United States Court of Appeals for the Federal Circuit

NIAZI LICENSING CORPORATION, Plaintiff-Appellant

v.

ST. JUDE MEDICAL S.C., INC., Defendant-Appellee

2021 - 1864

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

Decided: April 11, 2022

MICHAEL T. GRIGGS, Boyle Fredrickson, S.C., Milwaukee, WI, argued for plaintiff-appellant. Also represented by ADAM BROOKMAN, MARRIAM LIN, TIMOTHY NEWHOLM.

KALPESH SHAH, Benesch Friedlander Coplan & Aronoff, Chicago, IL, argued for defendant-appellee. Also represented by SAMUEL RUGGIO.

Before TARANTO, BRYSON, and STOLL, *Circuit Judges*. STOLL, *Circuit Judge*.

This appeal asks us to resolve numerous issues: validity and infringement of various claims of U.S. Patent No. 6,638,268; several evidentiary rulings; and the appropriateness of the U.S. District Court for the District of Minnesota's entry of sanctions against Appellant Niazi Licensing Corporation. First, Niazi appeals the district court's determination that all but one of the asserted claims of the '268 patent are invalid as indefinite. We conclude that, when read in light of the intrinsic evidence, a person of ordinary skill in the art would understand the scope of the claims with reasonable certainty. Accordingly, we reverse that determination and remand for the district court to resolve whether Appellee St. Jude Medical S.C., Inc. (St. Jude) has infringed those claims and whether its remaining invalidity defenses are applicable. Second, Niazi appeals the district court's summary judgment of no induced infringement of the only asserted claim it did not hold indefinite. We agree with the district court that Niazi failed to prove direct infringement—a necessary element of Niazi's inducement claim—and therefore affirm that judgment. Third, Niazi appeals the district court's sanction excluding portions of Niazi's technical expert and damages expert reports because Niazi failed to disclose the predicate facts during fact discovery and granting monetary sanctions. Because Niazi points to no abuse of discretion, we affirm the district court's entry of sanctions. Finally, Niazi appeals the district court's exclusion of portions of its damages expert report as unreliable. Because we agree that the damages opinion was conclusory and legally insufficient, we affirm that exclusion as well.

BACKGROUND

Ι

Congestive heart failure is a common medical condition leading to hospital admission in the United States. Heart failure is frequently a result of the left and right sides of the heart contracting out of sync. There are different

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methods available for treating heart failure, such as medication or a heart transplant. Another method is resynchronization therapy, which uses electrical leads (called pacing leads) to help keep the two sides of the heart contracting with regularity and in sync.

According to the '268 patent, at the time of the invention, physicians accomplished resynchronization therapy by inserting a catheter into the coronary sinus¹ and its branch veins (i.e., cannulating) to place pacing leads on the hearts of patients with heart failure. '268 patent col. 1 ll. 29–35. Because the target coronary branch veins arise at acute angles to the coronary sinus and because heart failure can cause changes in the heart's anatomy (including, for instance, the location, shape, and size of the coronary sinus and the branch veins), the specification explains that it can be "difficult to pass a lead" into the coronary sinus and its branch veins using a catheter. Id. at col. 1 l. 61-col. 2 l. 11. Recognizing this, the inventor of the '268 patent developed a double catheter-i.e., a catheter comprising an outer and inner catheter-for cannulating the coronary sinus "without significant manipulation," id. Abstract, which he claimed in the '268 patent.

Claim 1 (an apparatus claim) and claim 11 (a method claim) are representative of the claims on appeal and recite:

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;

¹ The coronary sinus is a major vein that "forms a part of the venous drainage of the heart." '268 patent col. 1 ll. 13–15.

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:

[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.

Id. at col. 6 l. 62–col. 7 l. 9, col. 7 l. 63–col. 8 l. 9 (emphases added to disputed limitations).

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Π

Niazi sued St. Jude for patent infringement. Niazi accused combinations of St. Jude's products, including the CPS Aim[™] SL Slittable Inner Catheter (Subselector/Cannulator), of directly infringing the '268 patent claims, and it further accused St. Jude of inducing infringement of the '268 patent claims.

The district court construed numerous terms in claims 1, 10–11, 13–15, 18–19, and 23–27 (the "asserted claims") that are relevant to this appeal. First, the district court determined that the terms "resilient" and "pliable" in independent claims 1, 13, 18, and 24 of the '268 patent rendered those claims and their dependents (claims 10, 14–15, 19, 23, and 25–27) indefinite. See Niazi Licensing Corp. v. Bos. Sci. Corp., Case Nos. 17-cv-5094 (WMW/BRT), 17-cv-5096 (WMW/BRT), 2019 WL 5304922, at *5–7 (D. Minn. Oct. 21, 2019) (Claim Construction Op.). The parties dispute this determination on appeal.

