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

REPLY BRIEF OF PLAINTIFF-APPELLANT

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August 23, 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.

August 23, 2021

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I. The terms "pliable" and "resilient" are not indefinite

St. Jude's indefiniteness argument is based on the erroneous assertion that mathematical precision is required to satisfy the definiteness requirement of §112. This Court's controlling precedent directly rejects the exacting standard that St. Jude demands. St. Jude also attempts to manufacture indefiniteness by improperly parsing the specification and taking small portions of the disclosure out of context. However, when the claims and the specification are read in their entirety in light of the underlying specification from the vantage point of a person skilled in the art,[1] the '268 patent clearly describes the functional characteristics of the components in question and also discloses various embodiments that apprise a person having ordinary skill in the art as to the scope of the claims with "reasonable certainty."

A. The definiteness requirement of §112 does not require disclosure of durometer, Young's modulus, or some other quantitative metric relating to a "pliable" inner catheter and a "resilient" outer catheter

The definiteness requirement under §112 does not require "absolute or mathematical precision." *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017) ("'Reasonable certainty' does not require 'absolute or

[1] NLC submitted a declaration from Dr. Niazi explaining that a person having ordinary skill in the art would have been an electrophysiologist or an engineer familiar with the anatomy of the right atrium, the coronary sinus, and its branches in a normal heart, and familiar with the procedures for implanting permanent pacing leads and existing equipment used to conduct those procedures. Appx357.

mathematical precision.'") [citation omitted]; *see also Guangdong Alison Hi-Tech Co. v. Int'l Trade Comm'n*, 936 F.3d 1353, 1362 (Fed. Cir. 2019) ("In other words, in Alison's view, the '359 patent fails to disclose precisely how much resilience is enough to satisfy the claim. With this argument, Alison seeks a level of numerical precision beyond that required...").

Despite this clear precedent, St. Jude's argues that the specification fails to define "pliable" and "resilient" with mathematical precision, such as providing "extrusion durometer" or "Young's modulus" for the components at issue. *See* St. Jude Opposition, pg. 24. Acceptance of St. Jude's argument would overturn this Court's precedent and invalidate tens of thousands of patent claims. *See Guangdong* at 1362 (rejecting the very argument now presented by St. Jude).

This Court explicitly rejected the need for specifying quantitative parameters in the claims or elsewhere in *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374 (Fed. Cir. 2015), holding that the functionality and inherent parameters of the invention apprise a skilled artisan of the scope of the claim with reasonable certainty. The claim at issue in *Biosig* required live and common electrodes of a heart rate monitor to be positioned in a "spaced relationship" to one another.[2] This Court first noted that the specification did not provide any

[2] While *Biosig* and *Guangdong* involved terms of degree, which is not the case here, they nevertheless refute the notion that quantitative parameters must be disclosed to satisfy the definiteness requirement of §112.

quantitative parameters for the "spaced relationship" between the electrodes. *Biosig*, 783 F.3d at 1382 ("…the specification of the '753 patent does not specifically define 'spaced relationship' with actual parameters, e.g., that the space between the live and common electrodes is one inch…").

This Court held that the patent's recitation of the functional characteristics of the invention defined the scope of the "spaced relationship" of the electrodes. For example, the Court noted that the distance between the electrodes could not be greater than the width of a user's hands because the claim requires detection of electrical signals at two distinct points of a hand. *Id*. Conversely, the distance could not be infinitesimally small because the claim required two distinct electrodes and signals. *Id*.

Here, the specification of the '268 patent clearly describes the functional characteristics of the catheters at issue, and even includes examples of specific materials. For example, the specification explains that "[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, 5:20-24. 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 if an inner catheter is able to navigate tortuous blood vessels, it is a "pliable" inner catheter in the context of the claim. Determining whether an inner catheter is "pliable" using this simple test would be well within the ability of a person having ordinary skill in the art. Similarly, if the shape of the outer catheter can be changed by inserting and withdrawing the inner catheter, such that the outer catheter returns to its original shape when the inner catheter is withdrawn, it is a "resilient" outer catheter in the context of the claim. One having ordinary skill in the art could easily determine whether a particular catheter exhibits this characteristic using simple observation. The claims, when read in light of this disclosure, satisfy the definiteness requirement of §112 by informing a person having ordinary skill in the art the scope of the claim terms with "reasonable certainty." *See Guangdong*, 936 F.3d at 1362 (Fed. Cir. 2019) ("…we agree with Aspen that a person of ordinary skill in this field can tell when a material has zero or a negligible amount of resilience without needing a mathematical definition.") [quotations omitted].

