulation with respect to our case.

THE COURT: Mr. Griggs, let me not assume that you would do something similar and let me hear what you'd like to do with respect to a -- same motion from the St. Jude folks on the 5,000 documents.

MR. GRIGGS: I think the ruling should just apply to both cases and we can work out whatever stipulations we can work out so that there's (inaudible).

THE COURT: I appreciate that we were able to work through that.

Let's go off the record again.

(Court adjourned at 2:03 p.m.)

* * *

DIGITAL REPORTER'S CERTIFICATE

I, Lynne M. Krenz, do certify the foregoing pages of typewritten material constitute a full, true and correct transcript of the digital recording, as they purport to contain, of the proceedings recorded at the time and place hereinbefore mentioned.

/s/Lynne M. Krenz
Lynne M. Krenz, RMR, CRR, CRC

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Niazi Licensing Corporation, Plaintiff, vs. St. Jude Medical S.C., Inc., Defendant.	File No. 17-CV-5096 (WMW/BRT) St. Paul, Minnesota April 30, 2020 1:30 p.m.

BEFORE THE HONORABLE BECKY R. THORSON
UNITED STATES DISTRICT COURT MAGISTRATE JUDGE
(TELEPHONIC MOTION HEARING)

Proceedings recorded by mechanical stenography via telephonic conference; transcript produced by computer.

APPEARANCES

For the Plaintiff:	Boyle Fredrickson, S.C. Michael Griggs, Esq. 840 N. Plankinton Ave Milwaukee, WI 53203
For the Defendant:	Benesch Friedlander Coplan & Aronoff Kalpesh Shah, Esq. Samuel Ruggio, Esq. 71 S. Wacker Drive Suite 16th Floor Chicago, MN 60606
	Merchant & Gould Rachel Hughey, Esq. 150 South Fifth Street Suite 2200 Minneapolis, MN 55402
Court Reporter:	Lynne M. Krenz, RMR, CRR, CRC Suite 146 316 North Robert Street St. Paul, Minnesota 55101

P R O C E E D I N G S

IN OPEN COURT

(VIA TELECONFERENCE)

THE COURT: Good afternoon. This is Magistrate Judge Thorson.

Before we --

MR. GRIGGS: Good afternoon, Your Honor.

THE COURT: I'm going to ask everyone to let me begin by making some comments and first determining whether we have the court reporter on the call.

(Court reporter responded.)

THE COURT: Thank you. I am next going to press the button required to make an audio recording.

(Brief break.)

THE COURT: This is Magistrate Judge Thorson and I would like to begin by outlining some of the ground rules before I get the introductions of counsel, though I appreciate your patience.

I'd also like to confirm that my law clerk is on the line.

THE CLERK: Yes, Judge. I'm here. Thanks.

THE COURT: Thank you.

Now, obviously we are conducting this hearing by telephone because of all the restrictions and concerns due

to the COVID-19 pandemic.

I'm in chambers by myself but everyone else, including the court reporter and my law clerk, are participating remotely.

We will start in a minute here with appearances of counsel, but I want to make sure we coordinate that since we don't have the visual cues. And I will first ask for the plaintiff to introduce -- plaintiff's counsel to introduce himself and then the lawyer arguing for St. Jude should introduce herself or himself, and then also introduce the other lawyers who are appearing in the case. And I think that will allow for a more coordinated presentation that will avoid any talking over one another.

Now, after I get your introductions I am going to continue to cover some ground rules and reminders, but let's get appearances on the record, starting with the plaintiffs.

MR. GRIGGS: Yes. Good afternoon. Thank you, Your Honor. Michael Griggs on behalf of the plaintiff.

THE COURT: And for the defendant?

MR. SHAH: Good afternoon, Your Honor. Kal Shah on behalf of defendant St. Jude.

And then with me on the phone as well, I believe are Rachel Clark Hughey with Merchant & Gould, Sam Ruggio with Benesch Law and then with the client, St. Jude, Rachel Bach.

THE COURT: Thank you.

Now because this hearing is being conducted by telephone I want to just go through a few reminders.

Now, we have the court reporter, and I thank the court reporter for being on the call and arranging her schedule, but it will be very important for you to keep in mind that we do have a court reporter taking down what you say.

And so when you're on the phone, it's easy to speed up, it's easy to be reading from something and to go too fast. And so please just put a little flag on your notes, or on your desk, or whenever you are, to make sure to really slow down and make sure to speak very clearly and speak directly into whatever microphone you have on whatever device you're using to participate.

Please also make sure every time you speak up to say who you are. And it is easy to forget that. In court we go back and forth across the courtroom, but here the court reporter needs to know who you are before you start to talk.

So every time the baton is passed in oral argument today, state your name and ideally the party you represent.

Another important ground rule is for you to pause if you're speaking in long sentences or before you move on to a different point. That allows me to ask questions and

ensures that you're at a good pace.

If you're not the one speaking, please mute your device. And that will help to avoid any background noise, or any echoing or anything like that.

Now, one of the things I want to remember to say is that the court reporter has my permission to jump in if there's something about the way that this hearing is being conducted where she does not believe she's able to make a good record. And so if you hear the court reporter jump in, stop talking.

Another reminder, because we're all in our remote locations, probably by ourselves, it feels more private than it is. This is a public hearing, this is a public courtroom. It's just a public courtroom that is being offered by telephone.

And so if you feel that you need to cover something that is confidential, you'll need to try to work around it and speak in more general terms because the record will be a public record. And so once the cat's out of the bag, if you're disclosing confidential information, that will be difficult to take that back. And so think about that when you're covering certain information.

I don't think, based upon what I've seen in the papers, that you'll need to cover anything confidential, but it's just part of my points that I cover at the beginning of

these telephone hearings.

All right. So let's begin the hearing.

This is the United States District Court for the District of Minnesota, and we are here for hearing on St. Jude's motion to enforce a court order and for sanctions. For the record, this is Case Number 17-CV-5096 WMW/BRT.

I'd like to set the stage a little bit for this motion to help the attorneys who will be arguing the motion address the order that I issued back in December and the allegation of a violation of that court order.

Back in December, this Court granted St. Jude's motion regarding Dr. Burke. I granted that motion from the bench. And then the transcript was ordered and made available, I believe, a few days later. That motion was back in December.

Before presenting my decision from the bench, after a recess I framed the Court's understanding of the scope of St. Jude's motion. And that framing can be found at Page 95 of the hearing transcript and I quote, "For the record, St. Jude's motion is to strike facts disclosed in Dr. Burke's expert report that were not disclosed by the fact discovery deadline. St. Jude also seeks to preclude Dr. Burke from testifying as a fact witness due to late disclosure."

In its December motion, St. Jude objected that Dr.

Burke was being offered as a fact witness months after the close of discovery.

At the hearing, St. Jude argued, and I quote, "We are now months after the close of discovery. Dr. Burke's not listed. That's the problem that we're dealing with here is that he is a surprise fact witness."

St. Jude also argued that allowing Dr. Burke to offer factual information at this phase would require the reopening of discovery.

In my oral ruling in December I set forth the analysis for granting St. Jude's motion.

After presenting analysis in granting the motion, I said, and I quote, "The Court finds that all of the factual disclosures at issue were untimely produced."

Then, since the Court found untimely disclosure, I considered the exclusion of the evidence pursuant to Rule 37.

The Court, in considering the exclusion of the evidence, looked at the potential prejudice if Dr. Burke was allowed to come into the case as a fact witness at that time.

I'm going to quote, and it's a long quote, from the record of the hearing. Quote, "The Court finds that defendants are prejudiced if the -- if the Court does not exclude the evidence because they should have had the

opportunity to take discovery on the factual information in a timely manner. They should have had opportunity to work with their clients and the experts earlier to digest factual information that is core to Plaintiff's case. The Court finds that there was unfair surprise as far as the disclosure of Dr. Burke as a fact witness is concerned. The Court finds that a continuance will not cure the problem created by plaintiff's own doing.

Reopening that discovery and opening of new discovery to further examination of these new facts and the impact of a new fact witness on infringement, and then to look at the change in expert analyses will be expensive. And a record, a clear record was made on the expense -- that the expense could involve hundreds and thousands of dollars is significant. Reopened discovery would likely involve the participation of third-parties. As St. Jude notes, had Dr. Burke's direct infringement been disclosed properly in discovery, St. Jude could and would have sought documents, communications and testimony related thereto.

St. Jude also could and would have taken corresponding discovery, including that of hospitals and manufacturers to determine the veracity and nature of Dr. Burke's claim. The fact that defendant's expert might be able to address the undisclosed information in their yet unserved expert reports does not cure the prejudice.

Defendants have been denied use of this information during the fact discovery period. Thus factor four shows that a continuance is not available to cure the problem."

The Court excluded the late disclosed factual information. The Court granted St. Jude's motion and stated that the hearing record would serve as the reasoning and analyses for this Court's decision. That was my decision on December 2nd, 2020, at docket number 145.

The transcript of the hearing was available as of December 4th, 2019, and that is at docket 152.

After that introduction, I will now hear the parties' arguments.

I'll begin with St. Jude, as this is their motion.

MR. SHAH: Good afternoon, Judge. Thank you very much for that.

I think your recitation of the facts and the background hit directly on point with respect to the basis of our motion.

My client, St. Jude -- and I apologize, this is Kal Shah on behalf of St. Jude. My client, St. Jude, has had to deal with what I would consider a repeated refusal and violation by the plaintiff to abide by this Court's order.

Your Honor just went through the expert and discussion that we all had to go through in December of 2019

regarding this particular issue with Dr. Burke, who had been on notice, as Your Honor would recall from their -- based on our prior motions, not disclosing a slew of information --

(Phone beeping.)

MR. SHAH: -- regarding use of St. Jude's products, his experience, third-party, other physiologists. And Your Honor clearly indicated that all of those facts that were late disclosed were excluded.

Yet, you know, this is the third time now that we are dealing with this at great expense to my client and, frankly, I think this is a great expense to the Court. Your Honor addressed it, Judge Wright addressed it because there was a motion challenging Your Honor's order, and all of that was disregarded.

And where we are now today is Your Honor has to do it again, but equally important -- and I think this is a slap in the face to both my client and this Court, is that plaintiff's have used the (indiscernible) information to support their summary judgment and their *Daubert* motion.

So now this Court has to wade through not only this motion to enforce, but all of that once again to determine whether or not or where the Court should consider what has or has not been stricken.

But, frankly, in our view, and I'm trying to hold back some of my frustration, Your Honor, but this is utter

disregard for both the plaintiff -- for both defendant, St. Jude, and for this Court, and for this Court's orders that are clearly meant to provide a fair litigation profile for both parties.

You know -- and I guess I'm happy to address anything that you'd like to go through, but Your Honor could not have been more clear, as you pointed out -- and one of the things I planned on highlighting was the scope of your order was not narrow.

Your Honor clearly said, "the Court finds that all of the factual disclosures at issue were untimely produced." And that's at Page 105 of your transcript.

Yet, as you'll see -- and I'm happy to go through that, but paragraph, for instance, 12, paragraph 13, paragraph 22, paragraph 26, paragraph 36 --

(Phone beeping.)

MR. SHAH: -- of plaintiff's expert reports -- I'm sorry, plaintiff's declaration by Dr. Burke, I'm sorry, for in support of the summary judgment and in support -- or in opposition to the *Daubert* motion have basically cookie cutter copies of the very language that was addressed in our prior motion and it's just back again.

And Your Honor, clearly struck --

MR. GRIGGS: Your Honor, I'm sorry. May I -- I need to interject?

This is Michael Griggs. I got dropped off the call. I have not heard -- I just got back on. I did not hear any of St. Jude's argument.

I apologize for that. I don't know what happened. But I cut out right when Mr. Shah just started speaking and now I just jumped back in.

THE COURT: This is Magistrate Judge Thorson.

I will ask Mr. Shah to begin his argument. We will not be obviously striking any of the record, the court reporter will continue just to transcribe what we have.

But, Mr. Shah, if you could begin anew.

MR. SHAH: Sure, Judge. Rarely do I get (indiscernible) so I'll give it a shot.

But, Your Honor -- and to just reiterate, and I'll be a little more bit more brief, but our point is simply this is a pattern by plaintiff of its violation and refusal to abide by this Court's orders.

We had this very issue come up and my client, St. Jude, briefed it at expense. Your Honor kindly addressed it after a full-day hearing, and taking resources and time away from the Court. We have a lengthy transcript that Your Honor just quoted from. And Your Honor could not have been clearer as to the scope of Your Honor's order.

Specifically, as Your Honor pointed out, that the Court found that all the factual disclosures that Dr. Burke

provided late were untimely disclosed and were (indiscernible).

Your Honor also made clear that this particular transcript was the basis and the scope of your order. There was no unequivocal -- it was unequivocal and there was no confusion or room in any way for confusion as to the scope in what Your Honor intended to do.

And in addition to that, plaintiff had the opportunity and took the opportunity to challenge Her Honor's order with Judge Wright.

Judge Wright's --

(Court reporter interrupted.)

MR. SHAH: Yeah, I'm sorry.

(Phone beeping.)

MR. SHAH: Let me see if I can -- give me one moment, I'll take the headphones off and see if that's an issue.

THE COURT: This is Magistrate Thorson.

Mr. Shah, I want to make sure that you cover everything that you wanted to cover in this new presentation because Mr. Griggs was not on the call during the first part.

And so I just want to make sure that you cover everything that you covered earlier and don't just kind of pick up in a summary fashion and give you that opportunity

and make clear that you should take that opportunity.

(Phone beeping.)

THE COURT: Is -- this is Magistrate Judge Thorson.

I keep hearing beeps coming in and out. Is Mr. Griggs on the call?

MR. GRIGGS: Your Honor, again, I apologize. I got dropped off. I've got a different phone now. Hopefully this will solve the problem. I don't know what is going on, but I am on now. Again, I was off for the last minute or two.

THE COURT: All right. What type of phone are you -- are you on a different cell phone now?

MR. GRIGGS: I'm on a different cell phone. I was using my work phone previously. And I don't know if that was the source of the problem but I switched over to my cell phone, so hopefully that will not be an issue.

THE COURT: All right.

A couple of reminders, the court reporter has jumped in and has indicated that it's a little fuzzy with the phone that or device that being used by Mr. Shah.

It's very important that you're speaking very clearly into the microphone and that everybody else who is not speaking is muted. That will help the audio quality.

And so we are going to pretend that we are

starting all over again. And I want Mr. Shah to be able to speak more clearly into his device and I want Mr. Griggs to have the benefit of hearing everything.

Now, I know that that feels like we're wasting time, but we're not.

And so let's pretend that we just heard my introduction and, Mr. Shah, introduce yourself and let's begin.

MR. SHAH: Thank you, Judge. I'm just moving in my house to see if I can get a better reception. So let me just get situated.

One second. I'm trying to get upstairs where I'm closer to a window and see if this is any better.

Is my sound coming through any better at this point?

THE COURT: It's better.

Just be very clear and enunciate even more clearly than you already or typically do. I'm not criticizing your way of speaking, I'm just saying this has got to be very slow, and deliberate, and clear.

And please remember to introduce yourself before you begin speaking.

MR. SHAH: Okay.

Okay, Judge. And, again, if I do for some reason cut in or out, please let me know, but I have switched

locations.

So on behalf of St. Jude, this is Kal Shah. And I thank you, Your Honor, for your time this afternoon.

And we bring this motion somewhat regrettably but because we have to because this is just part of plaintiff's continued pattern of failing to abide by and frankly violating this Court's orders.

As Your Honor just recited in December of 2019, we brought an initial motion based on disclosure that were provided in Dr. Burke's expert disclosure that related to factual issues that should have long prior been disclosed, to allow St. Jude to take proper discovery. This related to use of the particular products at issue. It related to alleged conversations with other physiologists, and a range of factual components and issues that were central to this case that until the expert deadline had not been disclosed.

Those issues were presented to Your Honor in a motion to strike by St. Jude. Your Honor held a full-day hearing in addition to briefing on that.

And as Your Honor pointed out at the outset, Your Honor found, and I quote from Page 105, "That the Court finds that all of the factual disclosures at issue were untimely produced."

Your Honor also was clear, and that was at page 109 of the record, this is docket entry 152, the

transcript from the hearing on our prior motion for St. Jude, "That this record will serve as the reasoning and analysis of this Court's decision."

The Court was clear and unambiguous as to the scope of Your Honor's motion in granting of our order to strike. Your Honor was also clear as to where we could find, to the extent there was any confusion, what the scope of that was and how it would entail -- what it entails.

Subsequent to that we are here today, Judge, because plaintiff sought to appeal that with Judge Wright. Judge Wright affirmed. And so from that point forward these factual disclosures that were highlighted, both in our motion and also identified and discussed in Your Honor's order in that transcript, should no longer be part of this case.

Yet, as far as -- when it came time for dispositive motions and when it came with to plaintiff's opposition to our *Daubert* motion, we saw all of these again. And as we pointed out in our motion, not only do we see these issues again, sometimes slightly reworded, but there are paragraphs and sections in Dr. Burke's new declaration that he submitted in opposition to the *Daubert* motion and in support of the summary judgment that are in direct violation and include the exact same language that Your Honor addressed and struck back in December of 2019. There

frankly, Your Honor, is no excuse for that that we can come up with.

Your Honor found back in December of 2019 that plaintiff's failure to provide this timely was "inexcusable." Yet here we are months later in the context of discovery -- dispositive motions and *Daubert* dealing with this all again.

And it is costly to St. Jude. This is now the third time we have had to deal with this and spend money on this issue. And it extends, obviously, not just to this issue, but we had to then address it and figure out what to do in our *Daubert* motion and, of course, in summary judgment because plaintiff is relying on this, even though he should not be able to.

And then, of course, there's the cost in briefing and the costs to this Court in having to address all of this again. On top of which there is a Court order that has been violated and there's, you know, the general notion of the respect for the law of the case in this Court's prior findings.

And so at this juncture, Judge, really we're kind of at our wits' end. I'm looking to Your Honor to enforce what Your Honor already has done, and we should not need further enforcement of, is to have these provisions and these factual disclosures no longer in the case.

And given where we are and the scope of this violation, we believe that includes and is not limited to dismissal of the case entirely.

As you may recall, there's only one claim left, and that claim they're relying on Dr. Burke for purposes of direct infringement. And much if not most of these facts relate to that.

But at the very least to strike this declaration in its entirety, that's the new declaration provided at docket number 195. That should be stricken in its entirety. And we believe, again, at the very least that that should be stricken and so should any corresponding motion that would include St. Jude's -- I'm sorry, plaintiff's summary judgment motion. And it would include granting St. Jude's *Daubert* motion because the opposition relies on that.

And, of course, we should get our fees. We believe St. Jude should not have had to have briefed this in the first instance.

As Your Honor found at docket 152 in that court hearing, the initial violation was a violation of this Court's order and that in and of itself warranted sanctions. Here we are now a third time. Certainly my client should get his fees back for having to go through this effort.

Now I'm happy to, if Your Honor would like, to go through those similarities in the prior declaration that was

stricken or the expert report versus the current declaration, but that's set forth pretty clearly in our briefing. And so to the extent there's questions I'll do that. But I think it's important to just give you the framework and emphasize the harm and prejudice that's befallen my client as a result of having to continually check plaintiff's compliance with this Court's orders.

THE COURT: Thank you.

This is Magistrate Judge Thorson. Can you address plaintiff's argument that St. Jude waived any objections to factual information being provided by Dr. Burke?

MR. SHAH: Sure, Judge.

I mean, I've not quite followed their argument. I believe their argument is that because we referenced the motion to strike in the background section of our summary judgment motion, that that consisted of a waiver of this Court's order.

I would say two things in that respect.

First, it's a Court order, so it's not just something we would waive or we can waive, Your Honor ordered this.

Second, providing -- and we've addressed this in our summary judgment brief, I believe we've addressed it -- if it's an argument they made in this here as well -- I'm sorry, I'll take a look, I did have to leave rooms.

But I believe -- I shouldn't say I believe, in this particular instance we did not at any point rely on the stricken material in a substantive way. We provided it by way of background to emphasize the history of this case and the limited nature of evidence that's available to the plaintiff with respect to, for instance, direct infringement because plaintiff had relied upon, but was stricken, this particular (indiscernible) background that we're talking about.

We did not as the -- for example, some of the cases have opened the door by introducing this information in an affirmative way, rather we simply suggested to the Court that there is very limited information in the record on direct infringement. And that's in -- particularly should be considered in reference to the motion to strike.

And quite frankly, that part of that obviously proved to be very important in that (indiscernible) this declaration (indiscernible) indication that this motion had ever occurred or was ever granted.

So certainly, I guess the bottom line is that we don't (indiscernible) certainly there was not an intentional relinquishment of some right, which is what a waiver required on the law by St. Jude, and we don't think that in any way the law supports, or the use or the reference to

this particular motion, generally speaking, as it was just a reference to what had occurred historically somehow could constitute a waiver.

THE COURT: This is Magistrate Judge Thorson.

I don't want to fail to say that you're still a little bit difficult to hear because of the device and -- it's -- and so I think you really, really, need to slow down and pause in case I need to break in or the court reporter needs to break in here. So just be mindful that it is not a very clear connection.