The court then considered independent claim 11, the only asserted claim that does not recite the terms "resilient" or "pliable." The parties first disputed whether the term "the catheter" in claim 11 rendered that claim indefinite based on a lack of antecedent basis in the claim. The court determined that the claim was not indefinite, construing "the catheter" to mean "the double catheter." *Id.* at *8. This construction, while relevant, is not disputed on appeal.

The parties' second dispute as to claim 11 concerned whether the steps recited in claim 11 must be performed in the order recited in the claim, or whether mere performance of all steps (in any order) was sufficient to meet the claim. The district court determined that "logic requires the steps of [c]laim 11 to be performed in the order listed" and accordingly concluded that claim 11 "is infringed only when the steps are performed in the order listed." *Id.* This

second construction is not meaningfully disputed on appeal.

Following fact discovery, the parties exchanged expert reports concerning infringement and validity of claim 11, as well as the amount of damages for any alleged infringement of that claim. St. Jude moved to strike portions of Niazi's technical expert (Dr. Martin Burke) report and its damages expert (Brad Carlson) report for improperly relying on facts that were not disclosed during fact discovery. Regarding Dr. Burke's report, St. Jude argued that Niazi did not disclose facts relating to alleged direct infringement—specifically, that Dr. Burke himself had directly infringed claim 11 using St. Jude's CPS catheter—which was relevant to Niazi's theory of induced infringement for this claim. As to Mr. Carlson's report, St. Jude argued that his reliance on several third-party license agreements to support his damages calculation was improper because those agreements had not been produced during fact discovery.

The magistrate judge agreed with St. Jude and, as a sanction under Federal Rule of Civil Procedure 37, excluded portions of both reports and further precluded Dr. Burke from testifying as a fact witness. See J.A. 140–54. Niazi objected to this decision, but the district court judge agreed with the magistrate judge's decision that this undisclosed evidence should be excluded and that Dr. Burke should be precluded from testifying as a fact witness. Niazi Licensing Corp. v. St. Jude Med. S.C., Inc., Case No. 17-cv-5096 (WMW/BRT), 2020 WL 1617879, at *1–3 (D. Minn. Apr. 2, 2020) (Sanctions Op. I).

Not long thereafter, the district court considered the parties' cross-motions to exclude certain expert testimony as unreliable under Federal Rule of Evidence 702 and *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Relevant to this appeal, St. Jude moved to exclude Mr. Carlson's damages opinion, arguing that he failed to properly apportion damages to the value attributable to

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claim 11's method. The district court agreed, reasoning that Mr. Carlson's opinion failed to "apportion" between infringing and noninfringing uses and improperly included leads in the royalty base. *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.,* Case No. 17-cv-5096 (WMW/BRT), 2020 WL 5512507, at *9–11 (Sept. 14, 2020) (*Daubert Op.*). The district court accordingly held Mr. Carlson's opinion inadmissible. *Id.*

The parties thereafter cross-moved for summary judgment on numerous issues, but only one of those-the issue of induced infringement of claim 11-is relevant here. Niazi submitted a declaration from Dr. Burke in support of its summary judgment motion. In St. Jude's view, Dr. Burke's declaration recounted various factual assertions that the magistrate judge previously ordered excluded. After the parties were unable to resolve the dispute regarding the scope of Dr. Burke's declaration, St. Jude moved to enforce the magistrate judge's exclusion order and sought monetary sanctions. The magistrate judge agreed with St. Jude, ordering all "facts disclosed by Dr. Burke that were not disclosed by the fact discovery deadline be stricken" from his declaration. J.A. 220 (Hr'g Tr. 63:15–19). The magistrate judge also awarded St. Jude attorney fees and costs associated with its motion to enforce the exclusion order. J.A. 220 - 21(Hr'g Tr. 63:20–64:3). Niazi objected to this decision, but the district court judge affirmed the magistrate judge's exclusion order and award of sanctions. Niazi Licensing Corp. v. St. Jude Med.S.C., Inc., Case No. 17-cv-5096 (WMW/BRT), 2020 WL 3638771, at *4 (D. Minn. July 6, 2020) (Sanctions Op. II).

The district court then addressed the merits of the induced infringement issue. As a result of the various exclusion orders (and a ruling on inadmissibility of certain evidence that is not challenged on appeal), Niazi's induced infringement case rested on St. Jude's instructions for use (IFUs) for its CPS catheter. The district court determined

that Niazi "failed to present evidence to support either" direct infringement or that St. Jude possessed specific intent to encourage another's infringement, both of which are necessary to impose liability for induced infringement. *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, Case No. 17-cv-5096 (WMW/BRT), 2021 WL 1111074, at *8 (D. Minn. Mar. 23, 2021) (*Summary Judgment Op.*).