Rather than focus on what ***is*** disclosed, viewed through the lens of a person having ordinary skill in the art, St. Jude focuses on what ***is not*** disclosed. St. Jude relies on testimony from its expert, Dr. Erdman, that the patent ***could have***

included various quantitative measurements such as Young's modulus or durometer measurements. This Court has rejected such arguments as irrelevant because the focus of an indefiniteness analysis is on what the specification discloses, as opposed to what the specification does not disclose. *BASF*, 875 F.3d at 1366 ("The mere observation of information not 'recited' does not answer the question whether a person of ordinary skill in the art would need to be given the level and measurement information to understand, with reasonable certainty, whether a composition is 'effective to catalyze' the SCR (of NOx) or AMOx reactions.").

St. Jude's flawed approach is best demonstrated in Paragraph 24 of Dr. Erdman's declaration.[3] First, Dr. Erdman provides a definition of the term "resilient:" "[r]esiliency is the ability of a material to absorb or store energy when deformed elastically (and the corresponding ability, or lack thereof, to return to the original geometric orientation when unloaded)." Appx3031. This definition mirrors the definition provided in the '268 patent: the outer catheter "has sufficient shape memory to return to its original shape when undistorted." Appx290, 4:21-23. This should be enough to end the inquiry.

[3] The district court did not cite to or otherwise overtly rely upon Dr. Erdman's declaration in rendering its decision, though St. Jude relies upon it for purposes of this appeal.

However, in the same paragraph, Dr. Erdman complains that the specification fails to offer various quantitative parameters relating to resilience, e.g., "[t]he '268 patent fails to inform one of ordinary skill in the art of how many pounds per square inch of radial pressure the catheter should withstand." *Id*. But such mathematical precision is not required to satisfy the definiteness requirement. *BASF*, 875 F.3d at 1365; *Guangdong*, 936 F.3d at 1362.

The terms "pliable" and "resilient" should be given their plain and ordinary meaning. As this Court explained in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), "[i]n some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. Dr. Erdman certainly understood the terms here.

B. St. Jude attempts to manufacture indefiniteness by parsing the specification

St. Jude parses the specification and juxtaposes snippets of disclosure, arguing that the claimed "pliable" inner catheter and "resilient" outer catheter are indefinite. For example, St. Jude argues that the term "pliable" is hopelessly ambiguous because the specification generally describes the inner catheter as "flexible" in one section and describes a specific embodiment of the inner catheter as "extremely flexible" in another. However, St. Jude cites isolated statements out

of context to manufacture confusion where none exists. Indeed, "pliable" and "extremely flexible" are used in the same paragraph to describe one embodiment of the inner catheter so that the two terms are easily understood as complementary:

> 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.

Appx291, 5:14-28. This disclosure identifies a material (silicone) and dimensions (2.6 mm outer diameter and 2.3mm inner diameter) attributable to one embodiment of a "pliable" inner catheter, thus apprising a person having ordinary skill in the art as to the scope of the "pliable" inner catheter with reasonable certainty.

St. Jude attempts to contrast this disclosure with a general statement in the specification describing both the outer and inner catheter as having a "certain degree of stiffness" but "still flexible enough to bend when required," apparently

arguing that use of the term "extremely flexible" to describe the inner catheter elsewhere in the specification somehow renders the claims indefinite. However, there is nothing inconsistent between the two passages. The longer, more detailed paragraph merely provides further description and explanation relating to a specific embodiment of a "pliable" inner catheter. The patentee should not be penalized for providing specific examples of the more general concept of pliability. To hold otherwise would discourage patentees from providing specific examples, which would tend to frustrate both the definiteness and enablement requirements.