I want to follow up on the waiver issue to understand what was used by St. Jude in the motion papers filed in support of the dispositive motions.

Are you saying that the testimony of Dr. Burke that was referenced by plaintiff's counsel in this motion to strike was only used by St. Jude to explain that that information should be stricken? I'm confused.

MR. SHAH: Yes. Yes, Judge. And I switched again, but I will talk even more slowly.

I believe -- and I unfortunately had to leave my desk so I can't pull up that paper. Mr. Ruggio is also on. He may be able to confirm as I speak after, because I don't want to misspeak. I don't have our summary judgment document right in front of me because I had to leave space based on the phone call.

But my understanding and recollection is that we did not quote even the sections that we're talking about in our motion for summary judgment or dispositive motion papers, rather there was a reference to the docket entry and the overall motion practice indicating that this had occurred, meaning that there was a close of fact discovery. But prior to the close of fact discovery, there was little, if any -- I believe there was no evidence of direct infringement.

And to keep in mind that Dr. Burke cannot keep a basis of an argument for direct infringement. And then citing to the record with respect to this particular back and forth that occurred over the course of time with Your Honor's order and Judge Wright's affirmation.

I don't believe -- and hopefully Mr. Ruggio can confirm while he's here, that in our summary judgment papers we affirmatively quoted the statements that are at issue here.

THE COURT: Thank you.

This is Magistrate Judge Thorson. I am not inviting anyone else to jump in here at this point.

If your colleague would like to send you an e-mail or something, that's fine, but I'm not going to have other lawyers jumping in to clarify things at this point.

I do have another question, and that is that the

material that is now at issue in this motion has already been submitted to the district judge. My understanding is that a hearing was held on the dispositive motions yesterday and I'm curious as to whether this issue came up specifically in the briefing and at the hearing?

MR. SHAH: Your Honor, this is Kal Shah on behalf of St. Jude's again.

The Judge, Judge Wright, here had to split the oral arguments. So before we were scheduled to perform oral argument yesterday as to both the dispositive motions -- well, I should say summary judgment motions, as well as *Daubert* motions, yesterday that was changed. So yesterday it was relegated only to the *Daubert* motion. And so we did have an argument on *Daubert*.

This issue was raised in our *Daubert* brief in the form of footnote that we are moving to strike and that it's improper for them to have relied on the declaration of Dr. Burke. But it did not come up substantially because we were addressing, frankly, plaintiff's violation of what we believe -- what we believe is plaintiff's violation of another Court order, which is that the parties, as Your Honor may recall earlier, had said that the parties must address both sides' claim constructions in their expert reports and Dr. Burke testified that he had not done that, and that we were -- we were debating the merits of our

Daubert motion in that light, more so than the use of the declaration.

Although, I will say, that plaintiff did rely on the declaration to suggest various components of their argument, which is another reason why, you know, it's improperly moved to strike that declaration.

THE COURT: Thank you. I will -- this is Magistrate Judge Thorson. I will now turn the virtual podium over to Mr. Griggs, who is here on behalf of the plaintiff.

MR. GRIGGS: Yes. Thank you, Your Honor. This is Michael Griggs on behalf of the plaintiff's NLC.

I'd first like to discuss the scope of relief that St. Jude asked for on the original motion to strike. I think we've outlined this in our papers.

That motion was directed to evidence of direct infringement that was presented by Dr. Burke in his report. St. Jude identified three or four paragraphs on pages 25 and 26 as the problematic disclosures in the report. And that was the focus of the original motion to strike.

As we noted, it is -- those paragraphs and those pages are what is identified in St. Jude's request for relief. And so that is the scope of what the original motion to strike was directed to.

As we also pointed out, five of the six paragraphs

that are challenged in the instant motion were included in Dr. Burke's report, but they were not mentioned or targeted in that original motion to strike.

And so NLC's submission of those should not be and cannot be considered a violation of the Court's order when they were not previously at issue.

St. Jude now is attempting to greatly broaden what it had asked for previously and is seeking drastic sanction based on this broadening of scope.

I think it's important when you walk through the actual paragraphs at issue here, and I'd like to do that. We did that in our brief.

If you look at our brief on page 4, the first paragraph is paragraph 12. And I don't see anything in there that can be fairly characterized as evidence of direct infringement.

What paragraph 12 is directed to is Dr. Burke's general history, and general use and familiarity with St. Jude's products. Again, this paragraph was included in Dr. Burke's expert report. It was not targeted by St. Jude the first time around, yet now St. Jude is seeking to strike this and arguing that the order encompasses this paragraph that was never previously targeted or discussed during the first go-around.

If you look at paragraph 13, which is on page 5 of

NLC's brief, this is a single-sentence paragraph which says, "I have firsthand knowledge of the St. Jude's CPS catheters because I have used these catheters." And then there's a highlighted portion, "in accordance with St. Jude's instructional and marketing materials on many occasions during my medical practice to implant permanent pacing leads into the coronary sinus and its branches."

Again, prior to St. Jude filing this motion, NLC agreed to remove the -- or withdraw the highlighted text there.

With that removal there is nothing in Paragraph 13 that relates or could be characterized as evidence of direct infringement. It doesn't mention in any way in which anything is being used. Again, this is background information that was not targeted on the first go-around. All it is being used for is to demonstrate that Dr. Burke has familiarity with St. Jude's products. And I believe he is allowed to say that.

On Page 6 of NLC's brief, paragraph 25 is another paragraph that is targeted in the instant motion. Paragraph 25 says, "St. Jude's instructions for the CPS Aim inner catheter direct an electrophysiologist to advance a guide wire through the inner catheter and outer catheters and into a branch vein of the coronary sinus, allowing for a range of diameter that includes a .014-inch guide wire."

And then there is a screen shot from that particular instruction.

Again, this was not targeted in St. Jude's original motion and it has nothing to do with direct infringement. This is part of Dr. Burke's analysis of the instruction that St. Jude has identified the submission of this paragraph as a violation the Court's prior order.

On page 7, paragraph 26, this relates to using a guide wire for an over-the-wire lead. Again, this paragraph was not targeted the first time around.

So the submission of this paragraph now cannot be considered to be a violation of the Court's order when St. Jude did not target this and did not subject this to its motion that it previously brought.

Similarly, Paragraph 28 is -- was also in Dr. Burke's report and was not targeted the first go-around. This, again, relates to Dr. Burke's analysis with respect to the telescoping action.

In paragraph 28, that's on page 8 of NLC's brief, you can see the highlighted -- the highlighted phrase there, NLC has agreed to withdraw that phrase as it, you know, could possibly be construed as some sort of evidence of direct infringement.

And, again, St. Jude didn't even identify this particular phrase as problematic, it was just, you know,

asking to strike the entirety of paragraph 28 even though it was not previously challenged.

And then paragraph 36 of Dr. Burke's summary judgment declaration is what really is and was the focus of St. Jude's initial motion to strike. This correlated to the paragraphs under a heading in Dr. Burke's report of evidence of direct infringement. And as we've laid out in the report, Dr. Burke and NLC took care to edit this to remove references of direct infringement.

And so the -- the claim that there is some sort of willful violation, or blind violation or, you know, repeated conduct in violation of the Court's order simply isn't true.

When you look back at what St. Jude -- how they framed the issue and the relief they asked for in the original motion to strike, it was targeted to pages 25 and 26 of Dr. Burke's expert report.

And when you compare that to the declaration that correlates to paragraph 36 of the summary judgment declaration which, as we've laid out in the brief, was edited to remove what NLC believes was the excluded statements.

And so that is -- the proper focus of this motion should be on paragraph 36, those prior paragraphs that were unchallenged before should not be a basis for sanctions when

St. Jude did not target those in the initial motion. As we mentioned here, that would be sanctioned by ambush.

NLC took great care and heeded the Court's order in revising the statements and removing the statements that didn't understand to be excluded based on the way St. Jude presented its prior motion and based on the relief that it asked for.

So if anything, if there is considered to be any type of violation here, it should be focused on what was done with respect to paragraph 36.

I'd also like to address the waiver issue. As we pointed out, the fact of the matter is is that St. Jude submitted deposition testimony where St. Jude, while it was deposing Dr. Burke, elicited testimony about direct infringement.

As we pointed out under Rule 56, the Court is free to consider that since it has been submitted into the record, regardless of the purpose.

So I believe that can fairly constitute a waiver on the issue since St. Jude submitted it. There is no need to submit it. NLC had no intent and is certainly not intending to submit any evidence of direct infringement by Dr. Burke or others.

And NLC in its summary judgment papers, the argument does not argue that there is direct infringement on

behalf of Dr. Burke or others. NLC's arguments are based on admissions by St. Jude's witnesses and based on circumstantial evidence relating to the instructions.

So whatever reason St. Jude decided to submit this deposition testimony is irrelevant. It has been submitted into the record and it is fair game for the Court to consider it.

So I believe this goes to the harm or the prejudice where the most direct evidence of direct infringement as it relates to Dr. Burke's direct infringement was submitted by St. Jude, not by NLC here.

I'd like to circle back around also to this drastic relief that St. Jude is requesting right now.

First, as we pointed out in the papers, St. Jude is relying on Rule 37. Based on my reading of Rule 37, it does not appear to be an appropriate basis.

Rule 37 is relating to ordered discovery matters, for example, failing to comply with an order compelling document production or to present a witness for deposition. This is -- Rule 37 is what we looked at during the original motion to strike.

So it's unclear and it does not seem that Rule 37 provides a proper legal basis for the relief that St. Jude is seeking.

And that aside, we've cited the case law about the

analysis and the showings that must be made in order to enter drastic remedies such as strike -- well, dismissal of the case first, striking pleadings, awarding attorney's fees and so on.

The case law says there has to be a willful violation of a court order here. A deliberate willful violation of a court order, bad faith.

And as we've laid out and as I've just explained, you know, NLC is not committing anything in bad faith here. On the contrary, NLC took very careful steps based on its review of the Court's order and based on St. Jude's motion in the relief it requested to attempt to comply with that. And I believe that NLC has done that.

You know, there was no deliberate resubmission of anything that NLC would -- would believe to be in violation of the Court's order.

We just walked through those other paragraphs that St. Jude is targeting and there is nothing in there that relates to direct infringement. NLC has agreed to withdraw anything that even comes possibly close to that type of a characterization.

NLC removed most of -- most of what was on pages 25 and 26. And certainly removed all the explicit references to direct enrichment.

So NLC and Dr. Burke have taken careful steps to

comply with the order yet now is faced with a motion for sanctions and allegations of bad faith, willful violation of an order, deliberate misconduct.

One of cases talking about attorneys' fees of the filing -- the Temple of Justice, practicing fraud on the Court. That, you know, is just an unfortunate characterization by St. Jude and that is not what has happened here. So to the extent the Court is -- finds there to be some sort of violation here, it certainly is not willful.

And if there is a violation, the appropriate remedy is for the Court to either strike those portions -- and, again, it should be focused on paragraph 36, to strike those portions that it believes are in violation or -- or just to simply disregard it.

You know, again, Your Honor, this is not the risk that's associated with presenting this to a jury. The Court is aware of the scope of its order and the Court can disregard what it wants to disregard to the extent it believes that the submission was in violation of the Court's order.

So in summary, St. Jude in its motion is greatly expanding the scope of what it asked for when it filed its original motion to strike, which was focused on three or four paragraphs on pages 25 and 26 of Dr. Burke's original

reports.

Now St. Jude comes in challenging a number of other paragraphs that, A, don't have anything to do with direct infringement. And more importantly, B, were never challenged the first time around.

And on top of that, St. Jude is seeking dismissal and attorneys' fees for submission of previously unchallenged statements. That -- like I said, that would be sanctioned by ambush and would be unfair to NLC.

THE COURT: Thank you, Mr. Griggs.

This is Magistrate Judge Thorson.

Mr. Griggs, I hoped that I would set up the hearing today in a way that would have you respond to my order. And to restate on the record, I framed what I believed to be the motion before the Court.

I quoted at the beginning of the hearing, and I'll quote it, again, for the record, "St. Jude's motion is to strike facts disclosed in Dr. Burke's report that were not disclosed during the fact discovery deadline. St. Jude also speaks to preclude Dr. Burke from testifying as a fact witness due to late disclosure."

That's my framing of the motion. I granted the motion and issued an order that addressed what had been done with respect to the expert report, but I was pretty clear that you can't disclose a fact witness and present factual

testimony after the fact discovery deadline.

And my order, and the reasoning for my order was clear. The facts need to be disclosed during the fact discovery period that both parties have the opportunity to examine the facts and then the experts opine. That was clear in the discussion.

And my order frames what we're dealing with here today, not the particular paragraphs that were raised by St. Jude. I made clear that Dr. Burke could not be a fact witness when you never disclosed him as a fact witness, and he cannot present facts. That was the framing and that was the order.

And so you need to respond. Not going back to what you're saying that St. Jude argued, but you need to respond to my order because that's the order that I'm looking at. I was there. I tried to set it up, but my framing and my order is what you need to deal with.

Can you respond to my order, not your framing of the order, but the Judge's framing of the motion and the subsequent granting of the motion?

MR. GRIGGS: Yes, Your Honor. Thank you.

And, again, I'd like to walk back through the particular paragraphs that are at issue here.

And if you look at paragraph 12, again, this is -- this is background with respect to an expert's. It's facts

that support Dr. Burke's expertise. I believe that is appropriate to include in an expert report.

And, again, my understanding of what was at issue before was facts not -- it was facts related to direct infringement. I mean, there is inherently an expert who's going to provide background information.

For example, Dr. Benditt in his similarly says, I've been a doctor for so and so long. I have done, you know, numerous coronary sinus. None of that was disclosed by St. Jude in fact discovery. That is a typical type of background information that is provided in an expert report. That is what is in paragraph 12.

And, again, St. Jude did not identify this the first time around. Their motion was focused on evidence of direct infringement. And I don't see how paragraph 12 can be in any way construed as evidence of direct infringement.

If you look at --

THE COURT: What --

MR. GRIGGS: -- paragraph --

THE COURT: I'm sorry to interrupt you. It's very -- it's very difficult if there's no pause.

But let me direct you to paragraph 26. And this is at document number 195, where plaintiff is presenting Dr. Burke's declaration stating -- and I quote here from paragraph 26, "St. Jude's instructions state that a guide

wire may be used if desire. However, in my experience a guide wire is almost always used (over 99 percent of the time) when delivering an over-the-wire lead.

It is not recommended or practical to implant an over-the-wire lead without using a guide wire. Further, it is my understanding and experience that electrophysiologists, including myself, almost always, or almost exclusively use over-the-wire leads as opposed to stylet-drive leads. For example, in my practice I implant over-the-wire leads over 99 percent of the time for a coronary sinus branch pacing. Based upon my conversations and experiences with other electrophysiologists, I believe that the frequency at which I use the over-the-wire leads is representative of the general electrophysiologist population."

Why isn't that a new fact?

MR. GRIGGS: Your Honor, that is opinion testimony.

This isn't like a survey or a factual, he is saying, here's is my experience, and it's even phrased as, my belief.

You know, this -- this is based on his experience. It's opinion testimony, it's not fact. And that is, you know, precisely what experts do.

So, I -- again, you know, I understand this to be

an expression of opinion here. He is saying, you know, here is my general practice, here's what I believe other people do. You know, that's an opinion, that is not -- that is not a fact. That's not factual matter, that's an opinion.

THE COURT: He's stating what he does.

MR. GRIGGS: He is. But, again, I mean, that goes as a foundation for his opinion.

You know, I don't think St. Jude asked a discovery request about, you know, how often do doctors use wires with leads. You know, I -- I don't -- I'm trying to understand here, you know, what an expert is allowed to say if he's not allowed to say something that's as presented in paragraph 26.

Again -- and maybe we can agree to disagree but, you know, in my experience, I mean, this is an opinion. This is a typical statement that would be made by an expert saying, you know, I -- I have experience in this area. This is how I've done it and I believe this is how other people do it. That's an opinion.

THE COURT: All right. What about paragraph 36? Is that a fact or opinion?

MR. GRIGGS: Your Honor, that's styled in the same way. And it's saying in his own personal experience here's how -- how I use these and this is how I believe other people use them.

Again, it's not -- it's not based on fact or survey evidence or anything, this is an opinion. It's just based on his experience working as a doctor.

THE COURT: All right. Are there any facts in your expert's declaration at docket number 195 that you think cross -- that are facts and not opinions that would be now, upon reflection, that you would think crossed over the line as to what we did in December?

MR. GRIGGS: Your Honor, I think what -- what comments -- and again, I've focused on the six paragraphs that St. Jude identified in their motion. And within those paragraphs I've highlighted what I believed would encroach -- or could possibly be characterized as encroaching on the Court's order.

For example, paragraph 13, on page 5 of NLC's brief, paragraph 13 says, "I have firsthand knowledge of St. Jude's catheters because I've used these catheters and we highlighted in accordance with St. Jude's instructional and marking materials."

You know, that statement could be arguably construed as some sort of vague reference to direct infringement, so we've agreed to withdraw that.

But when you withdraw that, the statement says, "I have firsthand knowledge of St. Jude's CPS catheters because I have used these catheters on many occasions during my

medical practice to implant permanent pacing leads into the coronary sinus and its branches." Again, this is just purely a background foundational statement for Dr. Burke showing that he is familiar with St. Jude's products because he's used them.

There was one other instance where we had agreed -- if you just bear with me, it's Paragraph 28. This is on Page 8 of NLC's brief.

Again, and this is -- Paragraph 28 relates to Dr. Burke explaining some aspects of St. Jude's instructions. And then there was the highlighted part at the end of this paragraph that says, "And used everyday by electrophysiologists around the world."

Again, that could possibly be characterized as some sort of vague reference to direct infringement and we've agreed to withdraw that statement.

But the remainder of that is Dr. Burke's opinion and analysis with respect to St. Jude's instructions.

THE COURT: Help me understand, Mr. Griggs, what -- and I'm trying to understand, what is the distinction that you're drawing between the sentence that you say you would have agreed to withdraw about his -- Dr. Burke's experience and the experiences that I highlighted for you in paragraphs 26 and 36?

MR. GRIGGS: Because 26 and 36 don't relate to the

issue of direct infringement. Direct infringement is the question of, has a doctor followed the steps of claim 11? You know, that's the issue of direct infringement.

So talking about, you know, whether doctors used a guide wire when doing an over-the-wire lead, you know, that is not -- that doesn't relate to the issue of direct infringement. There's no statement there about how they're using it. And, again, it all -- it all circles back that this is, you know, Dr. Burke's opinion based on his experience within the field.

THE COURT: And, Mr. Griggs, again, I very much apologize for interrupting, I'm not trying to cut you off in any way.

But why is it that you think my order was specific to the direct infringement?

MR. GRIGGS: Because that is how -- that is what St. Jude asks for.

THE COURT: But what about my order that I read a couple of times, and that you've had available and you appealed and Judge Wright didn't -- didn't change the finding?

My order is not narrow to a particular type of new fact. How is it that you think my order was -- my order, I'm -- I need you to point to something I said in my order that gives you the idea that it was so limited.

MR. GRIGGS: Well, because, I'm reading it. I'm looking at it right now on page 95, you know, and the Court says, "For the record, St. Jude's motion is to strike facts disclosed in Dr. Burke's expert report that were not disclosed by the fact discovery deadline."

So when I read that, you know, I need a little bit more specificity and I look back at what St. Jude asked for. And what they were asking for was facts of direct infringement.

THE COURT: And one other followup question to address, Mr. Griggs, is that the whole basis for my ruling was that fact discovery had closed and you hadn't identified Dr. Burke as a fact witness, and so you couldn't use him to offer factual information.

So let's -- let's go along with your idea that the order somehow would relate to your framing of the -- of the of the motion in the order. Why would you do that again? Why would you disclose factual information in a new document?

So let's -- let's say that you had something totally unrelated or maybe a new witness, why do you think you could do that under the scheduling order?

MR. GRIGGS: Well, Your Honor, I think the dispute is that I don't believe that's factual information, as we've just walked through the paragraphs that were challenged.

And, again, it -- those weren't challenged the first time around by St. Jude. They were not identified.

And I'm looking through the Court's order, I'm looking on page 97 and the Court says, "In this case plaintiff was alerted to St. Jude's evidentiary challenge regarding direct infringement of the method claim."

And then on page 98 it says, "Plaintiff's contentions, however, failed to identify a single instance of direct infringement underlying its assertion of indirect infringement."

THE COURT: Yes.

And, Mr. Griggs, I recall that that argument was based on that you had clear notice that you should diligently go get facts before the close of fact discovery, I don't think that framed the motion. That was just an argument about why you weren't diligent in getting that discovery during the fact discovery period.

And so it was a kind of a hand waive to you knew that this was a gap. So that, in my view, doesn't frame my order.

MR. GRIGGS: Well, Your Honor, those were statements from your order.

Here's another one on page 108 of your order. It says, "Reopened discovery would likely involve the participation of third parties. As the St. Jude notes, had

Dr. Burke's direct infringement been disclosed properly in discovery, St. Jude could and would have sought documents, communications and testimony related thereto."