As to direct infringement, the district court determined that the IFUs required the performance of the claim steps in an order different than that required by the claims and, therefore, that doctors performing the steps in the IFUs did not directly infringe claim 11 as a matter of law. *Id.* at *4–7. The district court also determined that there was no material dispute of fact as to the intent element. The court explained that, not only did St. Jude's IFUs "substantively differ" from the claimed method, but many of the steps recited in the IFUs were "optional," thus negating specific intent to induce. *Id.* at *7. The district court accordingly entered summary judgment of no induced infringement of claim 11 in St. Jude's favor and dismissed St. Jude's counterclaim of invalidity for that claim.

Niazi appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

On appeal, Niazi challenges: (1) the district court's determination that claims 1, 10, 13–15, 18–19, and 23–27 are invalid as indefinite; (2) the district court's summary judgment of no induced infringement of claim 11; (3) the district court's imposition of sanctions against Niazi under Federal Rule of Civil Procedure 37 excluding portions of Dr. Burke's and Mr. Carlson's expert reports and awarding monetary sanctions for violating that order; and (4) the district court's exclusion of Mr. Carlson's opinion as unreliable under *Daubert*. We address each in turn.

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Ι

We begin with Niazi's assertion that the district court erred in holding that the terms "resilient" and "pliable" render claims 1, 10, 13–15, 18–19, and 23–27 invalid as indefinite. For the reasons below, we agree with Niazi, and accordingly, we reverse.

А

Definiteness is a statutory requirement for patentability. Under 35 U.S.C. § 112, ¶ 2,² a patent's specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." A claim is indefinite only if, when "read in light of the specification" and "prosecution history," it "fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 901 (2014). Definiteness is a question of law that we review de novo. Mass. Inst. of Tech. v. Shire Pharms., Inc., 839 F.3d 1111, 1123–24 (Fed. Cir. 2016).

As the Supreme Court explained in *Nautilus*, language has "inherent limitations." 572 U.S. at 909. The reasonable certainty standard exists to strike a "delicate balance," "afford[ing] clear notice of what is claimed" while recognizing such inherent limitations. *Id.* (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002)). "Otherwise there would be '[a] zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." *Id.* at 909–10

² Because the '268 patent does not contain any claim with an effective filing date on or after September 16, 2012, the applicable version of § 112 is the one preceding the changes made by the America Invents Act. See Leahy–Smith America Invents Act, Pub. L. No. 112-29 § 4(e), 125 Stat. 284, 297 (2011).

(alteration in original) (quoting United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236 (1942)). While the legal test for definiteness "does not require that a potential infringer be able to determine *ex ante* if a particular act infringes the claims," Nevro Corp. v. Bos. Sci. Corp., 955 F.3d 35, 40 (Fed. Cir. 2020), the public notice function underlying this patentability requirement demands that a patentee apprise the public "of what is still open to them," Nautilus, 572 U.S. at 909 (quoting Markman v. Westview Instruments, Inc., 517 U.S. 370, 373 (1996)). This serves an important policy goal—providing clarity such that a person of ordinary skill in the art could determine whether or not an accused product or method infringes the claim. See Meds. Co. v. Mylan, Inc., 853 F.3d 1296, 1303 (Fed. Cir. 2017) (quoting Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1384 (Fed. Cir. 2003)). The definiteness requirement thus "mandates clarity, while recognizing that absolute precision is unattainable." Nautilus. 572 U.S. at 910.

While there must be objective boundaries, "we have explained that 'a patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement." Guangdong Alison Hi-Tech Co. v. Int'l Trade Comm'n, 936 F.3d 1353, 1359 (Fed. Cir. 2019) (quoting Sonix Tech. Co. v. Publ'ns Int'l. Ltd., 844 F.3d 1370, 1377 (Fed. Cir. 2017)). Indeed, patentees often use "[d]escriptive words ... to 'avoid[] a strict numerical boundary to the specified parameter." Braintree Lab'ys, Inc. v. Novel Lab'ys, Inc., 749 F.3d 1349, 1360 (Fed. Cir. 2014) (third alteration in original) (quoting Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995)). And we have recognized that "[c]laim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention." Interval Licensing LLC v. AOL, Inc., 766 F.3d 1364, 1370 (Fed. Cir. 2014).

True, descriptive words (or terms of degree) in a claim may inherently result in broader claim scope than a claim defined with mathematical precision. But a claim is not indefinite just because it is broad. See, e.g., BASF Corp. v. Johnson Matthey Inc., 875 F.3d 1360, 1367 (Fed. Cir. 2017) (reiterating, after *Nautilus*, that "breadth is not indefiniteness" (quoting SmithKline Beecham Corp. v. Apotex Corp., 402 F.3d 1331, 1341 (Fed. Cir. 2005))); Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp., 587 F.3d 1339, 1351 (Fed. Cir. 2009) (determining, pre-Nautilus, that a claim term. "even if construed to be as broad as the district court construed it to be, does not render the claim insolubly ambiguous"); Cap. Sec. Sys., Inc. v. NCR Corp., 725 F. App'x 952, 957 (Fed. Cir. 2018) (determining, post-Nautilus, that broad claim language did not render the claim indefinite when read in light of the written description). For purposes of the definiteness inquiry, the problem patentees face by using descriptive words in their claims is not the potential breadth of those claims. It is whether the use of descriptive phrasing in the claim results in a claim that "fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Nautilus, 572 U.S. at 901.