St. Jude further attempts to obfuscate the analysis by pointing to disclosure relating to the obturator. However, disclosure relating to the obturator is irrelevant to the interpretation of a "pliable" inner catheter. The obturator is a different component with a different purpose, different functionality, and different design than the inner catheter. The fact that the obturator and the inner catheter may be made of the same material is of no moment.

St. Jude also parses the claim language, arguing that the term "resilient" and "shape memory" must have different meanings. The entire phrase recited in the claims is an "outer, resilient catheter having shape memory." This should be construed as an outer catheter that is able to return to its original shape when undistorted.

The terms "resilient" and "pliable" are used in a manner consistent with their plain and ordinary meaning in the specification and in the claims, which satisfies the definiteness requirement under §112. *Phillips*, 415 F.3d at 1314 (in some instances, the meaning of a term is readily apparent). Moreover, the specification provides additional detail, including dimensions and materials for preferred embodiments, as well as describing various functional characteristics of the inner and outer catheter. This, coupled with the skills and knowledge of a person having ordinary skill in the art, reasonably apprises a person having ordinary skill in the art as to the scope of the claims with "reasonable certainty" with respect to the inner catheter and outer catheter.

C. The district court did not rely on the extrinsic record when it rendered its indefiniteness ruling, nor was the extrinsic record "uncontested"

St. Jude asserts that the district court considered the parties' expert testimony when rendering its opinion on indefiniteness. But St. Jude fails to identify a single reference to extrinsic evidence in the district court's opinion. That is because there is none. The district court did not cite to either of the parties' expert declarations in rendering the opinion.

Moreover, St. Jude erroneously describes the Dr. Erdman's testimony as "uncontested." On the contrary, NLC submitted a declaration from the inventor of the '268 patent – Dr. Imran Niazi – explaining that a person having ordinary skill

in the art would be familiar with existing catheters that were described as "pliable" and "resilient." *See, e.g.*, Appx366 (after discussing prior art references describing catheters as "resilient" and "pliable," testifying that "[a] person having ordinary skill in the art would have been familiar with existing catheters that were used to cannulate the coronary sinus, and specifically familiar with the stiffness of those catheters.").

D. The cases cited by St. Jude do not support a finding of indefiniteness

St. Jude claims that *Application of Lechene*, 277 F.2d 173 (C.C.P.A. 1960) supports its argument, but St. Jude mischaracterizes its holding. In *Lechene*, the court considered claims for a street sweeping brush that required "stiff, resilient" fibers. However, while that opinion uses the word "indefinite," the issue on appeal was not whether the claims met the definiteness requirement of §112. Rather, the issue was whether the prior art rendered the claims invalid. The court noted that the prior art disclosed brushes with "stiff, resilient" fibers, and held that the "stiff, resilient" fiber limitation was not a distinguishing factor over the prior art. *Lechene*, 277 F.2d at 176 (noting that the distinction between the prior art fibers and the claimed fibers was "too indefinite" to allow the claims). Accordingly, *Lechene* has no bearing on the indefiniteness issue here.

St. Jude further relies on *A. Schulman, Inc. v. Polyone Corp., Inc.*, 2017 WL 2805857, at *4 (N.D. Ohio Apr. 27, 2017), *aff'd sub nom. A. Schulman, Inc. v.*

Polyone Corp., 712 F. App'x 1007 (Fed. Cir. 2018), a district court case that is factually distinguishable from the case at hand. In *Schulman*, the claims required "a DOI of 70 or greater" or "a DOI of 85 or greater." However, there were various industry standard testing protocols that would produce differing results as to DOI, and the patent did not specify which test or tests should be used. Here, the claims at issue do not claim a quantitative limitation as in *Schulman*. Thus, disclosure of an appropriate method for determining a quantitative limitation is not at issue.