And, Your Honor, I'm pointing these out because when you read through your order in conjunction with St. Jude's motion, it was focused on facts relating to the issue of direct infringement.

St. Jude identified pages 25 and 26 of Dr. Burke's initial report and that was the scope. That is what they asked for in their -- in their relief. When you read through the Court's orders -- I understand the Court sort of broadly framed the issue at the beginning, but when you read through the discussion it's about the factual evidence relating to direct infringement.

And so those other paragraphs, the other five paragraphs that we've been discussing, other than paragraph 36, those do not relate to direct infringement. And I question whether they even would constitute facts to begin with, other than facts relating to Dr. Burke's experience that support -- that provide a foundation for his opinion.

With respect to paragraph 36, which corresponded to the statements on pages 25 and 26 of Dr. Burke's initial report, those were the facts.

They were -- Dr. Burke stated, I am a direct

infringer. I have been, you know, infringing this -- or I began infringing on such and such date. And I have spoke to other electrophysiologists and they are direct infringers.

Those are the facts that were targeted in St. Jude's motion and that were stripped out by Dr. Burke and NLC, and they were not presented in this declaration.

So circling back around, the -- the original motion was related to facts relating to direct infringement when you read through the Court's order, when you read through St. Jude's motion and that is what NLC understands to be, and that is what NLC abided by when it submitted this declaration.

THE COURT: All right. I think you've shared your position.

I'll turn it back to St. Jude. And we'll ask Mr. Shah to just remember that your device hasn't been as clear and so please, again, speak directly into the device, and keep it -- keep it slow.

MR. SHAH: Judge, this is Kal Shah on behalf of St. Jude. I have moved right next to the window, so I hope this will help. I'm unfortunately limited in my technology.

But a few -- I'd kind of like to point out three things in response.

First, as Your Honor pointed out, the scope of the order was not (indiscernible) somehow this notion of direct

infringement. Any claim by (indiscernible) that somehow -- well, even plaintiff's, you know, framing of that motion is just an indication of their willful and complete failure to abide by your order.

Let me start with what we actually put in our original motion since that appears to be plaintiff's foundation. On the very first page of our argument, this is at document number 130 --

THE COURT: All right. Let me -- slow down. Let's slow down, Mr. Shah.

Let us all just be able to have the opportunity to turn to that document. What document is that?

MR. SHAH: Sure. It's Document 130 in the record.

THE COURT: All right. So just hold on. Yes.

(Court reporter interrupted.)

THE COURT: All right. Thank you. I appreciate that good advice. And will just emphasis that we have to be very slow and deliberate with our presentation.

MR. SHAH: Thank you.

THE COURT: Pause after every sentence.

MR. SHAH: Yes, Judge.

I also -- this is Kal Shah on behalf of St. Jude.

I also am going to move outside where I get better signal. However, if the background noise is too much, please let me know.

I'm just going to sit here on my front steps. Perhaps that will be a little better as far as the signal.

So as I was saying, Your Honor, document 130 was our original motion to strike. And if you look even just at our introduction, the very first page before I get to the argument we note, and this is document 130, Page 2 of 18 in our introduction we note, that at "after a month" -- I'm sorry, "over a month after the close of fact discovery in the expert report of Dr. Martin Burke, plaintiff's expert on infringement, Dr. Burke provides vague and unsubstantiated statements that he personally engaged in direct infringement use."

He then goes on to say, "He claims that others did too, citing nebulous interactions, experiences and conversations with other electrophysiologists. These statements are not expert but factual evidence."

We continue, Judge, in that same document, starting on Page 7, which is the argument. And we outline not only the direct infringement components, but the factual components.

And you'll see on Page 7 of 18 of document 130 express reference, again, to certain "based upon my conversations and experiences with other electrophysiologists," and there's other aspects there about his facts or his use.

As Your Honor may recall, and certainly we have discussed today, that was the scope of your order. There are facts relating to other physiologists in any context that were not disclosed.

We did not have the opportunity to depose them as Your Honor pointed out. We did not have the opportunity to take that third-party discovery, as plaintiff even concedes today, that was the scope of your order, not just direct infringement, but any fact that was not yet of the record that should have been in the record that plaintiff intended to rely upon.

Secondly, Judge, even if we were to limit this, and this is where I think the willfulness of plaintiff's conduct comes into play, even if the original order and motion were limited to direct infringement, the statements that we have pointed out, many of them, relate directly to direct infringement.

So, for instance, I think there was discussion about paragraph 26 where there's a discussion upon -- first based upon, quote -- this is paragraph 26 of docket number 195, Dr. Burke's declaration at issue. And I quote, and this is part of the quote that Your Honor went through, quote, "Based upon my conversation and experiences with other electrophysiologists." Let me stop there.

First, in and of itself that is problematic.

We had -- and Your Honor decided that random discussions are undisclosed conversations that we could not take discovery on (indiscernible) --

THE COURT: You're breaking up. You're breaking up. This is Judge Thorson.

MR. SHAH: Thank you, Judge. I'm not -- it must be just a bad connection for this call.

Okay. Let me try again here.

At docket entry 195, paragraph 26, did you get that? Were we all there or did that not get there?

THE COURT: Why don't you cover that. I'm not sure your reception outside is any better.

But, I don't think you're slowing down enough and I don't think you're pausing between sentences enough.

It's really hard to do, it's awkward, but it will be helpful.

MR. SHAH: Thank you.

I am moving to another location. And I will try and also to slow down further.

What I was saying --

THE COURT: This is Judge Thorson. I'm sorry to interrupt, but just don't talk while you're moving from location to location. Get situated in the location and then begin speaking.

MR. SHAH: Thank you, Judge. I actually have

turned off my headphones. I am talking now directly into my device.

THE COURT: Thank you.

MR. SHAH: Okay. Let me -- let me try, again, Your Honor.

What I was getting at as far as my second point, I think the first point I made and I was moving on from was simply the same point Your Honor made, which is your order was not lifted to just direct infringement. It was clear and encompassed new facts that were not previously disclosed that plaintiff's sought to introduce through Dr. Burke.

And that is consistent with St. Jude's motion wherein, for instance, at docket 130, we identified not only Dr. Burke's alleged personal use of St. Jude's products, but also Dr. Burke's alleged conversations and interviews or surveys, quote, unquote, that were not disclosed, that he relied upon with respect to -- for a factual component of his opinion.

That was clearly sought as a problem or identified as a problem in our motion and it was clearly granted with respect to all aspects including those factual components.

And importantly, as I think everyone recognized today, that was because of the burden and discovery that we were deprived of as a result.

So turning next I think to Plaintiff's argument,

however, is somehow this testimony is impermissible because it does not -- because it does not relate to direct infringement.

I would have two responses really to that.

First, direct infringement, of course, is factual.

Second, these paragraphs relate to direct infringement, albeit, somewhat craftily in that they break it up into components, but that really indicates the willful nature of Plaintiff's violation. Instead of this time saying, I, Dr. Burke, use them and others used St. Jude's products this way, he breaks it up into, I believe others do and I have used this product. And then separately, if you use it this way it infringes, so one plus one still equals two.

And as an example, I was taking a look, for instance, at Paragraph 12, let's start with, at Docket 195, which is the declaration at issue.

First, "I have personally used various St. Jude's catheters to implant St. Jude permanent pacing leads into the coronary sinus in my medical practice over the past 12 years."

Well, of course, that is direct infringement because plaintiff asserts that using a St. Jude catheter to implant a St. Jude lead is infringing.

But it goes on in that same paragraph and says,

"Using St. Jude medical systems 20 to 30 percent of the time in these procedures, greater than 80 percent of the time, I have used St. Jude's sheaths and leads together as a system."

Again, Judge, that goes to direct infringement. Not only is he saying that he uses St. Jude systems, which Your Honor, I cannot now go and find out whether that's true or not, I have no record or evidence of a single instance of Dr. Burke performing surgery, let alone the components he's used.

And that's an important distinction. While he may have the background to be an expert, if he is going to testify that he is using our product, the accused product in a certain way and has done so, that is direct infringement.

And he goes even further here to suggest that because he does it 80 percent of the time, as we mentioned in one of the other paragraphs, others must as well. I don't know who those others are and what is happening.

There is a discussion Your Honor pointed out, paragraph 36, this is at Docket 195. "I believe that the frequency at which I use a delivery system, leads, and a pacing device from the manufacturer is representative of general electrophysiologist population."

Again, Judge, that's still direct infringement. Not only is it direct infringement, it goes to, I directly

infringe but so does the general population. And that's how plaintiff seeks to bypass their requirement to prove direct infringement by having Dr. Burke say, well, I do it and I think everybody else does it at this frequency.

So, ultimately, whether you use Plaintiff's interpretations of your order or you use what I believe is your own words and the actual interpretation, there is no excuse for those paragraphs.

And plaintiff's position that somehow the order should be read or your order should be read based on their varying level of interpretation, or that we should have known what paragraphs they may rely upon in the future is simply not tenable.

We took the effort to come to Your Honor to get the relief we sought. Plaintiffs should not have used any of those facts, that they're here again and they're here both in the context of testimony that I cannot now go look at from a factual perspective, as well as they directly bear on direct infringement drastically and completely in violation of Your Honor's order.

Again, I apologize for the connection but hopefully that last part was better than the starting part.

THE COURT: Thank you. This is Magistrate Judge Thorson.

I'd like you to respond to Mr. Griggs' argument

that the information that I cited in paragraphs 26 and 36 are not fact but are opinion and shouldn't be subject to any sanction on no matter how my order is interpreted because it is opinion and not fact.

MR. SHAH: What -- Your Honor, I guess I would say that in two ways.

First, as I read those paragraphs, he's clearly stating a fact.

For instance, paragraph 36, begins with, "In my own personal experience." That preface is, I am telling you a fact from my personal experience. And then he continues, "I typically (probably over 80 percent of the time) use a delivery system." And he goes on.

But that is clearly a fact. That he would like the jury to adopt that fact, that 80 percent of the time a doctor like him would use this particular system as a whole, i.e., directly infringes.

It's both a fact and it's an improper fact that relates to direct infringement, and it's particularly problematic because it's layered.

First, it's a fact because I personally do this, believe me, I'm an expert testifying.

Second, it relates to direct infringement because, hey, if I do it then you should believe that 80 percent of the rest of the doctors are doing this, too.

So you -- he is clearly conveying a fact adopted as a greater fact with no evidence or support. That's paragraph 36, at least in part.

Paragraph 26 I think is another one you mentioned. Again, as you mentioned, he is discussing not only use, but he goes to say, "I implant over-the-wire leads over 99 percent of the time for coronary sinus branch pacing."

That is a fact that he is conveying, a statistical fact, no less, of 99 percent of the time what he claims his process is that I cannot check in any way, because I can't get hospital records to see if that's consistent. I can't talk to other doctors or people that may have been in the room.

But importantly, that also goes to direct infringement, which I think is particularly problematic and why plaintiff's argument here just does not happen or it just rings hallow, then flies in the face of Your Honor's order. Because he wants the rest of the jury -- or the jury to believe that 99 percent of the time this procedure will be done and is used. And so, therefore, St. Jude's products must be infringing or used in an infringing way, by doctors, i.e., direct infringement.

And that's the only reason you would go on and say, "Based on my conversation and experience is" -- I'm sorry, let me start again.

Paragraph 195, again at -- I'm sorry, paragraph 26, docket 195, he also has that language, "Based upon my conversations and experience with other electrophysiologists, I believe that the frequency at which I use over-the-wire leads is representative of the electrophysiologist population."

Again, Judge, two issues.

First, there are several claim facts. He had conversations and he has experiences with physiologists, that's a fact, that's not an opinion. He's not saying, I think I've done this or that is a fact that he is claiming he's done.

He also says that he uses this product at a certain frequency and then he's offering a fact that's unsupported that I cannot test, that like others that goes further to direct infringement, which is that the frequency at which he uses this technique is the same as everybody also.

And plaintiff elsewhere says in their report that if you use this technique you must infringe.

So, again, that goes to the entire willfulness and improper nature of this -- of this declaration in that they've chopped up into finer pieces what Your Honor said they can't do to try to get for direct infringement and also facts that Your Honor has already ordered they cannot do.

THE COURT: Thank you.

Mr. Griggs, I'll let you take the time you need to respond and to have the last word here.

MR. GRIGGS: Thank you, Your Honor.

And, you know, counsel's suggestion that there is something deliberate or diabolical going on here that we've chopped up and reorganized is just simply not true.

This language is in Dr. Burke's original expert report in the way that it's presented with -- regarding what Mr. Shah was just referencing. This is not some after-the-fact reconfiguration.

Moreover, to read NLC's summary judgment papers, NLC is not arguing that it has direct evidence of direct infringement.

Counsel is trying to put forth some sort of argument that NLC is not making. It is not relying on these paragraphs as evidence of direct infringement.

So, again, to suggest there's some sort of willful manipulation of Dr. Burke's declaration in an attempt to circumvent the Court's order, again, it's just unfortunate and inaccurate.

As I explained earlier, St. Jude's original motion was directed to disclosure of facts relating to direct infringement. St. Jude identified what it believed those facts to be and it identified those in paragraph -- or pages

25 and 26 of Dr. Burke's expert report.

When we were craft -- when NLC was crafting this declaration with Dr. Burke, that was the guidance that we used, we removed what we believed to be all explicit references to direct infringement and then submitted the declaration.

As I said, if you review NLC's summary judgment papers, NLC is not hopping -- you know, hop, skip and jumping around and saying, all right, look at paragraph 25, and then look at 26, and then look at 24. When you put it all together, that equals direct infringement. That's an argument that St. Jude's counsel is presenting here, but it's not what NLC is presenting, it was not NLC's intent.

St. Jude's counsel is attempting to -- to concoct some sort of willful circumvention of the Court's order which simply is not present here.

You know, again, with respect to these facts, Dr. Burke is allowed to say -- or should be allowed to say that he has used these. And he should be able to say, I use a wire 99 percent of the time. That's just background as to how Dr. Burke uses it. It has no bearing on direct infringement.

So, with that said, St. Jude is asking for very drastic sanctions. They are asking for dismissal. They are asking to strike Dr. Burke's declaration in its entirety.

They're asking to strike NLC's summary judgment motion in its entirety. Those sanctions are very extreme and should be rarely entered by the Court.

Here, to the extent the Court believes there's some violation, the appropriate sanction would be to strike those portions that the Court believes were submitted in violation of the Court's order. And, again, I believe that analysis should focus on paragraph 36.

The other paragraphs were included in Dr. Burke's expert report, they were not identified by St. Jude in its motion or in its request for a lead, so I don't -- I believe they're outside the scope of the Court's order.

So unless the Court has any other questions for me, NLC respectfully requests that the Court deny St. Jude's motion in its entirety.

THE COURT: Thank you.

I think what I'll do here is I am going to take a brief recess and then I will come back and give you my decision.

I think in light of the connection that we have, I think I am going to end the recording and get off the call and then I will reinitiate the call so that the parties can dial back in. And let's -- it is 3:07 central time now. Why don't we reconvene at 3:30.

And so I will be the host on the call and get you

back on the line and confirm that we got counsel on the line, and then I will issue my order.

And let me ask the court reporter, if that's acceptable with your schedule.

(Court Reporter spoke.)

THE COURT: So we are in recess and we will be back at 3:30.

(Recess at 3:08 p.m.)

(Reconvene at 3:34 p.m.)

THE COURT: This is Magistrate Judge Thorson and we are back on the record.

Let me first ask if the court reporter is on the line, and can hear me?

(Court Reporter spoke.)

THE COURT: Thank you. Now let me hear if, Mr. Griggs, if you're on the phone?

MR. GRIGGS: Yes. Thank you, Your Honor. I'm here.

THE COURT: Thank you. And Mr. Griggs is plaintiff's counsel in this case.

And is Mr. Shah on the phone?

MR. SHAH: I am, Judge. Thank you.

THE COURT: All right. Thank you.

We are back on the record in the matter in Case Number 17-CV-5096 WMW/BRT. And we have taken a brief

recess.

I have heard oral argument today on St. Jude's motion and I have prepared a decision that I will give you from the bench.

St. Jude has brought a motion to enforce this Court's order and force sanctions.

This Court's order of December 2nd was clear and not pinpointed to particular paragraph.

Simply stated, Dr. Burke was precluded from offering testimony of fact in this case because he was not timely disclosed as a fact witness.

Once again, after believing this issue was put to rest with a prompt and clear order, Dr. Burke has resurfaced as a fact witness in the dispositive motion briefing.

The Court finds that there was no waiver of an objection to late-disclosed fact witnesses by St. Jude.

The Court finds that the insertion of facts into the Burke declaration violates this Court's order.

Finding a violation, once again, the Court must turn to the issue of sanctions.

Rule 37 authorizes the Court to impose sanctions. The Court finds that there was an order regarding discovery and in this Court's view there was a willful violation of the order.

This does not mean that there was bad faith. I

believe Mr. Griggs that he did not intend to practice a fraud upon the Court. But my order was clear and I find a willful violation.

The issue of prejudice, however, is the closer call. The closer call, for a number of reasons, but most importantly because a sanction less extreme than dismissal may address the issue.

I should also note -- and, of course, as counsel are aware, this Court does not have the power to order dismissal of the case as a sanction because that would be a dispositive order.

This Court could only recommend dismissal. And so with all of this in mind the Court will order the less extreme sanction of exclusion.

The Court will order, and the Court does order today, that the facts disclosed by Dr. Burke that were not disclosed by the fact discovery deadline be stricken from plaintiff's materials submitted to the Court for purposes of the pending dispositive motion.

The Court will also award attorney fees and costs to defendants for the fees and costs associated with bringing this motion.

St. Jude attempted to resolve this dispute before filing its motion. Response by plaintiff was not substantially justified and there are no other circumstances

that would make an award of reasonable expenses unjust. And I'm referring to Federal Rule of Civil Procedure 37(a)(5)(A) I through III.

The Court will confer with Judge Wright's chambers of the procedural mechanics of striking the improperly presented factual material so the process is sufficient for Judge Wright and her chambers.

What starts this process, each side must submit copies of documents highlighting the portions that should be stricken pursuant to this order. And those submissions should be made by both sides by May 7th, 2020.

Meanwhile, on or before May 7th, 2020, counsel for the defendants should file an affidavit supporting their requests for attorney fees and costs along with any supporting documents.

Plaintiff may file an objection to the amount of fees and of the costs reasonableness by May 11, 2020, not to be confused with any appeal plaintiff's May 11 submission, if made, may not reargue whether or not fees and costs should be awarded.

This hearing's record serves as a reasoning and analysis of this Court's decision.

We are in recess.

MR. GRIGGS: Your Honor?

THE COURT: Yes.

MR. GRIGGS: I'm sorry, I just wanted to clarify the submissions.

THE COURT: You'll have to, wait. Stop. Stop. You have to identify yourself.

MR. GRIGGS: I'm sorry, this is Michael Griggs on behalf of the plaintiff.

I just wanted to clarify submission for May 7th. You said each side independently is going to submit highlighted material that each side believes should be subject to the exclusion order?

THE COURT: Yes. And my order is clear, all facts not disclosed by the fact discovery deadline are to be excluded.

So this is not a rearguing of the order. It is your side's view of which parts of which paragraphs -- and I haven't gone through all of the dispositive motion materials, and so I will receive those materials by each side. This is not an opportunity to reargue.

And please understand I'm not suggesting that you don't have the independent right to appeal my order to Judge Wright, but I request each side's submission of the documents, we've covered a couple of them, but I don't know what else is there, so I want to approach Judge Wright with the benefit of getting that submission.

MR. GRIGGS: And, Your Honor, one more point of

clarification.

Is it the six paragraphs identified in St. Jude's motion or is it the entire declaration?

THE COURT: Pardon?

MR. GRIGGS: My understanding we're supposed to review Dr. Burke's declaration for fact.

Is the review of the entire declaration or is it just the six paragraphs identified in St. Jude's motion?

THE COURT: It is the entire declaration. I am not making a paragraph-by-paragraph ruling.

My ruling is that -- and I'll go back to it. Facts disclosed by Dr. Burke that were not disclosed by the fact discovery deadline be stricken from plaintiff's materials submitted to the Court for purposes of the pending dispositive motion.

So it's not limited to Document 195. I haven't gone through the record to see if Dr. Burke has offered other facts that were not disclosed during the fact discovery period.

And so you need to look at your materials, plaintiff's materials, that are submitted to the district judge and then to highlight facts that Dr. Burke is presenting that were not disclosed by the fact discovery deadline.

MR. GRIGGS: Okay. Thank you, Your Honor. This

is Michael Griggs.

THE COURT: I appreciate the question. Thank you.

MR. SHAH: Judge, Kal Shah on behalf of St. Jude. If I may ask a quick question?

THE COURT: You may.

MR. SHAH: Judge, with respect to the -- first, thank you very much for your time and effort today.

But the question is, with respect to our submission with respect to fees, would it make more sense to just push those dates back a week so we can include the fees it's going cost to take us to go through and mark up these documents as well that stems directly from this motion practice?

THE COURT: That is probably worth an amended timeframe.

I will push that back to be May 10th.