To that end, we have time and again had the occasion to consider the definiteness of claims containing descriptive words or terms of degree. For example, in *Sonix Technologies*, we considered whether the phrase "visually negligible" rendered indefinite claims directed to systems and methods for using a graphical indicator (like a barcode) to encode information on the surface of an object, the purported improvement over the prior art being a "visually negligible" graphical indicator. 844 F.3d at 1371–73. We explained that, while this phrase was a term of degree, the claim language itself provided "an objective baseline through which to interpret the claims"—whether it could be seen by the normal human eye. *Id.* at 1378. In other words, it was not a "purely subjective" phrase that failed to

inform a person of ordinary skill about the claim scope with reasonable certainty. *Id.* The written description, likewise, provided objective boundaries, including exemplary designs and specific examples of visually negligible graphical indicators as well as a specific requirement that the indicator be negligible to human eyes. *Id.* at 1379. We also found it highly relevant that the examiner understood this phrase throughout prosecution, as did both parties' experts during the course of litigation. *Id.* at 1379–81. Accordingly, we held that the phrase "visually negligible' [wa]s not a purely subjective term" and that the claims were not invalid as indefinite. *Id.* at 1381.

Our decision in Enzo Biochem, Inc. v. Applera Corp., 599 F.3d 1325 (Fed. Cir. 2010), is similarly instructive. There, we determined that use of the term "not interfering substantially" did not render a claim invalid as indefinite. The claim at issue required that the linkage group in a chemical compound was "not interfering substantially" with the ability of that compound to hybridize with a nucleic acid. Id. at 1329. We explained that, while the claims did not define "not interfering substantially" with mathematical precision, the intrinsic evidence provided guideposts for a skilled artisan to determine the scope of the claims. Id. at 1335. This evidence included certain dependent claims, which recited exemplary linkage groups that would not interfere substantially with hybridization, and additional exemplary linkage groups found in both the written description and prosecution history that, likewise, would not interfere substantially with hybridization. Id. at 1334–35. In other words, the intrinsic evidence provided a skilled artisan with examples with which she could compare an allegedly infringing product to determine whether any interference with hybridization was substantial.

By contrast, we have determined that terms of degree render a claim indefinite where the intrinsic evidence (or extrinsic evidence, where relevant and available) provides insufficient guidance as to any objective boundaries for the

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claims—including where the claims are "purely subjective" such that their scope cannot be determined with reasonable certainty. A classic example is the term "aesthetically pleasing," which we determined in Datamize, LLC v. Plumtree Software, Inc. rendered claims drawn to the "look and feel" of an interface screen invalid as indefinite. 417 F.3d 1342, 1345, 1349–56 (Fed. Cir. 2005). The scope of the claim changed depending on a person's subjective determination as to whether the interface screen was "aesthetically pleasing." We explained that "[w]hile beauty is in the eye of the beholder, a claim term, to be definite, requires an objective anchor." Id. at 1350. After considering the intrinsic record and extrinsic evidence, we concluded that there was nothing supplying "some standard for measuring the scope of the phrase," id. at 1351, and accordingly affirmed the district court's summary judgment of invalidity for indefiniteness, id. at 1356. We drew a similar conclusion as to the claim phrase "unobtrusive manner that does not distract the viewer" in Interval Licensing. 766 F.3d at 1371–74.

The claims at issue in Intellectual Ventures I, LLC v. T-Mobile USA, Inc. likewise employed a term of degree— "QoS requirements." 902 F.3d 1372, 1375-76, 1381-82 (Fed. Cir. 2018). We determined this term was "purely subjective," leaving a skilled artisan unable to determine the scope of the claim with reasonable certainty. Id. at 1381–82. The patent described "QoS requirements" as "defined by what network performance characteristic is most important to a particular user." Id. at 1381. The patent further characterized it as "a relative term, finding different meanings for different users." Id. We concluded, based on the intrinsic record, that this term rendered the claims invalid as indefinite because it was "purely subjective" and depended "on the unpredictable vagaries of any one person's opinion." Id. (quoting Datamize, 417 F.3d at 1350–51).

Ultimately, patent claims with descriptive words or terms of degree "must provide objective boundaries for those of skill in the art" in the context of the invention to be definite. *Interval Licensing*, 766 F.3d at 1371; *Intellectual Ventures I*, 902 F.3d at 1381. As with any question of claim construction, the intrinsic record—the patent's claims, written description, and prosecution history along with any relevant extrinsic evidence can provide or help identify the necessary objective boundaries for claim scope. *Guangdong*, 936 F.3d at 1360 (collecting cases).