St. Jude cites another district court case, *Pac. Coast Bldg. Prod., Inc. v. Certainteed Gypsum, Inc.*, 2018 WL 6268880, at *7 (N.D. Cal. Nov. 29, 2018), *aff'd*, 816 F. App'x 454 (Fed. Cir. 2020), that is factually distinguishable. In *Pac. Coast Bldg.*, which involved drywall, the patentee coined a phrase – "scored flexural strength" – that was not an industry term. For example, one claim required a "scored flexural strength" of "about 22 pounds per ½ inch thickness." The district court found that the patent did not adequately disclose a method for measuring the "scored flexural strength" of a drywall board. Similar to *Schulman*, the patentee claimed a quantitative limitation and did not adequately disclose a method by which to measure that limitation. Thus, one could not determine with reasonable certainty whether a particular product infringed the claim at issue. This is not the case here.

St. Jude generally cites to *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1363 (Fed. Cir. 2018), which held the claim term "archive exhibits minimal redundancy" to be indefinite. The phrase "minimal redundancy" is a term of degree, so the specification in that case must provide some objective criteria for measuring "minimal redundancy." This Court held that it did not and found the claim indefinite. Here, the terms "resilient" and "pliable" are not terms of degree, so the analysis of *Berkheimer* is inapplicable. In any event, the specification of the '268 patent offers functional criteria to determine whether the outer catheter is resilient (e.g., the catheter returns to its original shape when undistorted) and whether the inner catheter is pliable (e.g., the catheter can navigate tortuous vessels).

Finally, St. Jude cites to *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945 (Fed. Cir. 2006), arguing that the claims are indefinite because they recite an "outer, resilient catheter having shape memory." In doing so, St. Jude parses the claim language in an attempt to find indefiniteness. However, when the phrase is read together as a whole, the claim requires an outer catheter that returns to its original shape when undistorted. Neither of the terms "resilient" nor "shape memory" render the other meaningless. The latter merely limits the former. *See, e.g., Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1305, 1307 (Fed.Cir.2000) (claim language "only within a zone extending between latitudes 30°–45°" does not read on a device with radiation sources extending between 14°

and 43° because "[a]ny other conclusion renders the reference to 30° superfluous").

II. The district court's summary judgment ruling that claim 11 is not infringed should be vacated

St. Jude first argues that NLC waived arguments related to the district court's entry of summary judgment, but this plainly is not the case. NLC appealed the district court's summary judgment decision in its entirety. As to the basis for the district court's entry of summary judgment, St. Jude ignores the fact that the district court issued new, narrower claim constructions at the summary judgment stage, and that the court's ruling in St. Jude's favor was based on those new constructions. Rather than directly address how the district court interpreted the inserting, withdrawing, and advancing limitations of claim 11, St. Jude asks this Court to look the other way and to simply rubber stamp the district court's ruling.

A. NLC did not waive any issues relating to summary judgment

St. Jude makes the puzzling argument that NLC did not appeal some aspects of the district court's summary judgment decision relating to induced infringement of claim 11, namely the issues of intent and knowledge. On the contrary, NLC plainly appealed the entirety of the district court's summary judgment decision.

On the issue of knowledge and intent, the district court ruled that the differences between the instructions and the claim language (as erroneously

interpreted by the district court) precluded a finding of induced infringement. That analysis, i.e., the interpretation of the steps of claim 11 and the comparison of those steps to St. Jude's instructions, is precisely what has been presented for appeal. St. Jude concedes this point in its brief, identifying three bases for the district court's opinion, all of which depend upon the district court's erroneous claim constructions and application of those constructions to the instructions. St. Jude Brief, pg. 37. St. Jude's argument that NLC has waived any issues relating to the district court's summary judgment decision simply is not supported by this record.

B. The district court did not construe the advancing, inserting, and withdrawing steps of claim 11 prior to summary judgment

St. Jude does not dispute that it first raised its noninfringement positions relating to the advancing, inserting, and withdrawing steps of claim 11 at summary judgment. St. Jude did not ask the district court to construe these terms during the claim construction phase of the case, nor does St. Jude contend that it did so. St. Jude also does not dispute that its non-infringement contentions fail to identify arguments relating to the advancing, inserting, and withdrawing steps of claim 11. St. Jude first raised these new non-infringement positions based on proposed new claim constructions at summary judgment.