MR. SHAH: Thank you, Judge.

THE COURT: So my order is amended to change the deadline for St. Jude's submission of fees and costs, and that is now May 10th. That may be a Sunday. We'll say May 11th.

So for clarity in the record, St. Jude's submission of an affidavit supporting fees and costs is due May 11th, 2020.

MR. SHAH: Thank you, Judge.

THE COURT: Anything else from the plaintiff?

MR. GRIGGS: No, nothing. Thank you, Your Honor.

THE COURT: Anything else from the defendant?

MR. SHAH: No, Judge. Thank you, again.

THE COURT: All right. Thank you.

And my -- I thank the court reporter for bearing with us. It was a lesson on having a little bit more of a sound check before we get started. And I will incorporate that and we'll do that.

And so my apologies to the court reporter for having to struggle through some of the conditions here that she was subject to. I know the lawyers were very prepared on the substance and I appreciate that.

I think getting into a setting where there are no headphones, I think that's an ongoing issue, and looking at the looking at some testing with my colleagues might be helpful, too.

But I do appreciate that everyone was very prepared, and everyone was able to respond to my questions, and I appreciate that very much.

So, with that we are in recess. Thank you.

(Court adjourned at 3:47 p.m.)

* * * * * *

REPORTER'S CERTIFICATE

I, Lynne M. Krenz, do certify the foregoing pages of typewritten material constitute a full, true and correct transcript of my original stenograph notes, as they purport to contain, of the proceedings reported by me at the time and place hereinbefore mentioned.

/s/Lynne M. Krenz
Lynne M. Krenz, RMR, CRR, CRC

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Niazi Licensing Corporation,

Plaintiff,

v.

St. Jude Medical S.C., Inc.,

Defendant.

Case No. 17-cv-5096 (WMW/BRT)

ORDER

Plaintiff Niazi Licensing Corporation (NLC) and Defendant St. Jude Medical S.C., Inc. (St. Jude), cross-move to exclude expert testimony. (Dkts. 164, 196.) For the reasons addressed below, NLC's motion to exclude Dr. Arthur Erdman is denied, St. Jude's motion to exclude Dr. Martin Burke is denied, St. Jude's motion exclude Brad Carlson is granted in part and denied in part, and St. Jude's improper request for reconsideration is denied.

BACKGROUND

NLC owns United States Patent No. 6,638,268 (the '268 Patent), which issued on October 28, 2003. The '268 Patent is directed to a catheter system that can be inserted into the coronary sinus of the heart. This catheter system allows medical professionals to administer fluids and introduce pacing leads to the coronary sinus. Although the use of catheters in general was well established by 2003, the '268 Patent describes an invention that, based on its structure and shape, purportedly is better suited for "use in the coronary sinus, especially in patients suffering from congestive heart failure." The '268 Patent

claims a double catheter system with an "outer, resilient catheter having shape memory and a hook-shaped distal end" and an "inner, pliable catheter slidably disposed in the outer catheter." The '268 Patent also claims methods of using the catheter system.

NLC initiated this patent infringement lawsuit against St. Jude on November 13, 2017. NLC alleges that St. Jude infringed the '268 Patent either literally or through the doctrine of equivalents. According to NLC, St. Jude directly infringes the '268 Patent by using, manufacturing, selling, or offering to sell infringing catheter systems. NLC also alleges that St. Jude indirectly infringes the '268 Patent by inducing its customers—namely, medical professionals—to infringe the '268 Patent.

The '268 Patent includes 27 claims, some of which are directed to configurations of the catheter and some of which are directed to the method of using the catheter system. NLC alleges that St. Jude infringes independent Claims 1, 11, 13, 18 and 24 and dependent Claims 10, 14, 15, 19, 23, 25, 26, and 27. The Court determined that Claims 1, 13, 18, and 24 are invalid as indefinite and that because Claims 10, 14, 15, 19, 23, 25, 26, and 27 depend on Claims 1, 13, 18, and 24, they also are indefinite. Only a single method claim remains: Claim 11, which relates to a series of steps for "using a double catheter." On October 21, 2019, the Court issued a claim construction order as to Claim 11, construing "the catheter" to mean "the double catheter" and concluding that "Claim 11 is infringed only when the steps are performed in the order listed."

On November 4, 2019, St. Jude moved to strike facts disclosed in the expert reports of NLC's technical expert, Dr. Martin Burke, and NLC's damages expert, Brad Carlson, because those facts were not disclosed before the fact-discovery deadline. On

December 2, 2019, United States Magistrate Judge Becky R. Thorson granted St. Jude's motion to strike. NLC appealed, and the Court affirmed the magistrate judge's December 2, 2019 Order. Currently pending before the Court are NLC's motion to exclude the expert testimony of St. Jude's technical expert Dr. Arthur Erdman and St. Jude's motion to exclude the expert testimony of NLC's experts Dr. Burke and Carlson.

ANALYSIS

The admissibility of expert testimony is a question of law for the district court that is governed by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. "An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted." Fed. R. Evid. 703.

The proponent of expert testimony must prove its admissibility by a preponderance of the evidence. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir.

2001). "Rule 702 reflects an attempt to liberalize the rules governing the admission of expert testimony" and favors admissibility over exclusion. *Id.* (internal quotation marks omitted). Determinations as to the admissibility of expert testimony are within the district court's discretion. *See Arkwright Mut. Ins. Co. v. Gwinner Oil, Inc.*, 125 F.3d 1176, 1182 (8th Cir. 1997) (reviewing for an abuse of discretion).

It is a district court's obligation to ensure that testimony admitted under Rule 702 "is not only relevant, but [also] reliable." *Daubert*, 509 U.S. at 589. When determining reliability, a district court evaluates the expert's method as to (1) whether the method can be (and has been) tested, (2) whether the theory or technique has been subjected to peer review and publication, (3) the method's known or potential rate of error, and (4) the method's general acceptance. *Presley v. Lakewood Eng'g & Mfg. Co.*, 553 F.3d 638, 643 (8th Cir. 2009) (citing *Daubert*, 509 U.S. at 593–94). These factors are not exhaustive, and the district court must evaluate the reliability of expert testimony based on the facts of the case. *Id.* A district court also may consider "whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *Sappington v. Skyjack, Inc.*, 512 F.3d 440, 449 (8th Cir. 2008) (internal quotation marks omitted). When weighing these factors, the district court functions as a gatekeeper to separate "expert opinion evidence based on 'good grounds' from subjective speculation that masquerades as scientific knowledge." *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001).

Questions regarding the factual basis of an expert's testimony ordinarily, however, are issues of credibility of the expert's testimony, not issues of admissibility. *Sappington*, 512 F.3d at 450; *see also Minn. Supply Co. v Raymond Corp.*, 472 F.3d 524, 544 (8th Cir. 2006). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

I. NLC's Motion to Exclude Expert Testimony of Dr. Erdman

NLC moves to exclude the testimony of St. Jude's technical expert, Dr. Erdman. NLC argues that Dr. Erdman does not qualify as an expert under Rule 702 because he is not a medical doctor or electrophysiologist and, therefore, he is unable to testify regarding the medical procedure of implanting permanent pacing leads in a lateral branch of a coronary sinus. NLC also contends that permitting Dr. Erdman to present testimony on the issues of invalidity and non-infringement will unfairly prejudice NLC. St. Jude counters that Dr. Erdman will testify regarding the engineering aspects of non-infringement and invalidity, Dr. Erdman has skill in the art, and his testimony is offered in conjunction with Dr. David Benditt, an electrophysiologist. Moreover, St. Jude contends, NLC fails to challenge any aspect of Dr. Erdman's experience or any specific qualification or opinion of Dr. Erdman.

Rule 702 requires an expert to possess "knowledge, skill, experience, training or education sufficient to assist the trier of fact." *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006) (internal quotation marks omitted); *accord* Fed. R. Evid. 702. And such knowledge, skill, experience, training, or education must match "the

subject matter of the witness's testimony." *Robinson*, 447 F.3d at 1101. When issues of infringement and invalidity are disputed, courts analyze them from the perspective of a person having ordinary skill in the art. *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1361 (Fed. Cir. 2008). To opine on those issues that require the examination of evidence from the perspective of one of ordinary skill in the art, a witness must qualify as an expert in the pertinent art. *Id*. at 1363. There also must be an "adequate relationship between [the expert's] experience and the claimed invention." *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010) (distinguishing *Sundance* and holding that the proffered expert had the "knowledge, skill, experience, training, [and] education" of a "specialized" nature that was likely to "assist the trier of fact to understand the evidence or to determine" infringement for the purposes of Rule 702 (internal quotation marks omitted)).[1] Any gap in an expert witness's qualifications or knowledge generally pertains to the weight of the testimony, not its admissibility. *Robinson*, 447 F.3d at 1100.

St. Jude offers Dr. Erdman as a technical expert who will opine on the engineering aspects of non-infringement, invalidity, and the "specific aspects of the properties of the materials required to perform claim 11" of the '268 Patent. The parties agree that the disputed technology at issue, a catheter delivery system, involves design principals that are driven by the expertise of an engineer. Dr. Erdman's qualifications include a Ph.D. in

[1] *See also Birchwood Labs., Inc. v. Battenfeld Techs., Inc.*, No. 09-3555, 2012 WL 2045757, at *8 (D. Minn. May 21, 2012) (concluding that printing expert's testimony was relevant to the field of art when the patent-in-suit claimed firearm shooting targets because "[t]he general field of printing is not the whole field of relevant prior art, but printing is an important aspect of the relevant field of printed shooting targets").

mechanical engineering. He is the Director of the University of Minnesota's Medical Devices Center, serves as the Richard C. Jordan Professor and is a Morse Alumni Distinguished Teaching Professor of mechanical engineering at the University of Minnesota. Dr. Erdman has 45 years of experience in mechanical design, bioengineering, and medical device and product design, including catheter design. His credentials demonstrate that he possesses knowledge, skill, experience, training, and education sufficient to assist the trier of fact. Moreover, Dr. Erdman's education, experience, and training match the subject matter of his testimony.

NLC argues that Dr. Erdman is not qualified in the pertinent art. This argument, however, contradicts NLC's position as to who, in this instance, would be a person of ordinary skill in the art (POSITA). Even when parties attempt to narrowly construe who constitutes a POSITA, courts construe a POSITA broadly to account for a wide variety of expertise, experiences, and avenues of relevant knowledge acquired. *See, e.g.*, *Merck Sharp & Dohme Pharm. v. Teva Pharm. USA, Inc.*, No. 07-1596 (GEB)(DEA), 2009 WL 3153316, at *46 (D.N.J. Aug. 19, 2009) (defining POSITA as "one with substantial training in the chemical and biological sciences with an advanced degree in chemistry, training in the areas of synthetic organic chemistry and medicinal chemistry, and who has substantial experience working in the research and development of leukotriene antagonists *or* who understands the prior art references and [has] the capacity to draw inferences from them, individually and overall, in designing LTD_4 antagonists").

NLC has defined a POSITA in this case as "an electrophysiologist or an engineer familiar with the anatomy of the coronary sinus in a normal heart, and familiar with the

procedures and existing equipment used to conduct those procedures." To be considered a POSITA, according to NLC, an "engineer would have to have been 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." But NLC attacks Dr. Erdman's qualifications based on his inability to implant or direct a physician to implant a permanent pacing lead into the coronary sinus and based on the fact that he is not a medical doctor. In doing so, NLC fails to demonstrate how Dr. Erdman's qualifications do not permit him to serve as a POSITA in this instance. Contrary to NLC's position, Dr. Erdman's credentials qualify him as a technical expert who can opine on factual matters that require the perspective of one of ordinary skill in the art under NLC's POSITA definition—which includes expertise as "an engineer"—and as generally defined. Moreover, there is an adequate relationship between the claimed invention, a catheter delivery system, and Dr. Erdman's experience, which includes catheter design. NLC identifies no evidence that, as a biomedical engineer, Dr. Erdman is not qualified in the relevant art.

Equally unpersuasive are NLC's arguments that Dr. Erdman's testimony must be excluded because he is not a medical doctor, that he has never implanted a permanent pacing lead, and that he has never personally witnessed an electrophysiologist implant a permanent pacing lead in the coronary sinus. The record demonstrates that St. Jude does not rely on Dr. Erdman's experience with the placement *procedure* to establish him as an expert. Instead, Dr. Erdman's testimony relates to "specific aspects of the *properties of the materials* required to perform claim 11" of the '268 Patent. (Emphasis added.) These

material properties include the "physical strength and support capabilities of various components of the dual catheter system at issue relative to the specific sequence of steps recited in claim 11." Based on Dr. Erdman's education and experience in the fields of mechanical and biomedical engineering and his specific experiences related to catheter design, there is an adequate relationship between Dr. Erdman's experience and the claimed invention. Dr. Erdman applies that expertise to the facts of this case by examining the method described in Claim 11. NLC identifies no evidence to the contrary, nor does NLC argue that Dr. Erdman's background is unrelated to catheter delivery design.

NLC's attack on Dr. Erdman's experience with the catheters and leads involved in the procedure offers insufficient grounds to exclude Dr. Erdman, especially when Dr. Erdman's credentials, knowledge, skill, and training are considered. *See Robinson*, 447 F.3d at 1100 (an expert must merely possess "knowledge, skill, experience training or education sufficient to assist the trier of fact" that matches his or her proffered opinions (internal quotation marks omitted)). NLC identifies no other basis on which to exclude Dr. Erdman's testimony as NLC does not challenge the *substance* of Dr. Erdman's opinions. Dr. Erdman's testimony must be useful to the factfinder, based on sufficient facts or data, the product of reliable principles, and the result of reliable application of those principals and methods to the facts of the case. Fed. R. Evid. 702. NLC has not challenged Dr. Erdman on any of these grounds. To the extent NLC seeks to challenge the factual basis for Dr. Erdman's opinions or any purported gaps between

Dr. Erdman's expertise and the proffered testimony, NLC may do so on cross-examination.

In summary, because NLC's challenge to Dr. Erdman's qualifications lacks merit, NLC's motion to exclude Dr. Erdman's opinions and testimony is denied.

II. St. Jude's Motion to Exclude Expert Testimony of Dr. Burke

St. Jude moves to exclude the opinions of NLC's technical expert Dr. Burke as unsupported by sufficient facts and counter to the law and the facts of the case because Dr. Burke's opinions do not comport with this Court's October 21, 2019 claim construction order. NLC argues that Dr. Burke's misunderstanding of the difference between direct and indirect infringement is not a basis on which Dr. Burke can be disqualified. The fact that Dr. Burke did not read the Court's claim construction order is not a basis for disqualification, NLC contends. Moreover, NLC maintains, Dr. Burke applied the Court's claim construction as to the order in which Claim 11 must be performed as well as the claim construction of "the catheter." The Court addresses each proffered basis for exclusion in turn.

A. Dr. Burke's Understanding of Direct and Indirect Infringement

The opinions of Dr. Burke should be excluded, St. Jude argues, because Dr. Burke demonstrated that he does not understand the difference between direct and indirect infringement. Testimony proffered by a witness who lacks the relevant *technical* expertise does not meet the standard of admissibility under Rule 702. *Sundance, Inc.*, 550 F.3d at 1363. But a challenge to an infringement expert's expertise in *patent law* may not undermine the expert's qualifications and testimony in the area of expertise in

which the expert is offered. *See, e.g.*, *WNS Holdings, LLC v. United Parcel Serv., Inc.*, No. 08-CV-275-bbc, 2009 WL 2136961, at *4 (W.D. Wis. July 14, 2009) ("Plaintiff's challenges to Cotton's lack of expertise in patent law do not undermine Cotton's qualifications and testimony as an avionics expert."), *aff'd*, 368 F. App'x 144 (Fed. Cir. 2010). "Experts routinely rely upon other experts hired by the party they represent for expertise outside their field." *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1303 (Fed. Cir. 2015) (internal quotation marks omitted).

NLC offers Dr. Burke as an expert in electrophysiology to opine on the medical procedure for implanting permanent pacing leads into the coronary sinus. The parties do not dispute Dr. Burke's technical qualifications as St. Jude does not challenge Dr. Burke's knowledge, skill, or expertise as they relate to the method and devices at issue. Instead, St. Jude challenges Dr. Burke's ability to explain and understand the difference between direct and indirect infringement. But NLC does not offer Dr. Burke as an expert on patent law. And such a challenge is meritless when an expert witness's relevant expertise lies outside of the law. *See, e.g.*, *WNS Holdings, LLC*, 2009 WL 2136961, at *4. St. Jude cites no case law, nor has the Court's research produced any, that suggests that a technical expert *must* be capable of reciting the difference between direct and indirect infringement or that such an inability is an appropriate basis for exclusion.

Therefore, the Court denies St. Jude's motion to exclude Dr. Burke's opinions and testimony on this basis.

B. Dr. Burke's Review of the Court's Claim Construction Order

St. Jude also argues that the opinions of Dr. Burke should be excluded because Dr. Burke did not read the Court's claim construction order.

"An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." Fed. R. Evid. 703. In the patent-infringement context, an expert's opinion has sufficient foundation when the expert has examined the accused method, the patented method, and the court's claim construction order, which are "the items most germane to forming an infringement opinion." *LTJ Enters. v. Custom Mktg. Co.*, 168 F. Supp. 3d 1202, 1209 (D. Minn. 2016). An expert may use the Court's definitions in its claim construction order, as relayed by counsel, when forming an expert opinion. *Arason Enters., Inc. v. CabinetBed Inc.*, No. 16-cv-03001-PAB-NRN, 2019 WL 4597863, at *4. (D. Colo. Sept. 23, 2019) (refusing to disqualify an expert because the expert did not read the court's claim construction in full and instead relied on the court's constructions as provided by counsel).

In this instance, St. Jude attacks Dr. Burke's expert opinion based on Dr. Burke's failure to personally read the Court's claim construction order. NLC represents that Dr. Burke "understood from counsel that the Court had interpreted Claim 11 to require that the steps be performed in order," and Dr. Burke affirms as much in his declaration and in his rebuttal opinion on validity. Although Dr. Burke did not read the Court's claim construction order, the claim construction was communicated to him through counsel. At worst, Dr. Burke may have lacked the context provided by preforming an independent reading of the Court's claim construction order. But St. Jude fails to offer any argument

or legal authority as to the adverse effect of this manner of preparation on the admissibility of Dr. Burke's opinions.

Accordingly, the Court declines to exclude Dr. Burke's opinions and testimony on this basis.

C. Dr. Burke's Application of the Court's Claim Construction Order

St. Jude next challenges the admissibility of Dr. Burke's opinions on the ground that he did not apply the Court's construction of Claim 11.

Expert testimony that is unsupported by sufficient facts or contrary to the facts of a case is inadmissible. *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757 (8th Cir. 2006). "Once a district court has construed the relevant claim terms" in a patent, "that legal determination governs." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1321 (Fed. Cir. 2009). Expert testimony that conflicts with a district court's claim construction is inadmissible. *See Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1207 (Fed. Cir. 2010) (discussing with approval the district court's decision to exclude expert testimony that "attempted to resurrect a claim construction that the district court already rejected"). Likewise, expert testimony that ignores or fails to consider a district court's claim construction is inadmissible. *See, e.g.*, *MarcTec, LLC v. Johnson & Johnson*, 664 F.3d 907, 913 (Fed. Cir. 2012) (discussing exclusion of expert testimony that "ignored the court's claim construction" as "inadmissible under *Daubert*"). But expert testimony that merely is contradictory to prior testimony may be subject to cross-examination, not exclusion under *Daubert* or Rule 702. *In re AndroGel Antitrust Litig. (No. II)*, 888 F. Supp. 2d 1336, 1356 (N.D. Ga. 2012) (concluding that any inconsistency

between expert's deposition testimony and expert report "may be the subject of cross examination, but does not justify exclusion").

Dr. Burke's disputed opinion relates to the order in which Claim 11 must be performed. The Court's October 21, 2019 claim construction order concluded that the steps of Claim 11 must be performed in the order listed and that "Claim 11 is infringed *only* when the steps are performed in the order listed." (Emphasis added.) St. Jude points to several admissions made by Dr. Burke during his deposition regarding his application of the claim construction order. For example, Dr. Burke admitted that he applied the steps out of the sequence detailed in Claim 11 and that such an application may give rise to infringement. In addition, Dr. Burke marked an illustration during his deposition in a manner that suggests he applied the steps of Claim 11 out of sequence when rendering his infringement opinion.

Although testimony based on Dr. Burke's decision to apply the steps of Claim 11 out of order would be of little use to the jury because the question of infringement relates to completion of the steps of Claim 11 *in order*, a fulsome view of Dr. Burke's expert report and deposition testimony provides no grounds for his exclusion. Contradictory expert testimony is grounds for cross-examination, not exclusion. *Janopoulos v. Harvey L. Walner & Assocs., Ltd.*, 866 F. Supp. 1086, 1096 (N.D. Ill. 1994) ("[D]iscrepancies in [an expert's] testimony and declaration go to the weight rather than the admissibility of his opinions."). And deposition testimony that contradicts an expert report bears on the weight afforded the expert report, not on whether the expert should be precluded from testifying. *See, e.g., i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir.