В

With this background, we now consider the terms at issue here—"resilient" and "pliable." We agree with Niazi that the intrinsic record and extrinsic evidence inform a skilled artisan, with reasonable certainty, of the meaning of "resilient" and "pliable." The terms are broad, but they are not uncertain. The district court erred in holding otherwise.

Starting with the term "resilient," claim 1 recites "an outer, *resilient* catheter having shape memory." '268 patent col. 6 ll. 62–65 (emphasis added). The claim language itself provides guidance on what this term means—the outer catheter must have "shape memory," *id*. (claim 1) and "sufficient stiffness," *e.g.*, *id*. at col. 8 ll. 13–27 (claim 13). Numerous dependent claims further inform the meaning of this term by providing exemplary resilient materials of which the outer catheter could be made. *See, e.g.*, *id*. at col. 8 ll. 33–34 (claim 16 reciting "wherein the outer catheter is made of a braided silastic"); *id*. at col. 9 ll. 4–5 (claim 21 reciting same).

The written description provides similar guidance, explaining that the outer catheter has a "braided design," id. at col. 5 ll. 4–6, and is made of materials like silastic or similar materials such that the outer catheter has "sufficient shape memory to return to its original shape when undistorted," id. at col. 4 ll. 21–23. It further explains that

resilience provides for "torque control and stiffness." *Id.* at col. 3 ll. 11–13, col. 5 ll. 4–6. Thus, a person of ordinary skill reading the claims and written description would know of exemplary materials that can be used to make a resilient outer catheter, i.e., one that has shape memory and stiffness such that it can return to its original shape.

Turning to the term "pliable," the claims recite "an inner, *pliable* catheter slidably disposed in the outer catheter." E.g., id. at col. 6 ll. 66-67 (claim 1) (emphasis added). While the claim language provides less guidance on the meaning of pliable, the written description contains numerous examples of a "pliable" inner catheter. For example, the written description explains that relative to the resilient outer catheter, the inner catheter "is constructed of a more pliable, soft material such as silicone." Id. at col. 3 ll. 13-15; see id. at col. 5 ll. 14-16. It further explains that the inner catheter "has no longitudinal braiding, which makes it extremely flexible and able to conform to various shapes." Id. at col. 5 ll. 13-18. Thus, the written description provides an exemplary material that can be used to make a pliable inner catheter, explaining that the inner catheter is more flexible than the outer.

Taken as a whole, we conclude that the intrinsic record "is sufficient to dispose of" the indefiniteness issues as to the terms "resilient" and "pliable." *Guangdong*, 936 F.3d at 1361. The intrinsic record provides objective boundaries by which a skilled artisan could determine the scope of the claims. That puts this case in line with our decisions in *Sonix Technologies* and *Enzo Biochem*, where we held that examples in the written description helped provide sufficient guidance to render the claims not invalid as indefinite. The terms "resilient" and "pliable" are not purely subjective terms like those in *Datamize*, *Interval Licensing*, and *Intellectual Ventures I*, resulting in a variable claim scope depending on the particular eye of any one observer.

We note that extrinsic evidence further supports our conclusion. Niazi introduced dictionary definitions of both terms to demonstrate that the claims are not indefinite. Consistent with the claims and written description, "resilient" is defined as "returning to the original form or position after being bent, compressed, or stretched." J.A. 2963 (quoting *Resilient*, Dictionary.com, https://www.dictionary.com/browse/resilient). The same is true for "pliable," which is defined as "easily bent, flexible; supple." J.A. 2966 (quoting *Pliable*, Dictionary.com, https://www.dictionary.com/browse/pliable). These definitions confirm that the terms "resilient" and "pliable" would have had broad but understood meanings to a skilled artisan.

We are unpersuaded by St. Jude's arguments to the contrary. St. Jude argues that the written description is inconsistent in how it describes "resilient" and "pliable." E.g., Appellee's Br. 21–23, 28–30. On appeal, St. Jude, like the district court, focuses largely on a single sentence in the written description in support of this contention. See Claim Construction Op., 2019 WL 5304922, at *6. That sentence states that both the inner and outer catheters "preferably have 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." '268 patent col. 4 ll. 4–8. We disagree that this sentence renders the claims indefinite. While both the inner and outer catheters must have some degree of stiffness but be flexible enough to bend when required, it is evident from the description in the patent that the degree of stiffness and flexibility for each is relative: the outer catheter has a greater degree of stiffness and less flexibility compared to the inner catheter. A skilled artisan, viewing the written description as a whole, could readily differentiate between a "resilient" outer catheter and a "pliable" inner catheter. And, as explained above, the written description provides objective boundaries for determining whether a catheter is "resilient" or "pliable." We thus conclude that

these terms, when read in light of the intrinsic and extrinsic evidence, inform those skilled in the art about the scope of the invention with reasonable certainty. That is all the law requires.