St. Jude now attempts to flip the script, arguing that NLC has somehow belatedly raised the issue, ignoring the record that plainly demonstrates that St. Jude did not timely raise these issues or defenses with the district court. Had St. Jude timely raised these at claim construction or in its non-infringement contentions, NLC would have addressed the proposed claim constructions and defenses at that time.[4]

St. Jude argued for the first time at summary judgment that "inserting" the double catheter should be narrowly construed, requiring the inner and outer catheters to be simultaneously inserted into the coronary sinus. St. Jude's narrow construction, which was ultimately adopted by the district court, conflicts with the specification of the '268 patent, which discloses both simultaneous and sequential insertion of the outer and inner catheters. 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); Appx2397-2398 (NLC's expert explaining that the '268 patent discloses sequential insertion of the catheters into the coronary sinus).[5]

[4] While the district court construed the term "the catheter" as "the double catheter" in its claim construction order, the district court did not issue a construction on "inserting" or "withdrawing" the "double catheter" into the coronary sinus.
[5] St. Jude does not dispute that the '268 patent discloses sequential insertion of the outer catheter and then the inner catheter, as NLC pointed out in its opening brief.

St. Jude similarly argued for the first time on summary judgment that "withdrawing" the "double catheter" meant that both the outer catheter and inner catheter must be removed simultaneously. While the '268 patent does not explicitly describe either simultaneous or sequential removal, NLC submitted extrinsic evidence in the form of prior art patents and expert testimony demonstrating the convention of removing inner and outer catheters sequentially. Appx2399, Appx321 8:15-43; Appx304, 3:22-38. There is no basis to narrowly construe the withdrawing limitation in a manner that contradicts industry practice, particularly when the '268 patent did not suggest any deviation from the norm. *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).[6]

St. Jude also presented for the first time at summary judgment a narrow interpretation of the advancing steps (steps 2 and 3) of claim 11. St. Jude essentially argued that the guide wire must be ***fully advanced*** in step 2 before the inner catheter is inserted into the lateral branch vein, and that step 3 can only be satisfied if advancement of the inner catheter begins outside of the lateral branch vein. In other words, St. Jude argued that the claim does not encompass moving

[6] St. Jude does not dispute the industry practice of removing catheters sequentially.

the inner catheter from one point in the lateral branch vein over the guide wire to a point further along in the branch vein.

As with the "inserting" and "withdrawing" limitations, St. Jude's narrow constructions contradict disclosure in the specification and industry practice. The '268 patent describes moving the inner catheter from a first position within a vein to a second position further within a vein as ***advancing*** the catheter. Appx290, 4:51-55. The '268 patent also notes that in some instances it may be difficult to advance the guide wire into a lateral branch vein. Appx291, 5:53-58. In those instances, the inner catheter is placed in the lateral branch vein near the opening to help advance the guide wire into the lateral branch vein. *Id*. Once the guide wire is in place, the inner catheter is advanced over the guide wire into the lateral branch vein. *Id*. NLC also submitted testimony from Dr. Burke explaining this technique, known as a "telescoping" technique. Appx2405-2407. St. Jude does not address, let alone dispute, this disclosure and evidence in its response brief. Yet, the district court's narrow interpretation impermissibly precludes this methodology.

St. Jude cites to *In re Rambus Inc.*, 694 F.3d 42 (Fed. Cir. 2012), arguing that NLC cannot "rewrite" the claims. However, *Rambus* addresses exactly the opposite situation as presented here. In *Rambus*, the patentee argued for a narrower interpretation of a claim limitation than what was disclosed in the

specification. Specifically, the patentee argued that the term "memory device" should be limited to a "single chip component" in an effort to avoid prior art. This Court rejected the argument, holding that "the specification does not restrict the invention to single chip memory devices." *Rambus*, 694 F.3d at 47. This Court further held that the patentee did not explicitly narrow the claim, so the broader interpretation would apply.