2010) ("When the methodology is sound, and the evidence relied upon [is] sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility.").

St. Jude identifies numerous instances in which Dr. Burke contradicts *himself*, arguing that, because these internal inconsistences contradict this Court's claim construction order, Dr. Burke should be excluded. But Dr. Burke applied the Court's claim construction. Contrary to St. Jude's representations, during his deposition, Dr. Burke testified as follows:

> Q. And so what I'd like to know on behalf of St. Jude then is when you were assessing whether they infringed or not, would the presence of additional steps within claim 11, meaning you performed all of the steps listed in claim 11, but there were other steps done in between, would fall within the scope of infringement or noninfringement, as you applied the standard in this case?
>
> . . .
>
> A. Yea, I generally, as I understand it, relate it to the scope of my testimony as it relates to St. Jude infringing, *that they have to follow these steps.*

(Emphasis added). This exchange suggests that Dr. Burke was aware that the steps in Claim 11 must be followed in the order listed to give rise to infringement. And at other points in his deposition and expert reports, Dr. Burke acknowledges that the steps in Claim 11 must be completed in the order listed.

For example, St. Jude contends that Dr. Burke was presented with the St. Jude Instructions for Use (IFU) at his deposition and asked to identify the presence of each

step in Claim 11 in the sequence each step appeared in the IFU. In response, Dr. Burke identified and marked the steps out of sequential order as 4, 3, 2, and 1, in a manner that is contrary to the Court's claim construction order. Dr. Burke's testimony is inconsistent with his expert report in which he tracks each claim element in sequential order alongside St. Jude's product literature instructions in sequential order, as is required by the Court's claim construction order. Such inconsistencies between an expert report and deposition testimony are not a basis for exclusion. *See, e.g.*, *i4i Ltd. P'ship*, 598 F.3d at 852.

The evidence identified by St. Jude does not constitute grounds to exclude Dr. Burke. At best, St. Jude has identified inconsistent or contradictory positions between Dr. Burke's expert reports and Dr. Burke's deposition testimony. Such inconsistences are matters for cross-examination, not grounds for exclusion. Accordingly, the Court denies St. Jude's motion to exclude Dr. Burke's opinions and testimony on this basis.

D. Dr. Burke's Application of the Court's Construction of "the catheter"

St. Jude also argues that Dr. Burke's opinions should be excluded because he did not apply the Court's construction of "the catheter."

When a district court has construed the relevant claim terms, that legal determination governs. *Exergen Corp.*, 575 F.3d at 1321. A party may not contradict a district court's claim construction. *Id*. And an expert witness may not present testimony that conflicts with the district court's claim construction. *See Finjan*, 626 F.3d at 1207. Expert testimony that ignores or fails to consider the district court's claim construction is inadmissible. *See, e.g.*, *MarcTec, LLC*, 664 F.3d at 913.

In the Court's October 21, 2019 claim construction order, the Court construed "the catheter" to mean "the double catheter." Claim 11 defines "double catheter" to include an "outer catheter and an inner catheter." St. Jude relies on several admissions by Dr. Burke during his deposition pertaining to his application of the Court's construction of "the catheter." Dr. Burke was questioned during his deposition about the definition of "the catheter" and whether, in his application of Claim 11, "the catheter" referred to a "single catheter, the inner and the outer catheter, or any version." In response, Dr. Burke testified that in his application of Claim 11, "the catheter" pertained to "any version." St. Jude now argues that this testimony renders Dr. Burke's opinion unreliable because he did not apply the Court's construction of "the catheter."

Although it is true that failure to apply the Court's claim construction of "the catheter" is impermissible, a fulsome view of Dr. Burke's expert report and deposition testimony suggests that exclusion of his opinions and testimony is unwarranted on this basis. Dr. Burke was questioned about whether following the steps of Claim 11 with the use of an electrophysiology catheter before completion of the final step of Claim 11 would constitute infringement. In response, Dr. Burke testified that he "would stick to the concept that claim 11 is a method for placing an electrical lead in a lateral branch of a coronary sinus vein *using a catheter, including an outer and inner cath[eter]*." (Emphasis added). Dr. Burke also was questioned about whether use of the stylet method would result in infringement. Dr. Burke responded that "with . . . a dual outer and inner sheath system that has engaged the branch using a guidewire, you can infringe using the stylet method." In each response, Dr. Burke explicitly refers to the double catheter

whether by referring to the component parts comprising the double catheter or by referring to the catheter and the component parts.

Moreover, it appears from Dr. Burke's expert report that he applied the Court's construction of "the catheter." Notably, in addressing steps 1 and 2 of Claim 11, Dr. Burke opines that "[t]he instructions for the CPS inner catheters . . . direct the electrophysiologist to insert the inner and other catheter into the coronary sinus" and that "St. Jude's instructions for the inner [catheter] direct an electrophysiologist to advance a guide wire through the inner and outer catheters." In addressing step 3 of Claim 11, Dr. Burke opines that "[t]his step describes using the double catheter in a telescoping manner," and that "St. Jude's instructions for the inner catheter explicitly direct electrophysiologists to use the inner and outer catheters . . . , which an electrophysiologists would understand as advancing the inner catheter out of the front of the outer catheter along the guide wire." Dr. Burke refers to the double catheter by identifying the double catheter's component parts, namely, an inner and outer catheter. This aspect of Dr. Burke's report is consistent with the Court's claim construction.

Accordingly, because Dr. Burke's expert report is consistent with this Court's claim construction order, his opinions and testimony will not be excluded.[2]

III. St. Jude's Motion to Exclude Expert Testimony of Carlson

St. Jude also moves to exclude the opinions of Carlson, NLC's damages expert, as unreliable and speculative. In particular, St. Jude challenges Carlson's damages opinions

[2] Should Dr. Burke attempt to testify at trial in a manner that is contrary to the Court's claim construction, the Court will address any objection. That is not the Court's expectation, however.

that pertain to the appropriate royalty base, arguing that Carlson fails to apportion damages to the value attributable to the claimed method and improperly assumes that all of St. Jude's inner catheters are used in an infringing manner.[3]

Reasonable royalty damages are, by statute, "the minimum amount of infringement damages 'adequate to compensate for the infringement.' " *LaserDynamics, Inc. v. Quanta Comput., Inc.*, 694 F.3d 51, 66 (Fed. Cir. 2012) (quoting 35 U.S.C. § 284). Generally, reasonable royalties must "be based not on the entire product, but instead on the smallest salable patent-practicing unit." *Id.* at 67 (internal quotation marks omitted). As a "narrow exception" to this general rule, the "entire market value rule" permits a patentee to recover a royalty based on the revenue for an entire multi-component product if the patentee can show that "the patented feature drives the demand for [the] entire multi-component product." *Id.*

NLC concedes in its brief that "[t]his is not an entire market value rule case." Indeed, Carlson does not purport to invoke the entire-market-value rule in his report, nor does he attempt to establish a relationship between the claimed method and customer demand for any combination of St. Jude's products. To the contrary, Carlson observes in

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[3] St. Jude seeks exclusion of Carlson's opinions and testimony in their entirety, but St. Jude's arguments are directed solely at Carlson's opinions as to the royalty base. For instance, although St. Jude's reply brief repeatedly refers to Carlson's calculation of the royalty rate as "inflated," St. Jude offers no substantive factual or legal argument that specifically challenges Carlson's calculation of the royalty rate. As such, the Court limits its analysis to whether Carlson's royalty base opinions and testimony should be excluded. *See, e.g.*, *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1328–31 (Fed. Cir. 2014) (separately evaluating admissibility of expert opinions pertaining to royalty base and royalty rate, and concluding that the former were inadmissible whereas the latter were admissible).

his report that Claim 11 of the '268 Patent requires "an outer catheter, an inner catheter, a guide wire, and a lead," and that "these components comprise the smallest saleable component that is used by an electrophysiologist to practice the claimed methods." As such, Carlson derives a royalty base from this purported "smallest saleable" patent-practicing unit based on St. Jude's revenues for these four components.

When, as here, the entire-market-value rule is not implicated, "principles of apportionment apply." *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1326 (Fed. Cir. 2014). Because damages awarded for patent infringement "must reflect the value attributable to the infringing features of the product, and no more," apportionment requires a damages expert to "separate the value of the allegedly infringing features from the value of all other features." *Commonwealth Sci. & Indus. Rsch. Organisation v. Cisco Sys., Inc.*, 809 F.3d 1295, 1301 (Fed. Cir. 2015) (internal quotation marks omitted). Apportionment may be addressed in numerous 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, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014). The parties do not dispute that apportionment is required in this case. Instead, the parties dispute whether Carlson reliably applied apportionment when calculating the royalty base.

NLC contends that "Carlson has appropriately apportioned the royalty base by limiting the royalty base to sales of the components recited in the claim." These components, according to Carlson's report, comprise the smallest salable patent-

practicing unit. But "the requirement that a patentee identify damages associated with the smallest salable patent-practicing unit is simply a step toward meeting the requirement of apportionment." *VirnetX*, 767 F.3d at 1327. When "the smallest salable unit is, in fact, a multi-component product containing several non-infringing features with no relation to the patented feature . . . , the patentee must do more to estimate what portion of the value of that product is attributable to the patented technology." *Id.* Although "this process may involve some degree of approximation" as "absolute precision" is not required, a district court must "exercise[ ] its gatekeeping authority to ensure that only theories comporting with settled principles of apportionment [are] allowed to reach the jury." *Id.* at 1328. Accordingly, "a patentee must be reasonable (though may be approximate) when seeking to identify a patent-practicing unit, tangible or intangible, with a close relation to the patented feature." *Id.* at 1329. The record reflects that Carlson has not done so here.

In his report, Carlson concludes that the "smallest saleable" patent-practicing unit comprises "an outer catheter, an inner catheter, a guide wire, and a lead," because these four components are recited in Claim 11 of the '268 Patent. But NLC has identified no legal authority for satisfying the apportionment requirement in this way. Indeed, courts have rejected such an approach. *See, e.g.*, *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); *Cornell Univ. v. Hewlett-Packard Co.*, 609 F. Supp. 2d 279, 283–85 (N.D.N.Y. 2009) (same). Even if a component is "valuable, important,

or even essential" to practicing a patented method, "the patented feature must be separated" from the unpatented elements of the component. *VirnetX*, 767 F.3d at 1329 (quoting *LaserDynamics*, 694 F.3d at 68). An expert's testimony as to a royalty base is inadmissible if the expert "fail[s] to apportion value between the patented features and the vast number of non-patented features contained in the accused products" because such an approach does not "carefully tie proof of damages to the claimed invention's footprint in the marketplace." *Id.* at 1329 (internal quotation marks omitted).

Claim 11 of the '268 Patent pertains to a "method for placing an electrical lead in a lateral branch of a coronary sinus vein using a double catheter." Claim 11 covers a method, not the components involved in practicing the method. 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. For instance, although leads are recited in Claim 11, the '268 Patent does not teach or disclose leads. The parties' experts do not dispute this fact. Dr. Burke, NLC's technical expert, testified that the '268 Patent provides no discussion of how to accomplish the electrical features of a lead and that the leads "weren't part and parcel to the '268 Patent." The entirety of the '268 Patent's scope is limited to a "double catheter" for use in the "coronary sinus." This scope does not include leads. As such, Carlson's royalty base accounts for more than the *method* claimed. *See Cornell Univ.*, 609 F. Supp. 2d at 283–84 (excluding damages expert because the damages assessment was "in excess of the contribution of the claimed invention to this market"); *see also LaserDynamics*, 694 F.3d at 68 (rejecting damages award because the patent only covered a method practiced using an optical disc drive, but

damages were based on the entire computer). As in *VirnetX*, in this case, Carlson failed to apportion value between the claimed method and any other valuable features contained in the accused products. *See* 767 F.3d at 1329. In doing so, Carlson essentially opines that St. Jude's inner catheter, outer catheter, guide wire, and leads have no value other than to perform the claimed method. But the record does not support such a conclusion. Even NLC's technical expert, Dr. Burke, has testified that a lead is a "very complex" component with features that are not part of the claimed invention.

NLC contends that Carlson properly excluded "other devices involved in the medical procedure, such as pacemakers and defibrillators." But this fact does not excuse NLC from its obligation to apportion value with respect to the four components that comprise Carlson's royalty base. *See id.* at 1327 (explaining that when "the smallest salable unit is, in fact, a multi-component product containing several non-infringing features with no relation to the patented feature . . . , the patentee must do more to estimate what portion of the value of that product is attributable to the patented technology"). Even assuming that the four components Carlson used to calculate the royalty base represent the smallest salable patent-practicing unit, identifying the damages associated with these components "is simply a step toward meeting the requirement of apportionment," and is not sufficient on its own. *Id.*

NLC also contends that "Carlson used the inner catheter sales as a limiter to apportion the unit sales of outer catheters and leads." Carlson opines that, in a given year, St. Jude's gross profit margin for inner catheters has ranged from approximately 60 percent to 70 percent, St. Jude's gross profit margin for outer catheters has ranged from

approximately 83 percent to 86 percent, and St. Jude's gross profit margin for leads has ranged from approximately 82 percent to 89 percent. To calculate the royalty base, Carlson limits the number of outer catheters and leads by using the number of inner catheter sales for the same year because, according to Carlson, St. Jude's inner catheters had the lowest number of per-unit sales. But although this methodology reduces the overall royalty base, this reduction has no logical connection to the proportionate value of these components that is attributable to the claimed method of the '268 Patent. The purpose of apportionment is to ensure that a reasonable royalty damages award is "based on the incremental value that the patented invention adds to the end product." *Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp, LLC*, 879 F.3d 1332, 1348 (Fed. Cir. 2018) (explaining that when a patent claim "recite[s] both conventional elements and unconventional elements, the court must determine how to account for the relative value of the patentee's invention in comparison to the value of the conventional elements recited in the claim, standing alone" (internal quotation marks omitted)). Carlson's reduction of the royalty base fails to do so here. Because Carlson's method *arbitrarily* reduces the royalty base for outer catheters and leads to match the per-unit sales of inner catheters, his method does not "carefully tie proof of damages to the claimed invention's footprint in the market place." *VirnetX*, 767 F.3d at 1329 (internal quotation marks omitted).

It is true that, rather than addressing apportionment when calculating the royalty *base*, an expert may instead address apportionment by adjusting of the royalty *rate* "so as to discount the value of the product's non-patented features." *Exmark*, 879 F.3d at 1348

(internal quotation marks omitted). But NLC does not argue, and the record does not reflect, that Carlson used such an approach here. To the contrary, when addressing the royalty rate calculation in his report, Carlson opines that the "portion of the realizable profit that should be credited to the invention supports a higher royalty rate." According to Carlson, this is because "the claimed invention is not divorceable from St. Jude's catheters" and "the patent encompasses the entire product, not merely some component of the product." As such, 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—instead, Carlson concludes that no such value exists.

For these reasons, Carlson's calculation of the royalty base does not comport with settled principles of apportionment and, therefore, must be excluded. *VirnetX*, 767 F.3d at 1328. Accordingly, St. Jude's motion to exclude Carlson's opinions and testimony is granted in part. Carlson's opinions and testimony as to the royalty base are inadmissible.

IV. St. Jude's Request for Reconsideration

St. Jude requests that the Court reconsider its ruling on its construction of "the catheter" because of "the clear confusion expressed by NLC's own expert ***even after*** this Court's claim construction ruling." In support of its motion, St. Jude explains that "the ambiguity caused by the claim's failure to provide an antecedent basis for 'the catheter' injects confusion and allows gamesmanship as to which catheter is referenced, and where infringement begins and ends."

"Except with the court's prior permission, a party must not file a motion to reconsider. . . . A party who seeks permission to file a motion to reconsider must first file

and serve a letter of no more than two pages requesting such permission." LR 7.1(j). To the extent that St. Jude requests that the Court reconsider its prior ruling, that motion is not properly before the Court because St. Jude neither sought nor received permission from this Court before requesting reconsideration. Accordingly, St. Jude's request for reconsideration is denied.

ORDER

Based on the foregoing analysis and all the files, records and proceedings herein, **IT IS HEREBY ORDERED**:

1. Plaintiff Niazi Licensing Corporation's motion to exclude the expert testimony of Dr. Arthur Erdman, (Dkt. 196), is **DENIED**.

2. Defendant St. Jude Medical S.C., Inc.'s motion to exclude the expert testimony of Dr. Martin Burke and Brad Carlson, (Dkt. 164), is **GRANTED IN PART AND DENIED IN PART** as follows:

   a. St. Jude's motion is **GRANTED** as to the opinions and testimony of Carlson that pertain to the royalty base, which are excluded as addressed in Part III of this Order.

   b. St. Jude's motion is **DENIED** in all other respects.

Dated: September 14, 2020

s/Wilhelmina M. Wright
Wilhelmina M. Wright
United States District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Niazi Licensing Corporation, Plaintiff, v. St. Jude Medical S.C., Inc., Defendant.	Case No. 17-cv-5096 (WMW/BRT) **ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

This patent-infringement matter is before the Court on the parties' cross-motions for summary judgment. (Dkts. 180, 184.) For the reasons addressed below, Defendant's motion for summary judgment is granted and Plaintiff's motion for summary judgment is denied.

BACKGROUND

Plaintiff Niazi Licensing Corporation (NLC) owns United States Patent No. 6,638,268 (the '268 Patent), which pertains to a catheter system that can be inserted into the coronary sinus of the heart. This catheter system allows medical professionals to administer fluids and introduce pacing leads to the coronary sinus. Although the use of catheters was known in 2003 when the '268 Patent issued, the '268 Patent describes an invention that, based on its structure and shape, purportedly is better suited for "use in the coronary sinus, especially in patients suffering from congestive heart failure." The '268 Patent claims a double catheter system with an "outer, resilient catheter having shape

memory and a hook-shaped distal end" and an "inner, pliable catheter slidably disposed in the outer catheter." The patent also claims methods of using the catheter system.

NLC commenced this patent-infringement action against Defendant St. Jude Medical S.C., Inc. (St. Jude), on November 13, 2017. NLC alleges that St. Jude has indirectly infringed the '268 Patent by inducing its customers—namely, medical professionals—to infringe the '268 Patent. Only a single method claim remains in dispute in this lawsuit: Claim 11 of the '268 Patent, which claims a series of steps for "using a double catheter." In its entirety, Claim 11 provides as follows:

> **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.

In its October 21, 2019 claim construction order, the Court construed "the catheter" to mean "the double catheter" and held that "Claim 11 is infringed only when the steps are performed in the order listed."

The parties now cross-move for summary judgment. NLC argues that it is entitled to summary judgment in its favor on the issues of infringement, St. Jude's invalidity defenses, and St. Jude's challenge to NLC's entitlement to damages that accrued before the inventor assigned the '268 Patent to NLC. According to NLC, this matter should proceed to trial only on the issues of willful infringement and damages. St. Jude argues that it is entitled to summary judgment in its favor as to infringement and, in the alternative, contends that NLC cannot obtain pre-assignment damages as a matter of law.

ANALYSIS

Summary judgment is proper when the record before the district court establishes that there is "no genuine dispute as to any material fact" and the moving party is "entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A genuine dispute as to a material fact exists when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). When deciding a motion for summary judgment, a district court construes the evidence in the light most favorable to the nonmoving party and draws all reasonable inferences in the nonmoving party's favor. *See Windstream Corp. v. Da Gragnano*, 757 F.3d 798, 802–03 (8th Cir. 2014). When asserting that a fact is genuinely disputed, the nonmoving party must "submit affidavits, depositions, answers to interrogatories, or admissions on file and designate specific facts" in support of that assertion. *Gander Mountain Co. v. Cabela's, Inc.*, 540 F.3d 827, 831–32 (8th Cir. 2008); *see also* Fed. R. Civ. P. 56(c)(1)(A). A nonmoving party may not "rest on mere allegations or denials but must demonstrate on

the record the existence of specific facts which create a genuine issue for trial." *Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995) (internal quotation marks omitted).

I. Infringement

NLC and St. Jude cross-move for summary judgment as to St. Jude's alleged infringement of Claim 11 of the '268 Patent. A finding of infringement of a method claim requires that "each and every step of the method or process was performed." *Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech.*, 709 F.3d 1348, 1362 (Fed. Cir. 2013). By contrast, 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).

It is undisputed that St. Jude does not itself perform the patented medical procedure. Instead, NLC alleges that St. Jude has indirectly infringed Claim 11 of the '268 Patent by inducing its customers—namely, medical professionals—to practice the patented method via St. Jude's product instructions and marketing materials. "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). "In order to succeed on a claim of inducement, the patentee must show, first that there has been direct infringement, and second that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304–05 (Fed. Cir. 2002)

(citation omitted). The Court addresses, in turn, the issues of direct infringement and St. Jude's knowledge and intent.

A. Direct Infringement

Liability for the inducement of patent infringement "may arise if, but only if, there is . . . direct infringement." *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014) (internal quotation marks and alterations omitted). "A method patent claims a number of steps," and a method patent "is not infringed unless all the steps are carried out." *Id.* "Direct infringement of a method claim can be based on even one instance of the claimed method being performed." *Mirror Worlds, LLC v. Apple Inc.*, 692 F.3d 1351, 1359 (Fed. Cir. 2012). But a defendant "cannot be liable for inducing infringement" if the "performance of all the claimed steps cannot be attributed to a single person." *Limelight Networks*, 572 U.S. at 923.