For the above reasons, we hold that claims 1, 10, 13–15, 18–19, and 23–27 are not invalid as indefinite and accordingly reverse.

Π

We turn next to the district court's summary judgment of no induced infringement of claim 11. We review the district court's summary judgment under the law of the regional circuit, here the Eighth Circuit. *Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp., LLC,* 879 F.3d 1332, 1340 (Fed. Cir. 2018). The Eighth Circuit reviews a grant of summary judgment de novo. *Wilson v. Spain,* 209 F.3d 713, 716 (8th Cir. 2000). Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

A determination of infringement generally requires a two-step analysis—the court first determines the scope and meaning of the claims asserted, and then the properly construed claims are compared to the allegedly infringing device (for an apparatus claim) or allegedly infringing act (for a method claim). See CommScope Techs. LLC v. Dali Wireless Inc., 10 F.4th 1289, 1295 (Fed. Cir. 2021). For induced infringement under 35 U.S.C. § 271(b), the two steps become three. In addition to showing direct infringement by some party (e.g., a comparison of the properly construed claims to the allegedly infringing act), the patentee must also show that the alleged infringer "knowingly induced infringement and possessed specific intent to encourage another's infringement." Enplas Display Device Corp. v. Seoul Semiconductor Co., 909 F.3d 398, 407 (Fed. Cir. 2018) (quoting Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1304–05 (Fed. Cir. 2002)).

The first step—claim construction—is a question of law we review de novo to the extent it is decided only on the intrinsic evidence. Data Engine Techs. LLC v. Google LLC, 10 F.4th 1375, 1380 (Fed. Cir. 2021); Teva Pharms. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 331 (2015). Whether an allegedly infringing act includes all the steps of the properly construed claim is a question of fact. See SmithKline Diagnostics, Inc. v. Helena Lab'ys Corp., 859 F.2d 878, 889 (Fed. Cir. 1988). Likewise, whether an alleged infringer knowingly induced and possessed specific intent to encourage that direct infringement is a question of fact. Enplas, 909 F.3d at 407. Summary judgment of noninfringement is appropriate when no reasonable juror could find that every step of a properly construed method claim was performed by the accused direct infringer. Cf. Advanced Steel Recovery, LLC v. X-Body Equip., Inc., 808 F.3d 1313, 1317 (Fed. Cir. 2015).

Niazi's arguments on appeal focus almost entirely on the first step of the analysis: whether the district court misconstrued steps 1, 2, 3, and 5 of claim 11's method in determining that summary judgment of no induced infringement was proper. For the reasons below, we disagree with the district court's constructions of steps 1 and 5 and cannot affirm the summary judgment of no induced infringement on that basis. We agree, however, with the court's construction of steps 2 and 3 and its determination that Niazi failed to meet its burden to prove direct infringement,³ a necessary element of its inducement claim. Accordingly, we affirm on that basis and do not reach Niazi's arguments on specific intent to induce infringement.

³ As we discuss below, we affirm the district court's decision excluding Dr. Burke's factual allegations regarding his own alleged direct infringement. Our discussion here is therefore limited to St. Jude's IFUs.

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We start with steps 1 and 5 of method claim 11. Step 1 recites "inserting the catheter into the coronary sinus," and step 5 recites "withdrawing the catheter leaving the lead in the branch vein." '268 patent col. 7 l. 63-col. 8 l. 9. As noted above, the district court construed the term "the catheter" to mean "the double catheter," which is not challenged on appeal. On summary judgment, the district court held that St. Jude's IFUs do not establish direct infringement of these two steps as a matter of law. Specifically, the court reasoned that because the IFUs do not instruct "simultaneously" inserting or withdrawing the inner and outer catheters (i.e., the double catheter), the IFUs are "inconsistent with the claimed method as construed by the [c]ourt." Summary Judgment Op., 2021 WL 1111074, at *4, *6. Niazi challenges this conclusion, arguing that nothing in the claims requires simultaneous insertion and withdrawal of the inner and outer catheters. Rather, Niazi argues that the claims also cover inserting and withdrawing the inner and outer catheters sequentially. We agree.

Method claim 11 comprises certain steps, including "inserting" and "withdrawing" the catheter. While the district court construed "the catheter" to mean both the inner and outer catheter (i.e., the "double catheter")—which is not disputed on appeal—the phrases "inserting" or "withdrawing" "the catheter" do not include a temporal requirement. Rather, the phrases are broad enough to cover sequentially inserting (or withdrawing) the outer catheter followed by the inner catheter (or vice versa). "The catheter" (as construed by the district court) is still inserted or withdrawn, just in two steps instead of one.