Thus, *Rambus* supports NLC's position here – the claim limitations should be given their appropriate breadth as supported by the specification and industry norms. For example, the claims here are not explicitly limited to simultaneous insertion, nor does the specification restrict the "inserting" limitation to simultaneous insertion. On the contrary, the specification explicitly discloses sequential insertion of the outer catheter and the inner catheter. The claims broadly recite "inserting" the double catheter and are not limited to either method.

These limitations should be given their appropriate scope in accordance with the disclosure in the specification and industry norms. The "inserting" should be construed as: ***positioning the outer catheter and inner catheter in the coronary sinus***, whether simultaneously or sequentially. The "advancing" limitation of Step 3 should be construed as: ***moving the inner catheter further into the branch vein along the guide wire***. The "withdrawing" limitation of Step 5 should be

interpreted as ***removing the outer catheter and the inner catheter***, whether simultaneously or sequentially.

C. The district court's factual findings were made using erroneous claim constructions and therefore constitute clear error

The district court's grant of summary judgment of non-infringement was based on its erroneous, narrow interpretation of the claim limitations discussed above. NLC submitted evidence that St. Jude's instructions direct physicians to practice the steps of claim 11 in the order claimed when that claim is properly construed. *See, e.g.*, Appx2403. At the very least, the interpretation of the instructions presents a question of fact that precludes summary judgment in St. Jude's favor, particularly when viewing the facts in the light most favorable to NLC.

St. Jude also points to the district court's determination relating to the so-called "optional" instructions. The evidence is to be construed in the light most favorable to NLC for purposes of St. Jude's motion for summary judgment. At the very least, whether the qualification of various instructions with the phrase "if desired" eliminates any intent on the part of St. Jude is a factual question for the jury to decide. The district court committed clear error by failing to view this evidence in the light most favorable to NLC – a reasonable juror could conclude that the explicit inclusion of the step constituted a recommendation on the part of

St. Jude. Moreover, 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 erred in not viewing this evidence in the light most favorable to NLC.

III. The district court abused its discretion when it excluded Mr. Carlson's third-party licenses and Dr. Burke's testimony regarding direct infringement

The four factors for exclusion of evidence in the Eighth Circuit are set forth in *Citizens Bank of Batesville, Arkansas v. Ford Motor Co.*, 16 F.3d 965 (8th Cir. 1994): (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.

With respect to the first factor, St. Jude admits that Dr. Burke's testimony as a direct infringer was important, which weighs against exclusion. St. Jude does not dispute that the license agreements supporting Mr. Carlson's report were important evidence and therefore weighs against exclusion. Thus, the first factor weighs against exclusion of the evidence.

As for the second factor, NLC explained that it did not begin working with its experts until the expert discovery phase of the case began, which is when it learned about the evidence at issue. St. Jude simply argues that NLC should have

prepared the expert reports during the fact discovery phase, but such a requirement would obviate the need for an expert phase of the case. It was not unreasonable for NLC to begin substantive expert work during the expert phase of the case. The record forming the subject matter of the opinion was not fully established until then. Thus, this factor weighs against exclusion.

For the third factor – potential prejudice to St. Jude – St. Jude fails to assert any prejudice had the evidence been allowed. The evidence was disclosed approximately a month after the close of fact discovery, there was no trial date set, and the evidence was disclosed before St. Jude deposed Dr. Burke and Mr. Carlson. While St. Jude raises the possibility of third-party discovery, such discovery could have been conducted before the depositions as there was no trial date set in the case. Moreover, St. Jude would have incurred the same expense associated with such third-party discovery had the evidence been disclosed during the fact discovery period. St. Jude's characterization of such expense as "additional" expense is inaccurate. "Deferred" would be more precise. In any event, this expense alone does not demonstrate prejudice.

Finally, St. Jude does not dispute NLC's assertion that a continuance could have been granted by the Court. There was no trial date set, and the discovery schedule could have been extended to accommodate whatever additional time St. Jude believed to be necessary. Instead, St. Jude makes an argument that is not

relevant to the availability of a continuance – that St. Jude was "unfairly surprised" by the disclosure. St. Jude Brief, pg. 63. Moreover, St. Jude previously moved to extend deadlines in the case, asking the district court to extend the expert discovery deadlines pending the issuance of the claim construction order. Appx3450. Thus, before filing its motion to exclude, St. Jude had no problem extending deadlines in this case.