This Court previously held that Claim 11 of the '268 Patent is infringed only if the steps of the patented method are performed in the order listed. As such, to be entitled to summary judgment of infringement, NLC must prove that St. Jude induced a single person to actually perform every step of Claim 11 in the exact order that those steps are listed in the '268 Patent. *See Mformation Techs., Inc. v. Research in Motion Ltd.*, 764 F.3d 1392, 1398–99 (Fed. Cir. 2014). Conversely, if NLC fails to prove that any one step of the method was not so performed, St. Jude is entitled to summary judgment of non-infringement. *See Aristocrat Techs.*, 709 F.3d at 1362; *cf. Medgraph, Inc. v. Medtronic, Inc.*, 843 F.3d 942, 949 (Fed. Cir. 2016).

NLC first contends that St. Jude's experts have admitted that direct infringement has occurred. In support of this argument, NLC relies on the following statement from the rebuttal report of St. Jude's damages expert, Dr. Mohan Rao: "In fact, based on my discussion with [St. Jude's technical expert] Dr. [David] Benditt, I understand that in practice, physicians utilize the method as listed in Claim 11 of the '268 patent less than 1 percent of the time." But for at least two reasons, this evidence is insufficient to satisfy NLC's burden to prove infringement. First, the statement in Dr. Rao's expert report is hearsay within hearsay and, therefore, inadmissible in evidence. *See Rainforest Cafe, Inc. v. Amazon, Inc.*, 86 F. Supp. 2d 886, 902–03 (D. Minn. 1999) (observing that "testimony of a witness that another individual told him or her" a particular statement "is inadmissible hearsay"); *Multi-Tech Sys., Inc. v. Hayes Microcomputer Prods., Inc.*, 800 F. Supp. 825, 844 (D. Minn. 1992) (observing that plaintiff "may not rely solely on inadmissible hearsay" to prevail on summary judgment).[1]

Second, even if Dr. Rao's statement were not inadmissible hearsay, it is inadmissible for another reason: namely, because it clearly reflects a hypothetical assumption, which is unfounded speculation. The purpose of Dr. Rao's rebuttal expert

[1] NLC contends that Dr. Rao's statement is not hearsay, pursuant to Rule 801(d)(2)(B), Fed. R. Evid., which provides that a statement is not hearsay if the statement "is offered against an opposing party and . . . is one the party manifested that it adopted or believed to be true." To be admissible under this rule, "the Court must determine, by a preponderance of the evidence, that a reasonable jury could properly find Defendant adopted the [statement] as an admission." *Cowden v. BNSF Ry. Co.*, 980 F. Supp. 2d 1106, 1119 (E.D. Mo. 2013). The record in this case does not establish that St. Jude "adopted or believed to be true," as a factual admission of liability, the statement from Dr. Rao's report on which NLC relies. To the contrary, St. Jude has consistently maintained that it has *not* infringed the '268 Patent.

report is to opine as to the extent of NLC's recoverable damages *assuming* that NLC were to prove infringement, which is not an uncommon practice. *See, e.g.*, *Sys. Dev. Integration v. Comput. Scis. Corp.*, 886 F. Supp. 2d 873, 882 (N.D. Ill. 2012) ("It is entirely appropriate for a damages expert to assume liability for the purposes of his or her opinion. To hold otherwise would be illogical."). Neither Dr. Rao nor Dr. Benditt purport to have either personal knowledge or data from which they have concluded that direct infringement of Claim 11 of the '268 Patent has occurred. Instead, the statement in Dr. Rao's report reflects Dr. Benditt hypothesizing as to the possibility of infringement occurring, which cannot demonstrate infringement.[2] *See ACCO Brands, Inc. v. ABA Locks Mfr. Co.*, 501 F.3d 1307, 1313–14 (Fed. Cir. 2007) (observing that hypothetical instances of infringement cannot establish liability, which requires evidence of "specific instances of direct infringement" or that defendant's product "necessarily infringes"). To hold otherwise would permit a patentee to satisfy its affirmative burden of proof any time an accused infringer denies infringement liability but attempts to mitigate potential damages by offering, in the alternative, a rebuttal expert opinion on the issue of damages

[2] In addition to being speculative, Dr. Benditt's alleged statement (as paraphrased by Dr. Rao) that "physicians utilize the method as listed in Claim 11 of the '268 patent less than 1 percent of the time" cannot establish infringement for at least two other reasons. First, use of the patented method "less than 1 percent of the time" includes the possibility that the patented method is never used. Second, nothing in Dr. Benditt's alleged statement establishes a connection between St. Jude and any use of the patented method. Indeed, Dr. Benditt's speculation that the patented method might be used "less than 1 percent of the time" does not suggest that *St. Jude's customers*, using *St. Jude's written instructions*, are among those rare physicians who might use the patented method. As such, even if this evidence were not purely speculative double hearsay, this evidence would be insufficient to satisfy NLC's burden to prove that St. Jude induced at least one of its customers to infringe Claim 11 of the '268 Patent.

based on an assumption of liability. Such a result would be illogical and contrary to the law, common sense, and common practice. *See, e.g.*, *Sys. Dev. Integration*, 886 F. Supp. 2d at 882. Because the expert statements on which NLC relies are inherently hypothetical and speculative, such evidence is insufficient to prove direct infringement.[3]

NLC next argues that the written instructions St. Jude provides to end-users of its catheter products are circumstantial evidence of direct infringement. "In order to prove direct infringement, a patentee must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit." *ACCO Brands*, 501 F.3d at 1313. "Hypothetical instances of direct infringement are insufficient to establish . . . indirect infringement," and the "mere sale of a product capable of substantial non-infringing uses does not constitute indirect infringement of a patent." *Id.* at 1313–14 (internal quotation marks omitted).

It is true that a patentee may prove infringement using circumstantial evidence. *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1364 (Fed. Cir. 2012). But the "[c]ircumstantial evidence must show that at least one person directly infringed an asserted claim during the relevant time period." *Id.* Such evidence is insufficient if it merely shows that the defendant's product is "capable of" infringing and the defendant's "user manuals simply described how to use the product in an infringing manner." *Id.* at 1365. Instead, to prove direct infringement through circumstantial evidence when a

[3] NLC contends that Dr. Rao's statement is *not* speculative because he prefaces the statement with the phrase "[i]n fact." Simply put, it is absurd to argue that beginning a sentence with a figure of speech such as "in fact" converts any speculation that follows into non-speculative evidence. NLC's argument lacks merit.

defendant has sold products that merely are *capable of* infringing, the patentee must present evidence that "the accused infringer designed its products to practice the claimed invention and instructed its customers to use the accused product in an infringing way." *Id.* (observing that defendants "go beyond *describing* the infringing mode; they *recommended* that customers use the infringing mode" (emphasis added)). Such instructions must evince the defendant's "intent to *encourage* infringement," and "[m]erely describing" an infringing use "is not the same as recommending, encouraging, or promoting an infringing use, or suggesting that an infringing use should be performed." *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015) (internal quotation marks, alterations, and citations omitted). Accordingly, to prevail, NLC must present evidence that St. Jude affirmatively instructs, encourages, or recommends that its customers use its products to perform the steps of Claim 11 in the order that those steps are listed in the '268 Patent.

Claim 11 includes five steps:

> [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.

The Court next addresses, in turn, NLC's evidence as to each of these five steps.[4]

1. Step 1

The first step of Claim 11 is "inserting the catheter into the coronary sinus." The Court previously construed "the catheter" to mean "the double catheter"—*i.e.*, both the inner and outer catheter. NLC contends that St. Jude induces its customers to perform this step in its written instructions by directing users to "[i]nsert the inner catheter into the outer guide catheter." But prior to this instruction, St. Jude's written instructions direct users to "[f]ollow normal accepted practice for . . . outer guide catheter insertion." This instruction indicates that the outer catheter should be inserted *before* the inner catheter is inserted rather than inserting both catheters simultaneously. This is inconsistent with the claimed method as construed by the Court. Therefore, NLC's evidence does not establish that St. Jude instructed customers to perform the first step of the Claim 11 method.

2. Step 2

The second step of Claim 11 is "advancing a guide wire through the catheter into a coronary sinus lateral branch vein." According to NLC, St. Jude instructs users to perform this step by directing users to, "[i]f desired, insert a guidewire . . . through the inner catheter lumen into the branch vein." But Claim 11 requires performing this step *before* advancing the inner catheter into the branch vein. In contrast, St. Jude's

[4] In opposing St. Jude's motion for summary judgment of non-infringement, NLC relies on an "abbreviated overview" of the same arguments and evidence that NLC relies on in its motion for summary judgment of infringement. As such, NLC's arguments and affirmative evidence of infringement are coextensive with its arguments and evidence seeking to counter St. Jude's non-infringement arguments.

instructions reference the use of a guidewire only *after* first directing users to "subselect[ ] the desired coronary sinus branch vein" when inserting the inner catheter. As such, St. Jude's written instructions do not follow the same order listed in Claim 11 and, therefore, do not instruct customers to infringe the patented method.

In addition, St. Jude's instructions do not recommend or encourage the use of a guidewire. Instead, the instructions provide that a physician *may* insert a guidewire "[i]f desired." Evidence 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. *Toshiba Corp.*, 681 F.3d at 1365 (observing as significant the fact that defendants "go beyond *describing* the infringing mode; they *recommended* that customers use the infringing mode" (emphasis added)). Notably, the record undisputedly 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. Moreover, NLC's reliance on articles, instructions, and marketing materials produced by individuals and entities other than St. Jude is inapposite. Such evidence is immaterial because it has no relevance to whether *St. Jude* recommended or encouraged infringement.

In summary, 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.

3. Step 3

The third step of Claim 11 is "advancing the inner catheter out of a front end opening of the outer catheter along the guide wire into the branch vein." As evidence of infringement, NLC first relies on testimony by St. Jude's technical expert that it "is desirable" to advance the inner catheter into a branch vein. But such testimony does not establish that St. Jude encouraged or recommended doing so in a manner that infringes Claim 11 of the '268 Patent.

NLC also relies on the following excerpts from St. Jude's written instructions:

> 5. If desired, insert a guidewire (up to 0.035 inch (0.089 cm) diameter) through the inner catheter lumen into the branch vein.
>
> 6. If desired, advance the outer guide catheter over the inner catheter into the branch vein.

However, neither of these instructions describes 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. To the contrary, as addressed above, St. Jude's written instructions describe advancing the inner catheter into a branch vein *before* the *optional* insertion of a guidewire.[5] And St. Jude's instructions clearly involve advancing "the outer guide catheter" into the branch vein, *not* advancing the

[5] Indeed, St. Jude's sixth step describes optionally advancing the outer catheter "over the inner catheter into the branch vein," which suggests that the inner catheter has previously been advanced into the branch vein.

inner catheter into the branch vein as required by the third step of Claim 11. Moreover, 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." As such, 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.[6] Instead, these steps are merely described as steps that St. Jude's products are capable of performing. This type of circumstantial evidence is insufficient to prove infringement. *See Toshiba Corp.*, 681 F.3d at 1365 (distinguishing user manuals that "simply described" how to perform an infringing method from instructions that affirmatively "recommended" doing so).

For these reasons, NLC's evidence does not establish that St. Jude instructed customers to perform the third step of the Claim 11 method.

4. Step 4

The fourth step of Claim 11 is "inserting the lead through the outer and inner catheters to a target location in the branch vein." According to NLC, St. Jude directs

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[6] NLC contends that "the only reason to use a .035 guide wire is to advance the inner catheter into the branch vein" and that "when a physician advances the outer catheter into the branch vein . . . the inner catheter and the outer catheter are manipulated in a telescoping fashion that includes advancing the inner catheter into the branch vein." But 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. Significantly, "instructions that require one to look outside the label to understand the alleged implicit encouragement [to infringe] do not, without more, induce infringement." *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1369 (Fed. Cir. 2017) (internal quotation marks omitted). Moreover, St. Jude's instructions do not *recommend* use of a .035-inch guidewire. The instructions merely indicate that, *if* a guidewire is used, the guidewire can be "up to 0.035 inch (0.089 cm) diameter" in size.

users to perform this step of the patented method in the eighth step of St. Jude's written instructions, which provides: "Introduce the lead through the inner catheter and into position in the branch vein. If desired, an over-the-wire technique may be used." Although this step of St. Jude's instructions indicates that use of an over-the-wire technique is optional, an over-the-wire technique is not required by the fourth step of Claim 11. As such, St. Jude's written instructions direct users to insert a lead through the outer and inner catheters to a target location in the branch vein, which is all that is required by the fourth step of Claim 11.

5. Step 5

The fifth step of Claim 11 is "withdrawing the catheter leaving the lead in the branch vein." Because 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. St. Jude's written instructions, however, describe *only* the removal of the inner catheter. NLC cites no evidence that St. Jude instructs, encourages, or recommends removing both the inner catheter and the outer catheter simultaneously.[7] Therefore, NLC's evidence does not establish that St. Jude instructed customers to perform the fifth step of the Claim 11 method.

The Court is mindful that a patentee may prove induced infringement with circumstantial evidence "that the accused inducer promoted the infringing use with

[7] To the contrary, the record includes the following testimony from St. Jude's technical expert, Dr. Benditt, about removing the inner and outer catheter simultaneously: "[N]obody does that. Well, nobody that I know of does that. Too hazardous to remove them in one step."

knowledge that such use directly infringes the patent claims." *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347, 1352 (Fed. Cir. 2020). But when, as here, an alleged infringer's instruction manuals do not "teach all of the steps of the claimed method together, much less in the required order," a patentee's circumstantial evidence of infringement "requires too speculative a leap to conclude that any customer actually performed the claimed method." *E-Pass Techs., Inc. v. 3Com Corp*, 473 F.3d 1213, 1222 (Fed. Cir. 2007) (affirming summary judgment of noninfringement). Such is the case here. St. Jude's written instructions do not precisely describe all of the steps of the claimed method. The instructions do not describe those steps in the order required by the patented method. And the instructions do not affirmatively recommend each step of the patented method because some of the required steps are characterized as optional. As such, the leap required to conclude from NLC's circumstantial evidence that any of St. Jude's customers actually performed the patented method is too speculative. *See id.*

In summary, NLC's evidence does not demonstrate that St. Jude instructed, encouraged, or recommended the performance of each of the five steps of the patented method, either in the order listed in Claim 11 of the '268 Patent or otherwise. Accordingly, the record contains insufficient evidence of direct infringement—a necessary element of NLC's induced-infringement claim.

B. Knowledge and Intent

In addition to proof that direct infringement occurred, an induced-infringement claim requires the defendant to know that the induced acts result in patent infringement.

Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 765–66 (2011). A plaintiff also must establish that it was the defendant's specific intent to encourage another's infringement. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006). Here, the parties' dispute primarily pertains to whether NLC has presented evidence that St. Jude specifically intended to encourage infringement of Claim 11.

NLC relies exclusively on St. Jude's written product instructions as circumstantial evidence of St. Jude's alleged intent to induce infringement. When evaluating whether product instructions evince the requisite intent to induce infringement, "[t]he focus is not on whether the instructions describe the mode of infringement, but rather on whether the instructions teach an infringing use of the device such that [the court is] willing to infer from those instructions an affirmative intent to infringe the patent." *HZNP Meds. LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 701 (Fed. Cir. 2019) (internal quotation marks omitted). Thus, when a plaintiff attempts to prove intent through a product label or instruction manual, courts must examine whether the instruction "encourages, recommends, or promotes infringement," because "[m]erely describing the infringing use, or knowing of the possibility of infringement, will not suffice." *Id.* at 701–02 (internal quotation marks and alterations omitted). In particular, when product instructions describe an infringing step but make clear that such step is optional, the instructions are insufficient to demonstrate an intent to encourage infringement. *See, e.g.*, *id.* at 702 (concluding that defendant's product instructions did "not encourage infringement" when they described as optional certain steps in the patented method).

As addressed above, St. Jude's written instructions do not encourage, recommend, or promote infringement for at least three reasons. First, St. Jude's instructions substantively differ from steps of the patented method in several ways, including the absence of any direction to insert or withdraw the inner and outer catheters simultaneously and the absence of any direction to advance an inner catheter out the front end of an outer catheter along a guidewire. Second, even if St. Jude's written instructions accurately described every step of the patented method, there is no evidence that St. Jude has instructed its customers to perform those steps in the precise order listed in Claim 11 of the '268 Patent. Third, several steps in St. Jude's written instructions are optional, which a physician may perform "[i]f desired." A patentee cannot demonstrate that a defendant specifically intended to induce infringement based solely on a defendant's instructions if those instructions expressly describe as optional the performance of a step that is necessary to infringe the patented method. *See id.* (affirming summary judgment of noninfringement because product instructions, which described steps of the patented method as optional, did not demonstrate that defendant intended to "encourage infringement"). Nor does such evidence create a material dispute of fact as to the intent element, even if the defendant has actual knowledge that some users of its product might be infringing the plaintiff's patent. *Id.*

In summary, to succeed on a claim of indirect infringement by inducement, NLC must prove both direct infringement by at least one person *and* that St. Jude knowingly induced infringement and possessed specific intent to encourage another's infringement.

As addressed above, NLC has failed to present evidence to support either of these two essential elements of its patent-infringement claim. Accordingly, NLC's motion for summary judgment of infringement is denied and St. Jude's motion for summary judgment of non-infringement is granted.

II. Invalidity and Damages

In the alternative, NLC argues that it is entitled to summary judgment on St. Jude's two invalidity defenses. Also, the parties dispute the scope of damages that NLC is entitled to recover. In light of the Court's conclusion that St. Jude is entitled to summary judgment of non-infringement, the Court declines to address these alternative arguments.

ORDER

Based on the foregoing analysis and all the files, records and proceedings herein, **IT IS HEREBY ORDERED**:

1. Plaintiff Niazi Licensing Corporation's motion for summary judgment, (Dkt. 180), is **DENIED**.

2. Defendant St. Jude Medical S.C., Inc.'s motion for summary judgment, (Dkt. 184), is **GRANTED**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: March 23, 2021

s/Wilhelmina M. Wright
Wilhelmina M. Wright
United States District Judge

Exhibit A

US006638268B2

(12) **United States Patent**
Niazi

(10) **Patent No.: US 6,638,268 B2**
(45) **Date of Patent: Oct. 28, 2003**

(54) **CATHETER TO CANNULATE THE CORONARY SINUS**

(76) Inventor: **Imran K. Niazi**, 9080 Upper River Rd., River Hills, WI (US) 53217

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 150 days.

(21) Appl. No.: **09/828,502**

(22) Filed: **Apr. 6, 2001**

(65) **Prior Publication Data**

US 2001/0052345 A1 Dec. 20, 2001

Related U.S. Application Data

(60) Provisional application No. 60/195,701, filed on Apr. 7, 2000.

(51) **Int. Cl.**[7] **A61M 25/098**

(52) **U.S. Cl.** **604/528**; 604/528; 604/523; 604/530; 604/164.01; 604/264; 604/96.01

(58) **Field of Search** 604/528, 523, 604/164.01, 530, 264, 266, 96.01, 93.01, 95.01

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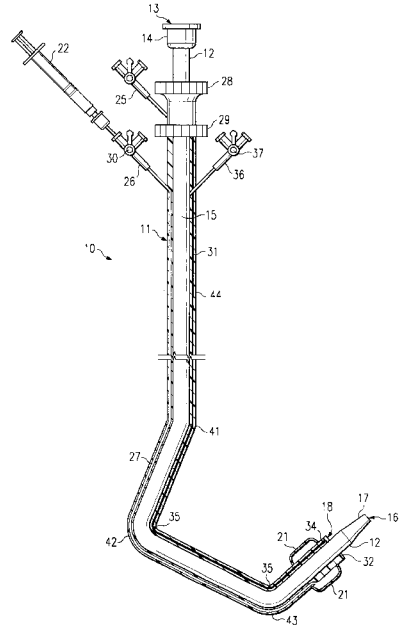
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Primary Examiner—Ira S. Lazarus
Assistant Examiner—Tu Cam Nguyen
(74) *Attorney, Agent, or Firm*—Philip G. Meyers

(57) **ABSTRACT**

A double catheter includes an outer, resilient catheter having shape memory and a hook-shaped distal end, 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 preferably having an internal lumen suitable for the introduction of contrast media, and a mechanism operable from the proximal end of the outer catheter for changing the curvature of the hook shaped distal end of the outer catheter. Such a catheter of the invention can cannulate the coronary sinus without significant manipulation.