The written description supports this interpretation. In one embodiment, the '268 patent describes simultaneous insertion of the inner and outer catheters. *See, e.g.*, '268 patent col. 4 ll. 33–36 ("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 into the left [] subclavian vein." (emphasis added)). But the '268 patent describes sequential insertion of the inner and outer catheters in a second embodiment. *See id.* at col. 5 ll. 46–64 (describing, for a triple catheter of the invention, cannulation of the coronary sinus with the outer catheter 51 followed by insertion of the inner catheter 52 into the branch vein). Thus, the written description supports our interpretation that the claims broadly encompass both simultaneously and sequentially inserting or withdrawing the inner and outer catheters.

As the district court recognized. St. Jude's IFUs instruct users to "[f]ollow normal accepted practice for ... outer guide catheter insertion" before "[i]nsert[ing] the inner catheter into the outer guide catheter." E.g., Summary Judgment Op., 2021 WL 1111074, at *4 (fourth alteration added); see J.A. 1087 (St. Jude's IFUs, steps 3 and 4). Sequential insertion of the outer and inner catheters in the IFUs comes within step 1 of claim 11's method as properly construed. As to step 5, while the IFUs do not describe removal of the outer catheter (only removal of the inner catheter), the district court granted summary judgment based on the lack of evidence of removing the inner and outer catheters "simultaneously." Summary Judgment Op., 2021 WL 1111074, at *6. Because we do not agree with the district court's construction, we cannot affirm summary judgment of no induced infringement based on these steps.

В

Turning to steps 2 and 3 of method claim 11, we agree with the district court's construction, as well as its determination that Niazi failed to present sufficient evidence to carry its burden to prove direct infringement of these steps. We therefore affirm the district court's summary judgment of no induced infringement.

Step 2 recites "advancing a guide wire through the catheter into a coronary sinus lateral branch vein."

'268 patent col. 8 ll. 1–2. Step 3 follows step 2 and recites "advancing the inner catheter out of a front end opening of the outer catheter along the guide wire into the branch vein." *Id.* at col. 8 ll. 3–5. The district court construed claim 11 to require performance of the claim steps in the order listed. Thus, under the district court's construction, the inner catheter must be advanced along the guide wire into the branch vein after the guide wire is first advanced into the branch vein.

Turning to St. Jude's IFUs—the key evidence Niazi relies on for direct infringement—we agree with the district court that St. Jude's IFUs recite the steps required by claim 11 in an order opposite to that required by claim 11 (as construed). No reasonable juror could find otherwise.

After inserting the outer catheter, St. Jude's IFUs direct the user to then "[i]nsert the inner catheter into the outer guide catheter, subselecting the desired coronary sinus branch vein." J.A. 1087. "Subselecting" in this context means selecting and inserting the inner catheter into the branch vein. Oral Arg. at 9:00–10:30, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=21-

1864_12092021.mp3. Then, "[i]f desired," St. Jude's IFUs direct the user to "insert a guidewire . . . through the inner catheter lumen into the branch vein." J.A. 1087. In sum, St. Jude's IFUs direct the user to insert the inner catheter into the branch vein first, followed by the guidewire (if desired), whereas claim 11 requires inserting the guidewire into the branch vein followed by the inner catheter. The two methods are opposite. Because St. Jude's IFUs "do not describe [the claimed] steps in the order required" by claim 11, we agree with the district court that it is simply "too speculative a leap to conclude that any customer actually performed the claimed method." *Summary Judgment Op.*, 2021 WL 1111074, at *6 (quoting *E-Pass Techs., Inc. v. 3Com Corp.*, 473 F.3d 1213, 1222 (Fed. Cir. 2007)). Accordingly, we agree with the district court's summary

judgment conclusion of no triable issue of the required direct infringement of steps 2 and 3 of claim 11.

Niazi nonetheless argues that the district court erred in construing claim 11 to exclude a method of (1) advancing the inner catheter into the branch vein; (2) advancing the guide wire into the branch vein; and then (3) advancing the inner catheter further into the branch vein along the guidewire. We disagree.

This argument is contrary to the claim language defining the act covered by step 3. In that step, claim 11 requires "advancing the inner catheter along the guide wire into the branch vein." '268 patent col. 8 ll. 3-5 (emphasis added). The district court logically concluded, and we agree, 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." Claim Construction Op., 2019 WL 5304922, at *8. Under Niazi's proposed construction, the inner catheter would already be in the branch vein prior to inserting the guidewire. If the inner catheter is already in the branch vein (as Niazi proposes), it cannot be advanced "into" the branch vein as required by the claims. Like the district court, we think it is clear from the claim language that initial entry into the branch vein, not just further movement once inside the branch vein, must take place in the sequence specified. But there is no evidence of such a sequence here. Accordingly, we adopt the district court's construction with respect to steps 2 and 3 and affirm the summary judgment of no induced infringement.