The district court also abused its discretion by excluding Mr. Carlson's third-party licenses and Dr. Burke's testimony regarding direct infringement. "Exclusion of evidence is a harsh penalty, and should be used sparingly." *ELCA Enterprises, Inc. v. Sisco Equip. Rental & Sales, Inc.*, 53 F.3d 186, 190 (8th Cir. 1995). With respect to Dr. Burke, whom the district court considered an undisclosed fact witness, "use of an undisclosed witness should seldom be barred unless bad faith is involved." *Bergfeld v. Unimin Corp.*, 319 F.3d 350, 355 (8th Cir. 2003). Here, there was no finding of bad faith on the part of NLC. On the contrary, these facts were disclosed to St. Jude in Mr. Carlson's and Dr. Burke's initial expert reports shortly after NLC learned of them, a little more than a month after the close of fact discovery. St. Jude had every opportunity to probe this evidence at their depositions, and in fact did so. There was no trial det set, so, to the extent additional time was needed to investigate the evidence, the schedule

could have accommodated such discovery. The district court's order excluding this evidence should be vacated.

IV. The district court abused its discretion when it sanctioned NLC

St. Jude sidesteps the issues raised on appeal with respect to the district court's Sanctions Order and instead asks this Court to rubber stamp the extreme relief handed down by the district court, i.e., finding sanctionable conduct and awarding $35,986.75 in fees.

Of critical importance, St. Jude fails to reconcile the district court's explicit finding that there was ***no*** bad faith on the part of NLC, Appx219-220, with controlling Eighth Circuit law that a finding of bad faith is required to award 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."). St. Jude did not even address the district court's finding of no bad faith or the applicable law. This alone warrants reversal of the district court's Sanctions Order.

NLC explained in its opening brief how St. Jude's original Motion to Exclude was narrowly limited to discrete portions of Dr. Burke's report. St. Jude does not address this point and therefore concedes it. NLC also explained how the district court's Sanctions Order went far beyond the scope of the original relief requested by St. Jude, and presumably granted by the district court. St. Jude

remains silent on this issue and therefore concedes it. St. Jude also does not dispute that the testimony at issue on the sanctions motion was ***not challenged*** by St. Jude in the original Motion to Exclude, nor does St. Jude dispute that it was this ***previously unchallenged*** testimony that served as the basis for the sanctions award.

NLC also demonstrated that the district court's Exclusion Order is ambiguous. For example, the district court's oral ruling did not identify any specific facts or testimony that were excluded. The district court abused its discretion by expanding its Exclusion Order beyond the relief originally requested by St. Jude. St. Jude does not dispute the ambiguity in the Exclusion Order, and therefore concedes the point. The ambiguity in the Exclusion Order is an alternative basis for reversing the district court's Sanctions Order.

Finally, St. Jude mischaracterizes the record. St. Jude claims that NLC "relied on" declaration testimony in attempt to present Dr. Burke as a direct infringer. This simply is not the case. NLC's summary judgment brief presents no such argument. NLC was mindful of the district court's Exclusion Order and made no deliberate attempt or argument to present Dr. Burke as a direct infringer.

St. Jude also erroneously claims that "NLC does not challenge that it violated the exclusion order by reincorporating facts previously stricken." St. Jude Brief, pg. 66. On the contrary, as explained in detail in NLC's opening brief, NLC

deliberately omitted the sections of Dr. Burke's report that were challenged by St. Jude on its Motion to Exclude. The Sanctions Order was based upon statements from Dr. Burke that were not challenged in St. Jude's Motion to Exclude. Moreover, NLC vigorously opposed St. Jude's argument that NLC violated the Exclusion Order and subsequently filed an objection to the magistrate judge's entry of sanctions (which the district judge denied). NLC has contested the notion that it violated the Exclusion Order at every turn.