27 Claims, 5 Drawing Sheets



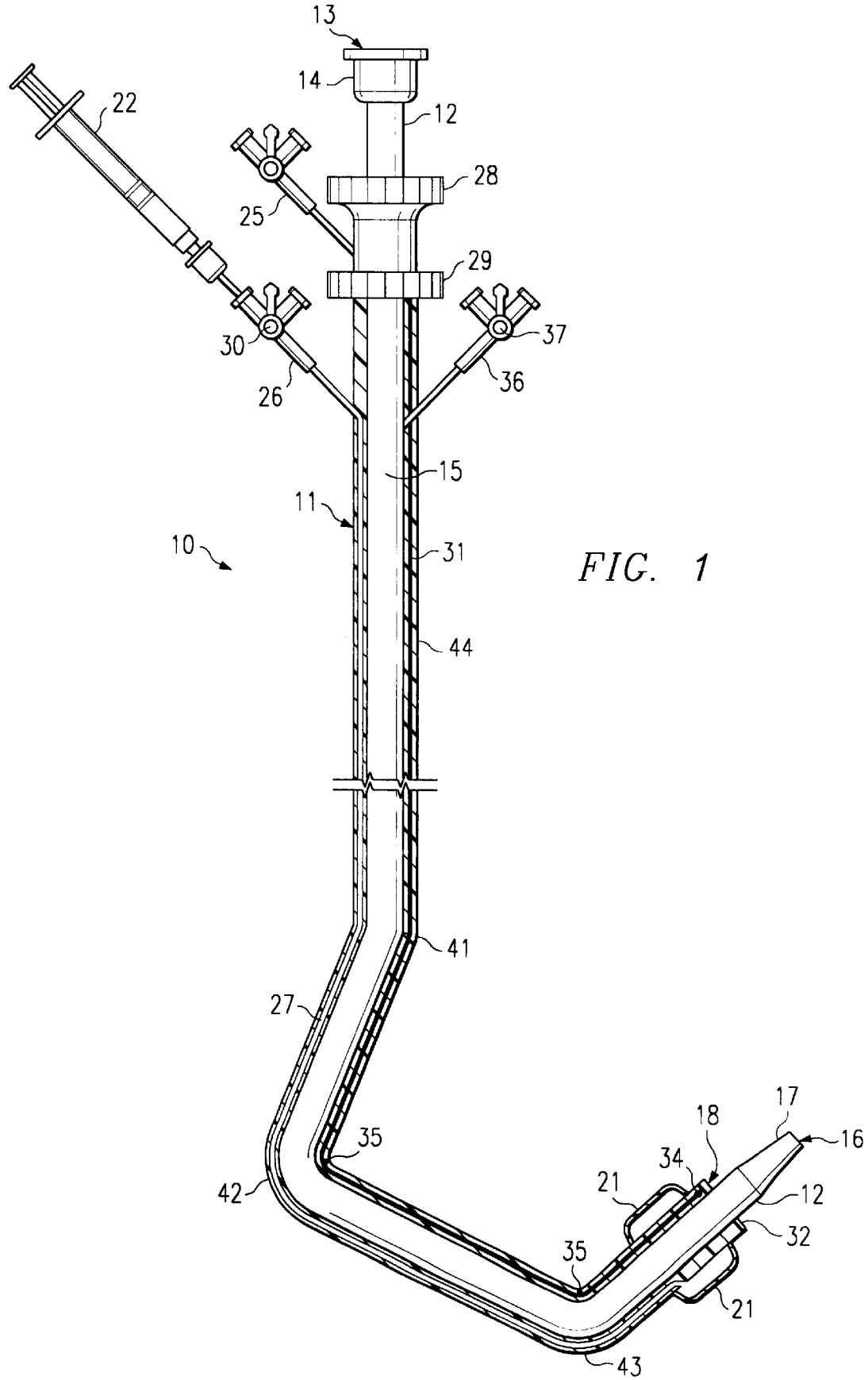

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FIG. 1

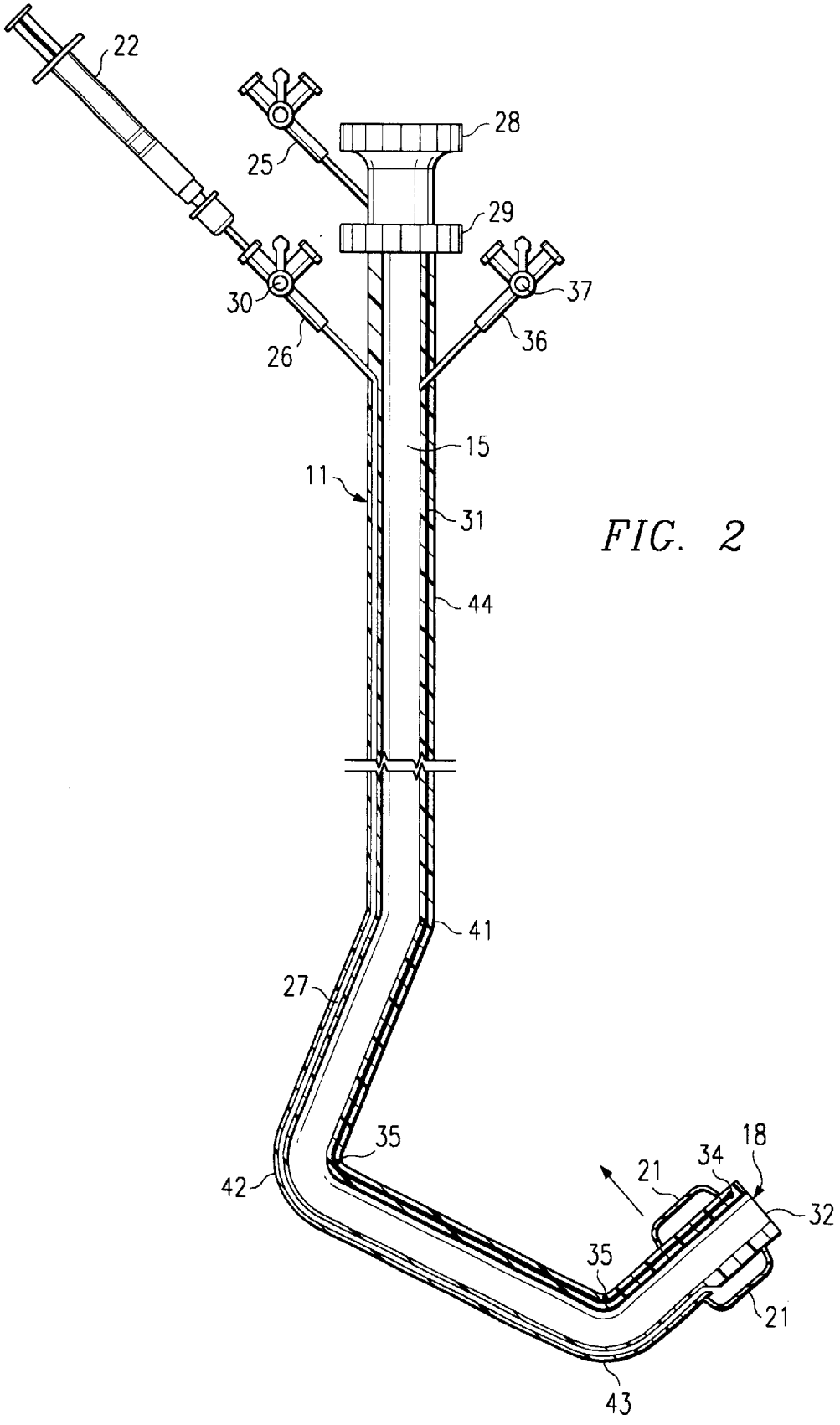


FIG. 2

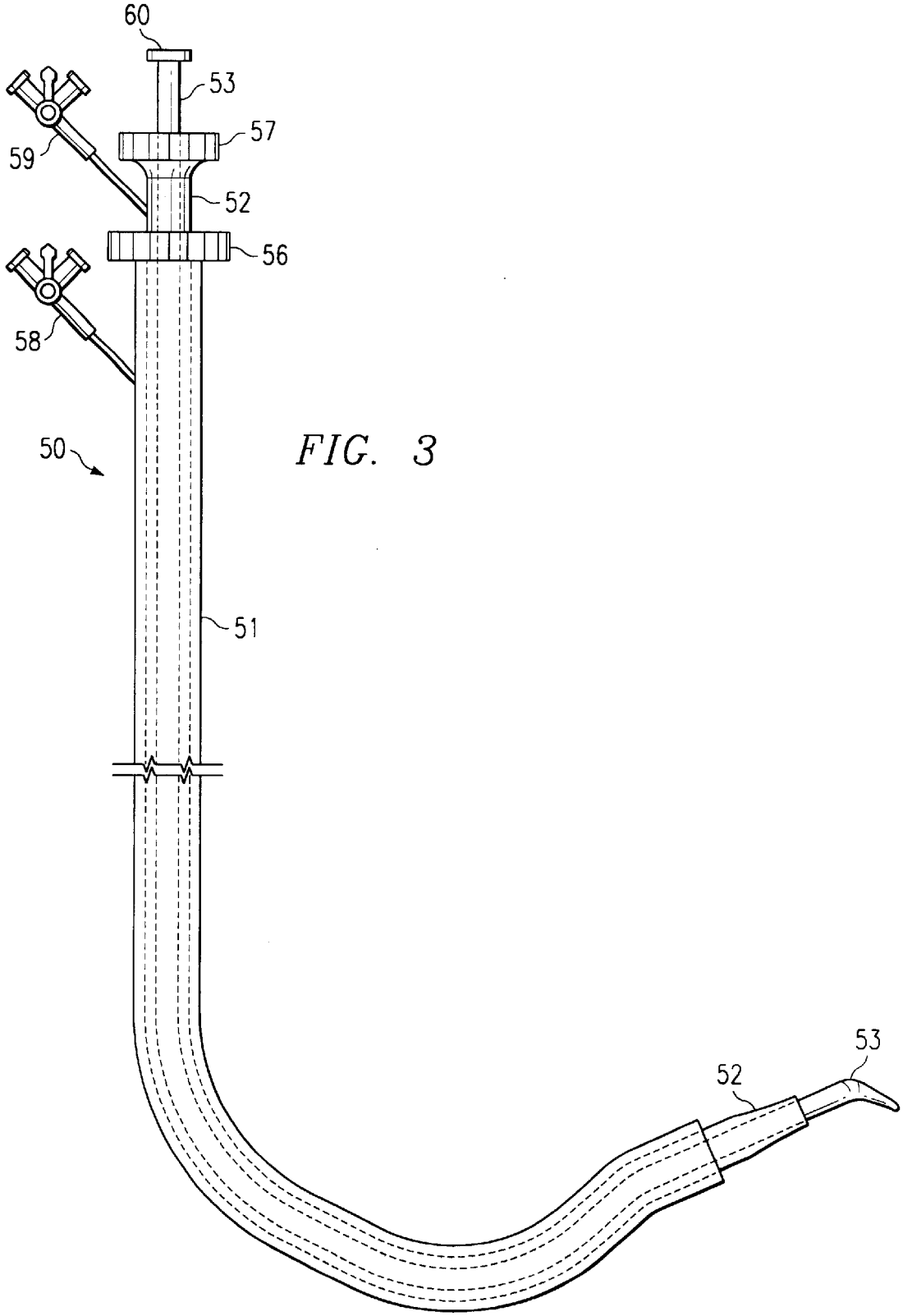


FIG. 3

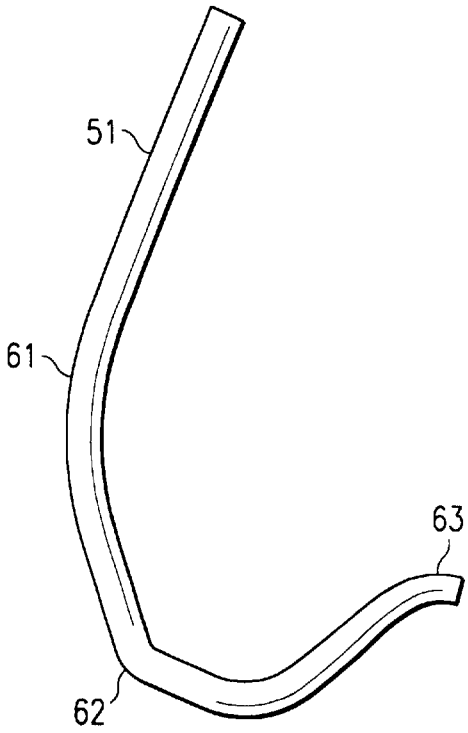


FIG. 4

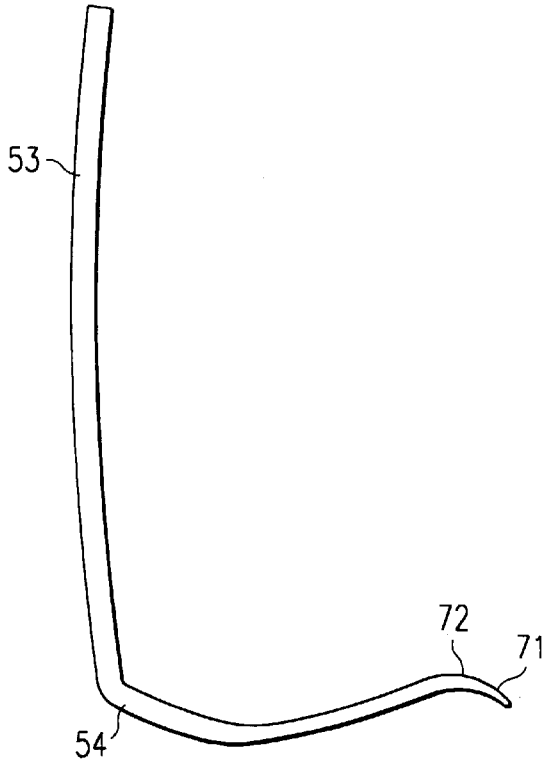


FIG. 5

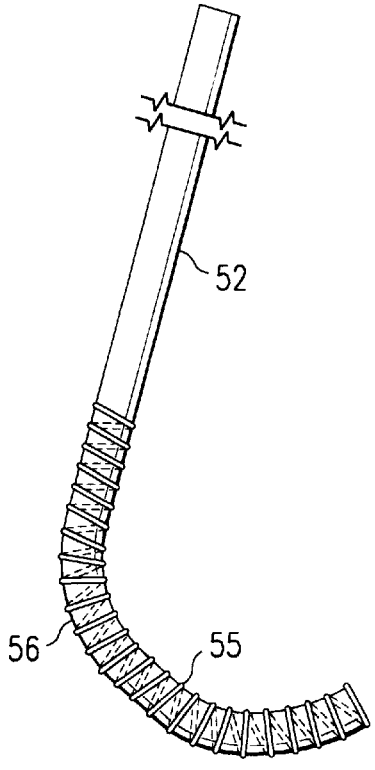


FIG. 6

FIG. 7

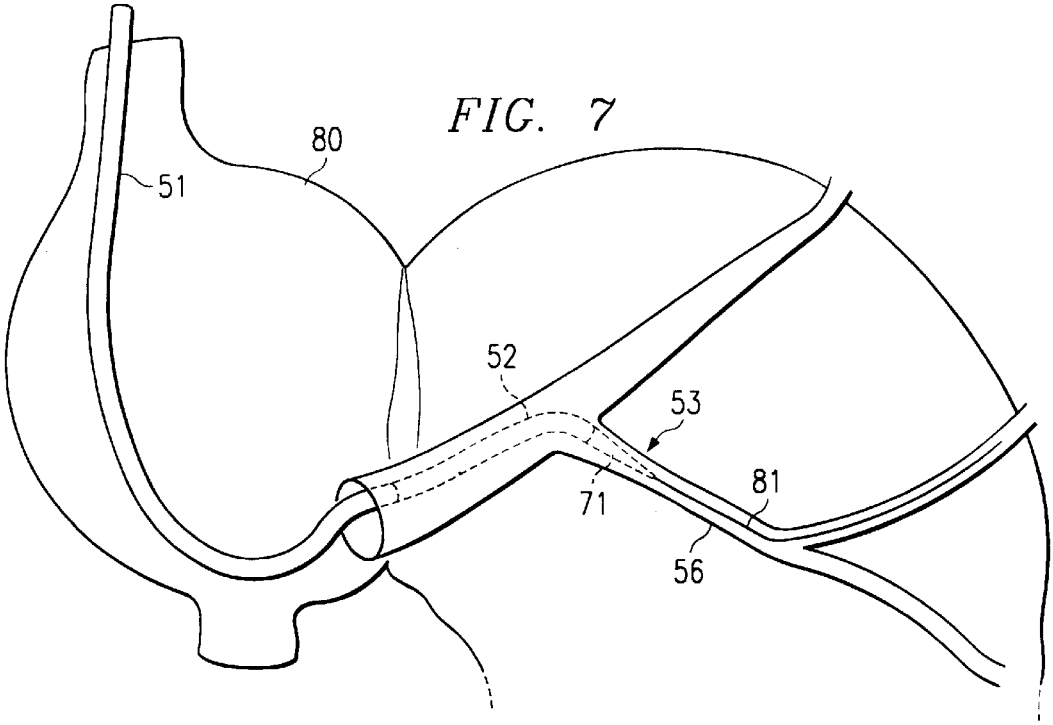
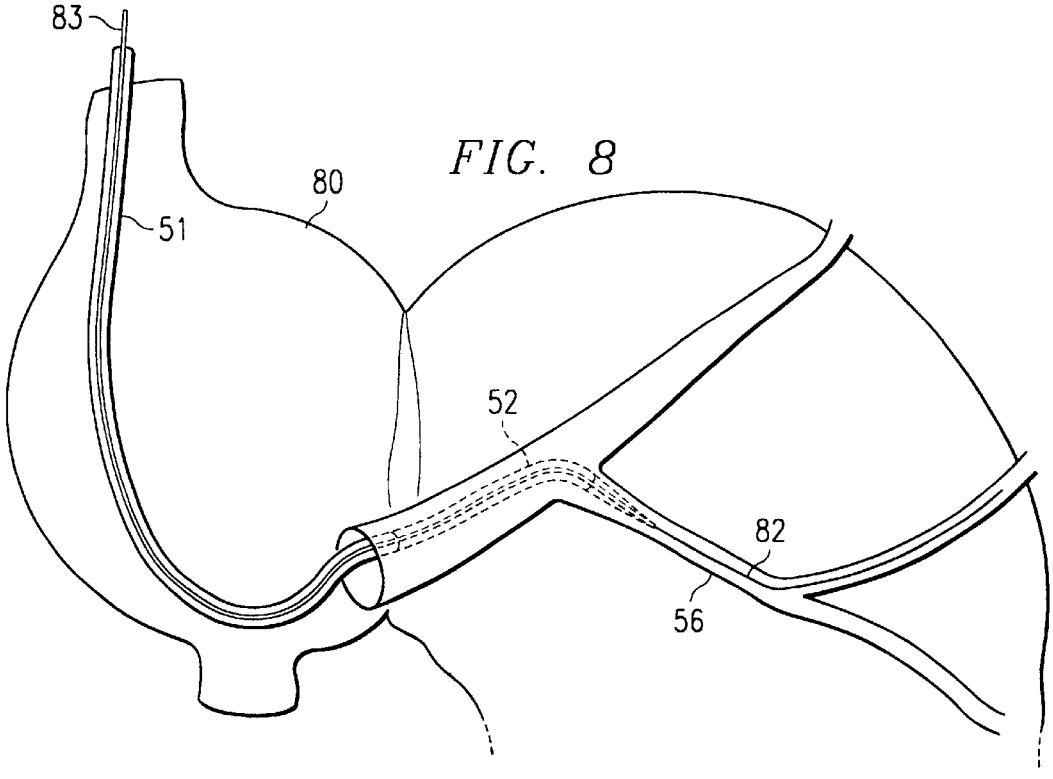


FIG. 8



CATHETER TO CANNULATE THE CORONARY SINUS

This application claims priority of U.S. Provisional Application No. 60/195,701, filed Apr. 7, 2000.

FIELD OF THE INVENTION

This invention relates to medical devices, particularly to catheters of the type used to cannulate the coronary sinus.

BACKGROUND OF THE INVENTION

The coronary sinus is a venous structure that is three to four centimeters in length and one centimeter in diameter. It forms a part of the venous drainage of the heart. The coronary sinus arises from the posterior inferior aspect of the right atrium and courses over the posterior surface of the heart, ending in the great cardiac vein. It is the final common venous drainage of most of the heart.

Cannulation of the coronary sinus has until recently not been considered important from a medical viewpoint. Medical researchers have cannulated the coronary sinus in animals and in humans to obtain information about the functioning of the heart. Cardiac surgeons will, during cardiac surgery, cannulate the coronary sinus for retrograde cardioplegia. However, routine cannulation of the coronary sinus is not performed when there is no therapeutic advantage to performing coronary sinus angiography.

It has recently become apparent that the coronary sinus and its branches can be used to place catheters (fine pacing catheters) on the epicardium of the left ventricle. The left ventricle can then be paced via these catheters. Preliminary studies show that pacing the left ventricle produces significant benefit in patients with heart failure, especially those with conduction disturbances. Therefore, studies are underway to study the coronary sinus anatomy and place the pacing catheters in the appropriate branch of the coronary sinus. Unlike for coronary arterial circulation, which has been well studied because of its therapeutic benefit, there are no presently available preformed catheters that will slip easily into the coronary sinus. U.S. Pat. No. 5,423,772 exemplifies one proposed device designed for use in the coronary sinus wherein the catheter has a double curve.