St. Jude also argues that NLC somehow admitted that it "failed to properly instruct Dr. Burke regarding the prior exclusion." St. Jude Brief pg. 65. However, St. Jude cites only to a brief it filed with the district court rather than any actual evidence in support of this statement. In any event, Dr. Burke's summary judgment declaration omits the portions of his report that were challenged by St. Jude on its Motion to Exclude. St. Jude's suggestion that NLC and/or Dr. Burke ignored the district court's Exclusion Order simply is not true. Indeed, the district court found there was no bad faith underlying NLC's submission of the declaration.

Finally, St. Jude cites to two cases that have no relation to awarding attorneys' fees as a sanction for violation of a court order. St. Jude Brief, pg. 66. In *SanDisk Corp. v. Memorex Prod., Inc.*, 415 F.3d 1278 (Fed. Cir. 2005), this Court upheld the district court's preclusion of untimely claim construction and

infringement arguments. The issue of awarding attorneys' fees as a sanction was not addressed.[7] Similarly, in *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355 (Fed. Cir. 2006), this Court upheld the district court's refusal to allow a party to supplement its expert report. The "diligence" comment to which St. Jude refers relates to the fact that the party seeking supplementation failed to explain why the new theory was not included in the original expert report. *O2 Micro* has nothing to do with awarding attorneys' fees as a sanction.

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

St. Jude argues that Mr. Carlson "failed to apportion damages to the value of claim 11's method," arguing that Mr. Carlson "arbitrarily lumped four components (outer catheter, inner catheter, guidewire, and lead) together…" St. Jude Brief, pg. 68. Contrary to St. Jude's assertion, this group of components is by no means arbitrary – these are the four components recited in claim 11. It is perfectly appropriate to include the components required to perform the claimed method in the royalty base.

Moreover, St. Jude fails to appreciate this Court's precedent that apportionment can be accomplished by adjusting the royalty rate. In *Exmark Mfg.*

[7] *SanDisk* does, however, support preclusion of the untimely claim construction and non-infringement arguments that St. Jude first presented at summary judgment.

Co. Inc. v. Briggs & Stratton Power Prod. Grp., LLC, 879 F.3d 1332 (Fed. Cir. 2018), this Court explained that "[w]e 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.'" *Exmark*, 879 F.3d at 1348, *quoting Ericsson, Inc. v. D–Link Sys., Inc.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014).

As explained in NLC's opening brief, Mr. Carlson opined that a reasonable range for the royalty was between 6.0% and 16.63%, which accommodates for variations in factual determinations that may be made by the jury. For example, St. Jude takes issue with the fact that Mr. Carlson relied upon the assumption that the method of claim 11 is the predominant method used by physicians. If St. Jude can demonstrate that it is not the predominant method, then the jury could adopt a royalty rate at the lower end of Mr. Carlson's range. Adjusting the royalty rate to reflect use of the invention is precisely how the concept of apportionment may be applied, as this Court explained in *Exmark*.

Here, claim 11 is a method claim. There are no "patented features" recited in the claim attributable to the components that are used to perform the method, i.e., an outer catheter, an inner catheter, a lead, and a guide wire. Rather, the focus of the damages analysis is use of the claimed method and consideration of whether

there are other methods that may be implemented using the components recited in the claim.

St. Jude does not contend that Mr. Carlson's royalty rate is inappropriate. Instead, St. Jude argues the facts, i.e., that the claimed method is not the predominant method that is used to implant a pacing lead when using the components recited in the claim. This is a question of fact for the jury to resolve.

This district court abused its discretion when it held that Mr. Carlson failed to consider the principle of apportionment, focusing its analysis exclusively upon the royalty base. But, as explained in *Exmark* and as acknowledged by St. Jude, the royalty rate may be used to address apportionment. And this is precisely what Mr. Carlson has done here. His proffered royalty rate range, as applied to the components recited in claim 11, appropriately accounts for the fact that the jury will determine the extent to which the claimed method is used. The district court's ruling that Mr. Carlson cannot opine as to the royalty base should be reversed. Mr. Carlson should be allowed to present his opinion in its entirety.

Dated: August 23, 2021

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Date: August 23, 2021

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