Congestive heart failure is one of the commonest diagnoses leading to hospital admission in the United States. There are 2 to 5 million patients diagnosed with CHF in the U.S. annually, and 15 million worldwide. Treatment of heart failure consists of medications, and cardiac transplantation in severe cases. Other forms of surgery, e.g. valve surgery, are also sometimes helpful. Attention has recently focused on resynchronization therapy. About 30–50% of people with severe CHF have asynchronous contraction of the cardiac chambers. This can be corrected by pacing the right atrium, the right ventricle and the left ventricle at optimal intervals to provide synchrony. Leads to pace the right atrium and right ventricle have been used for years. Recently, leads have been devised to pace the left ventricle by passing the lead through the coronary sinus into a branch vein that overlies the left ventricle. Delivery systems to guide the leads into the appropriate branch veins are now being researched.

Currently available catheters and catheter systems have several disadvantages which render lead delivery difficult. For example, the anatomy of the right atrium and the coronary sinus origin is different in patients with congestive heart failure than in patients with normal sized hearts. These differences in part form the basis for the design of the delivery system of the present invention. Such differences include that the os of the coronary sinus lies higher in the right atrium in such persons than in normal persons. The eustachian ridge is unusually prominent, and the right atrium is usually larger than normal. Subeustachian fossae are more well developed in the large right atria. There is great variation in the size of the coronary sinus and its shape and direction, and the target coronary branch veins arise at acute angles from the main coronary sinus in many patients. This renders it difficult to pass a lead into these branches. Venous valves obstruct the passage of the lead. These are variably placed, frequently close to the origin of the coronary veins. The present invention provides a catheter especially adapted for use in the coronary sinus, especially in patients suffering from congestive heart failure.

SUMMARY OF THE INVENTION

A double catheter according to one aspect of the invention includes an outer, resilient catheter having shape memory and a hook-shaped distal end configured for cannulation of the coronary sinus, 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 preferably having an internal lumen suitable for the introduction of a fluid, such as contrast media, into the coronary sinus and also for passage of a pacing lead, and a mechanism operable from the proximal end of the outer catheter for changing the curvature of the hook shaped distal end of the outer catheter. Such a catheter of the invention can cannulate the coronary sinus without significant manipulation, enable an angiogram of the coronary sinus by means of an occlusive balloon which includes the proximal coronary sinus at the time of contrast media injection, serve as a conduit for the passage of a fine coronary sinus pacing lead (5 French in diameter), provide backup support for introducing this lead over a guide wire into the distal branches, and minimize the steps necessary for the placement of a coronary sinus lead, thereby allowing rapid introduction of such a lead.

The invention further provides a method of using a catheter to place a pacing lead in a transverse branch of the coronary sinus in order to treat a related condition such as congestive heart failure. Such a method for placing an electrical lead in a lateral branch of a coronary sinus vein using a double catheter includes the steps of 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. If necessary, the curvature of the double catheter can be adjusted in order to enter the coronary sinus. These and other aspects of the invention are discussed in the detailed description that follows.

BRIEF DESCRIPTION OF THE DRAWING

In the accompanying drawing, wherein like numeral denote like elements:

FIG. **1** is a side view of a double catheter of the invention;

FIG. **2** is a side view of the outer catheter of FIG. **1**;

FIG. **3** is a side view a second embodiment of a catheter according to the invention;

FIGS. **4** and **5** are diagrams illustrating preferred shapes for the outer guide and obturator of FIG. **3**;

FIG. **6** is a diagram illustrating an alternative inner catheter for use in the embodiment of FIG. **3**; and

FIGS. **7** and **8** are diagrams illustrating use of the catheter of FIG. **3** a method of introducing a pacing lead according to the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

FIGS. **1** and **2** illustrate a double catheter **10** according to the invention having a typical length of 60 cm. An outer catheter **11** is made of a braided silastic or similar material to allow torque control and stiffness. An inner catheter **12**, which slides in and out of outer catheter **11**, is constructed of a more pliable, soft material such as silicone. The combination of outer and inner catheters **11**, **12** provides a number of advantages, including variability in the reach of the catheter, and outer catheter stiffness necessary for manipulation along with inner catheter softness, which permits safe cannulation of the coronary sinus and advancement of catheter **11** into the distal coronary sinus for purposes of support. It also allows the inner catheter **12** to conform to the torturous course of a coronary sinus.

Inner catheter **12** fits into lumen **15** of outer catheter **11**, and is preferably coated with a hydrophilic lubricious material which allows catheter **12** to slide in and out of outer catheter **11** with ease. A proximal end **13** of inner catheter **12** terminates in a hemostatic valve **14** having an adjustable diaphragm. Valve **14** prevents leakage of blood when a 5 French pacing lead is introduced through inner catheter **12** into the coronary system. Preferably, a distal end **16** of inner catheter **12** has a tip **17**, for example, about 1 cm long, made of a material softer than the remainder of inner catheter **12**. This may, for example, be accomplished by making tip **17** thinner than the remainder of catheter **12**, or by making a bilayered inner catheter **12** wherein the one layer extends further than the other to form the tip and optionally is made of a material softer than that of the other layer.

Outer catheter **11** has several functions. Because of its stiffness and torque, it can be manipulated in the right atrium to allow cannulation of the coronary sinus. Such stiffness also lends support to the pacing lead as it is introduced into the distal coronary sinus. A distal end **18** of outer catheter **11** has an external inflatable cuff or balloon **21**. Balloon **21** can be inflated with air by means of a syringe **22** connected to balloon **21** as described below. Inflation of balloon **21** allows occlusion of the proximal coronary sinus, which is necessary for obtaining a coronary sinus angiogram.

The proximal end of outer catheter **11** has several features. A port **26** including a shutoff valve **30** is provided for introduction of air into balloon **21**. This port **26** is connected by means of a passage **27** in the wall of catheter **11** with the distal balloon **21**. A torque coupling **28** of a type known in the art may be tightened down on inner catheter **12** to prevent it from moving within outer catheter **11**. A torque screw **29** is attached to a cable or wire **31** that runs in the wall of outer catheter **11** and may be wound over one or more small rounded corners or small pulleys **35** set in the wall of catheter **11**. This cable **31** is anchored, as by embedding a enlarged end thereof, at a point **34** close to a tip **32** of outer catheter **11**. Rotation of torque screw **29** causes cable **31** to be retracted, which changes the shape of the outer catheter **11** (making the hooked shape more pronounced as shown by the arrow) and counter-rotation does the opposite. Torque screw **29** may, for example, comprise a spool or reel having an external circumferential groove on which cable **31** is attached and is wound or unwound as needed. A port **36** with an associated shutoff valve **37** is provided through the wall of outer catheter **11** for delivering a saline flush through lumen **15**.

For optimum deployment in the coronary sinus, inner and outer catheters **11**, **12** preferably have a predetermined shape and a certain degree of stiffiess to maintain such shape during manipulation in the heart, but still flexible enough to bend when required. As shown in FIG. **2**, the hook-shaped distal end of outer catheter **11** may comprise substantially straight segments spanning three bends **41**, **42** and **43**. First bend **41** adjoining a straight, proximal portion **44** of outer catheter **11** is in the range of about 130° to 180°, especially 130° to 175°. Second, intermediate bend **42** extends in a direction opposite bend **41** and is in the range of about 75° to 100°. Third bend **43** near the distal end of outer catheter **11** extends in the same direction as bend **42** and is in the range of about 130° to 175°. These ranges refer to the angle formed by the straight segments adjacent each bend when the catheter is in an undistorted state. Operation of the deflection device to tighten the cable will reduce these angles, especially for second bend **42**. The material of which outer catheter **11** is made, e.g. silastic, has sufficient shape memory to return to its original shape when undistorted. The undistorted shape of outer catheter **11** can be varied and catheter **10** thereby made in several sizes to accommodate different heart sizes. For example, for a normal size atria with a prominent Eustachian valve, outer catheter **11** may be substantially J-shaped with no first bend (bend **41**=180°), whereas for large atria with a prominent Eustachian valve, it may be useful to make catheter **11** more in a question mark shape (shown inverted in FIGS. **1–2**).

Coronary sinus catheter **10** may be deployed in the following fashion. Distal balloon **21** is deflated, inner catheter **12** is withdrawn completely into outer catheter **11**, and catheter **10** is inserted through a venous sheath introduced in the left XX subclavian vein. It is guided into the right atrium over a guide wire, and the guide wire and sheath are then removed. Catheter **10** is rotated until tip **17** lies within the tricuspid valve, then advanced until tip **17** is seen to lie in the inferior-most portion of the tricuspid valve. If the reach of catheter **10** in this configuration is not sufficient to cannulate the tricuspid valve, then inner catheter **12** is advanced out of outer catheter **11** to make the entire system longer.

Subsequent manipulation is carried out in a left anterior fluoroscopic view. Counterclockwise torque is exerted on catheter **10**. At the same time, inner catheter **12** is gradually withdrawn. Eventually, catheter **10** slips over the tricuspid annulus and, because of the counterclockwise torque, twists and pops into the proximal coronary sinus. In some instances, it may come to lie at the mouth of the proximal coronary sinus. 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. Distal balloon **21** on outer catheter **11** is inflated using syringe **22** to occlude the proximal coronary sinus. Contrast medium is injected via a port **25** through the lumen of inner catheter **12** to obtain a coronary sinus angiogram. Port **36** is then hooked up to a saline flush. A coronary sinus lead is introduced through a hemostasis valve **14** into inner catheter **12**. It is positioned using a guide wire in an appropriate branch of the coronary sinus.

A triple catheter **50** according to the invention is designed to overcome the obstacles described above that are encountered with congestive heart failure patients and further provide a more economical catheter system that does not rely on specialized miniature adjustment mechanisms. The

system includes an outer guide catheter **51**, an inner guide catheter **52** nested therein, an obturator **53** nested inside the inner guide **52**. In 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. In this respect, it can resemble an angioplasty guiding catheter. The shape of outer guiding catheter **51** is similar, but not identical, to a left amplatz curve. The proximal end terminates in an screw-adjusted hemostatic valve **56**, to allow introduction of leads or wires of different diameters without leakage of blood. There is also a side-port **58**, preferably with a 3-way valve, to allow injection of contrast medium and saline.

Inner guiding catheter **52** made of a soft, pliable material such as silicone, and in this example is 2.6 mm in outer diameter and 2.3 mm in inner diameter. It has no longitudinal braiding, which makes it extremely flexible and able to conform to various shapes. Inner catheter **52** is designed to advance over a guide wire into a side branch of the coronary sinus, in conjunction with the obturator **53**. Its 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. Inner guide **52** is longer than outer guide **51**, e.g., 68 cm in length. The proximal end of guide **52** has a hemostasis valve **57** to prevent back bleeding and a side port **59** to permit contrast medium injection.

Obturator **53** is preferably made of very pliable silicone, and has a central lumen that will accommodate an 0.038 inch guide wire. Obturator **53** fits into inner guide **52**, and in one embodiment is 70 mm long, 2.1 mm in outer diameter tapering to 1.25 mm diameter at its tip. In use, obturator **53** tracks over a 0.038" guide wire **81** into a targeted side branch **56**, in concert with the inner guide catheter **52**. A tapered tip **71** of obturator **53** may protrude from the front end opening of inner catheter **52**. Without such a protruding tip **71**, the edge of inner catheter **52** might catch on venous valves or sharp angles. The terminal 7 mm of obturator **53** may have a bend **72** therein of up to about 30 degrees, i.e., defining an angle from 150–180 degrees. This allows tip **71** to function as a guiding device for the 0.038" guide wire **81**, which can then be directed into acutely angled side branches. The proximal end of obturator **53** terminates in a standard port **60** allowing attachment of a 10 cc syringe.

Referring to FIGS. **7** and **8**, outer guiding catheter **51** is initially connected to a syringe and pressure monitoring system and then inserted into the right atrium **80**. The physician attempts to use it to cannulate the coronary sinus without the use of the other components. If this succeeds, an 0.038" hydrophillic-coated guide wire **81** is advanced through it, and used to cannulate the target lateral coronary sinus side-branch **56**. (If the side branch **56** cannot be easily cannulated, the angled obturator **53** can be extended and used to direct the guide wire **81** as illustrated in FIG. **7**.) The inner guide **52**, with obturator **53** inside, is then passed through outer guide **52** over the 0.038" wire into the target side branch **56**. Obturator **53** is then withdrawn, and an electrical lead **83** is then advanced through the catheter over a 0.014" guide wire **82** to its final resting place in the target branch **56**, and ultimately connected to a pacemaker after the catheter is withdrawn in order to apply electrical heart stimulation to that location. Guide wire **82** is only used if needed; it may be possible to place lead **83** without it.

An advantage of this three-part system is that it allows a standard lead (not an over-the-wire design) to be positioned in a transverse branch **56** which has a relatively sharp angulation at its origin from the main coronary sinus. Although not deflectable using an screw adjustment mechanism as described above in connection with the first embodiment, this embodiment can nevertheless be used to cannulate the coronary sinus whether the latter is placed normally, higher than normal, or lower than normal. The angle of outer guide **51** can be changed by inserting or withdrawing the inner guide **52**. Inserting inner guide **52** without obturator **53** before cannulation straightens outer guide **51**, i.e., makes the angle of the outer guide **51** shallower, allowing engagement of a lower origin of the coronary sinus. Inserting both obturator **53** and inner guide **52** makes the outer guide angle even shallower. Thus, the outer guide alone, the outer guide plus inner guide, and outer guide plus inner guide plus obturator can be used as needed to cannulate coronary sinuses of varying heights of origin.

This three-part telescoping embodiment thus eliminates the need for a cable system to change the curvature of the catheter during manipulation As shown in FIG. **4**, outer guide catheter **51** preferably has three bends in a manner similar to outer catheter **11**, with the first or proximal bend **61** ranging from about 150–180 degrees, the second (middle) bend **62** ranging from about 120–180 degrees, and the third proximal bend from 90 to 160 degrees in a direction opposite to that of the other two bends, as shown. Inner guide catheter **51** preferably has three bends in a manner similar to the outer catheter **11**, with the first or proximal bend **61** ranging from about 150–180 degrees, the second (middle) bend **62** ranging from about 120–180 degrees, and the third proximal bend **63** from 90 to 160 degrees in a direction opposite to that of the other two bends, as shown. In one preferred form, outer guide **51** is 9 French diameter, 60 cm length, inner guide **52** is made of a soft material 8 French diameter, 68 cm length, and obturator **53** is 5 French diameter, 75 cm length.

Referring to FIG. **5**, obturator **53** stiffens and shapes inner guide **52** when inside of it. It may be pre-formed with a right angle bend **54** as shown to conform more easily to the shape of outer guide **51**, but this is not essential. However, tip **71** of obturator is **53** bent to an angle in the range of about 150–180 degrees to better aid in introducing a lead into a transverse vein as described above. Obturator **53** preferably tapers to a blunt point having a small opening therein just large enough to admit the largest size guide wire to be used in the procedure, in this example, 0.038 inch.

In an alternative version of catheter **50**, the radial strength of the inner guide or catheter **52** prevents its collapse when obturator **53** is withdrawn. For this purpose, as shown in FIG. **6**, a bend **56** in inner guide **52** is reinforced with a helical wire coil **55** that is embedded therein, or a series of spaced wire rings or hoops. These hoop reinforcements prevent inner guide **52** from collapsing during withdrawal of obturator **53** but do not prevent inner guide **52** from bending in a flexible manner.

The claims which follow define certain aspects of the invention but do not limit the invention. It will be evident, for example, that a catheter according to the invention can be used to reach other hard to access parts of the human body, both in the heart and elsewhere, due to its unique structure.

What is claimed is:

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.

2. The double catheter of claim **1**, wherein the mechanism for changing the curvature of the hook shaped distal end further comprises an obturator slidably disposed inside of the inner catheter, wherein the obturator is configured to reduce the curvature of the hook shaped distal end when inserted in the inner catheter.

3. The double catheter of claim **1**, further comprising a balloon mounted on the outside of the distal end of the outer catheter positioned for occlusion of the proximal coronary sinus, and a conduit permitting inflation of the balloon at the proximal end of the outer catheter.

4. A double catheter, comprising:

an outer, resilient catheter having shape memory and a hook-shaped distal end 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 suitable for the introduction of a fluid therethrough; and

a mechanism operable from the proximal end of the outer catheter for changing the curvature of the distal end of the outer catheter, wherein the mechanism for changing the curvature of the hook shaped distal end comprises a cable anchored to the outer catheter at a point proximate the distal end of the outer catheter and at a point proximate the proximal end of the outer catheter, whereby shortening of the cable from the point proximate the proximal end of the outer catheter results in increased curvature of the hook shaped distal end.

5. The double catheter of claim **4**, wherein the cable runs inside a wall of the outer catheter.

6. The double catheter of claim **1**, further comprising a mechanism operable from a proximal end of the outer catheter for securing the inner catheter against sliding movement relative to the outer catheter.

7. The double catheter of claim **6**, further comprising a port for introducing a fluid into a space between the inner and outer catheters.

8. The double catheter of claim **1**, wherein the hook-shaped distal end comprises substantially straight segments spanning three bends.

9. The double catheter of claim **8**, wherein a first bend adjoining a straight, proximal portion of the outer catheter is in the range of 130° to 175°, a second, intermediate bend is in the range of 75° to 100°, and a third bend nearest the distal end of the outer catheter is in the range of to 130° to 175°.

10. The double catheter of claim **1**, wherein the mechanism for changing the curvature of the hook shaped distal end comprises a portion of the inner catheter configured to reduce the curvature of the hook shaped distal end when inserted in the outer catheter.

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.

12. The method of claim **11**, further comprising:

adjusting the curvature of the double catheter in order to enter the coronary sinus.

13. An outer catheter configured for use with an inner, pliable catheter which can be 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, the outer catheter comprising a resilient tube having shape memory and sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus, and having a hook-shaped distal end wherein a first bend adjoining a straight, proximal portion of the outer catheter is in the range of 130° to 180°, a second, intermediate bend is in the range of 75° to 100° in a direction opposite the first bend, and a third bend nearest the distal end of the outer catheter in the same direction as the second bend is in the range of to 130° to 175°.

14. The catheter of claim **13**, wherein the first bend equals 180°, rendering the outer catheter substantially J-shaped.

15. The catheter of claim **13**, wherein the first bend is in the range of 130–175°, rendering the outer catheter substantially question mark-shaped.

16. The catheter of claim **13**, wherein the outer catheter is made of a braided silastic.

17. The catheter of claim **13**, wherein the outer catheter further comprises:

an external inflatable cuff near the distal end of the outer catheter; and

means for inflation of the cuff sufficient to permit occlusion of the proximal coronary sinus.

18. A double catheter, comprising:

an outer catheter comprising a resilient tube having shape memory and sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus, and having a hook-shaped distal end wherein a first bend adjoining a straight, proximal portion of the outer catheter is in the range of 130° to 180°, a second, intermediate bend is in the range of 75° to 100° in a direction opposite the first bend, and a third bend nearest the distal end of the outer catheter in the same direction as the second bend is in the range of to 130° to 175°, and

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, wherein the inner catheter has an internal lumen suitable for the introduction of a fluid therethrough and a hemostatic valve at a proximal end thereof that prevents leakage of blood when a pacing lead is introduced through the inner catheter into the coronary system.

19. The double catheter of claim **18**, wherein the first bend equals 180°, rendering the outer catheter substantially J-shaped.

20. The double catheter of claim **18**, wherein the first bend is in the range of 130–175°, rendering the outer catheter substantially question mark-shaped.

21. The double catheter of claim **18**, wherein the outer catheter is made of a braided silastic.

22. The double catheter of claim **18**, wherein the outer catheter further comprises:

an external inflatable cuff near the distal end of the outer catheter; and

means for inflation of the cuff sufficient to permit occlusion of the proximal coronary sinus.

23. The double catheter of claim **18**, further comprising a mechanism operable from a proximal end of the outer catheter for changing the curvature of the distal end of the outer catheter.

24. A method for placing a electrical lead in a lateral branch of a coronary sinus vein using a double catheter including an outer catheter comprising a resilient tube having shape memory and sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus, and having a hook-shaped distal end, and 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 method 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.

25. The method of claim **24**, wherein a first bend adjoining a straight, proximal portion of the outer catheter is in the range of 130° to 180°, a second, intermediate bend is in the range of 75° to 100° in a direction opposite the first bend, and a third bend nearest the distal end of the outer catheter in the same direction as the second bend is in the range of to 130° to 175°.

26. The method of claim **25**, wherein the first bend equals 180°, rendering the outer catheter substantially J-shaped.

27. The method of claim **25**, wherein the first bend is in the range of 130–175°, rendering the outer catheter substantially question mark-shaped.

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Date: June 21, 2021

/s/ Michael T. Griggs

Michael T. Griggs
Adam L. Brookman
Timothy E. Newholm
Marriam Lin
Boyle Fredrickson, S.C.
840 N. Plankinton Avenue
Milwaukee, WI 53203
(414) 225-9755

Attorneys for Plaintiff-Appellant
Niazi Licensing Corporation