Ш

We now consider Niazi's challenges to the district court's order excluding portions of Dr. Burke's and Mr. Carlson's expert reports under Federal Rule of Civil Procedure 37 because they relied on facts not disclosed during fact discovery. We also consider Niazi's challenge to the district court's award of sanctions for violating its

order. We review a district court's decision to sanction a litigant under Rule 37 under the law of the regional circuit, here the Eighth Circuit. *Transclean Corp. v. Bridgewood Servs., Inc.,* 290 F.3d 1364, 1370–71 (Fed. Cir. 2002). The Eighth Circuit reviews a district court's entry of sanctions under Rule 37 for an abuse of discretion. *See Vanderberg v. Petco Animal Supplies Stores, Inc.,* 906 F.3d 698, 702 (8th Cir. 2018). For the reasons below, we conclude that the district court did not abuse its discretion on either front. We therefore affirm.

А

We start by addressing Niazi's challenges to the exclusion of portions of its experts' reports as a sanction under Rule 37. From the outset of litigation, St. Jude argued that Niazi's induced infringement claim was deficient because Niazi "failed to identify a single instance of direct infringement underlying its assertion of indirect infringement." J.A. 143 (Hr'g Tr. 98:6–11). In his expert report (served after the close of fact discovery), Dr. Burke explained for the first time that he himself had directly infringed claim 11 of the '268 patent when using St. Jude's products. There is no dispute that Niazi never disclosed this fact to St. Jude Nor did Niazi ever identify during fact discovery. Dr. Burke as a potential fact witness—as required under Federal Rule of Civil Procedure 26(a) (initial disclosures) or (e) (supplemental disclosures)—despite being on notice of this alleged deficiency in its induced infringement claim.

Mr. Carlson, for his part, relied on several license agreements he had identified in third-party databases in support of his opinion on a reasonable royalty. St. Jude specifically requested "[d]ocuments that [Niazi] may rely on in any way to support its claim for damages" during fact discovery. J.A. 147–48 (Hr'g Tr. 102:21–103:2). But again, these license agreements were not produced during fact discovery, depriving St. Jude of the opportunity to conduct meaningful discovery with respect to these agreements.

Thus, when St. Jude moved to strike these facts from Dr. Burke's and Mr. Carlson's reports under Rule 37, the magistrate judge granted St. Jude's motion and further determined that Dr. Burke could not testify as a fact witness. The district court judge agreed with the magistrate judge's conclusion that this evidence should be excluded.

On appeal, Niazi argues that the district court abused its discretion in its application of the four-factor test for exclusion of previously undisclosed evidence set forth in *Citi*zens Bank of Batesville, Arkansas v. Ford Motor Co., 16 F.3d 965, 966-67 (8th Cir. 1994). Appellant's Br. 41-42. But the district court did not rest its analysis on these four factors. Instead, the district court considered whether Niazi's failure to disclose these facts or identify Dr. Burke as a fact witness was "substantially justified or harmless" under Rule 37(c)(1). Sanctions Op. I, 2020 WL 1617879, at *2-3; see Vanderberg, 906 F.3d at 702-03 (explaining Rule 37(c)(1)'s requirement that undisclosed information or witnesses are excluded "unless the failure was substantially justified or harmless"). The court determined that Niazi's failure to disclose was not "substantially justified or harmless." Sanctions Op. I, 2020 WL 1617879, at *3. Because Niazi does not challenge the actual basis for the district court's conclusion, we affirm.⁴

⁴ In its exclusion order, the district court explained that the Eighth Circuit has been silent on whether this four-factor test has survived Rule 37's enactment. *Sanctions Op. I*, 2020 WL 1617879, at *2 & nn.2–3. Accordingly, it did not analyze the four factors in agreeing with the magistrate judge's conclusion that this evidence should be excluded. Niazi does not challenge the district court's legal determination that it need not consider these factors. Even assuming, without deciding, that this four-factor test is applicable—*see id.* at *2 n.2 (citing *Carmody v. Kan. City Bd. of Police Comm'rs*, 713 F.3d 401, 405 (8th Cir. 2013)

В

This takes us to the district court's entry of monetary sanctions against Niazi for violating the exclusion order. For the reasons below, we conclude that the district court did not abuse its discretion in awarding St. Jude costs and attorney fees in connection with its motion to strike, and we therefore affirm.

Niazi submitted a declaration from Dr. Burke in support of its motion for summary judgment of induced infringement. That declaration included numerous factual assertions related to Dr. Burke's personal experience using St. Jude's CPS catheter, as well as his recounting of conversations he had with electrophysiologists. St. Jude moved to strike these factual assertions from Dr. Burke's declaration because he had not been disclosed as a fact witness. Nor were these facts disclosed during fact discovery, and their inclusion in his declaration directly contravened the court's prior exclusion order. The magistrate judge agreed, explaining that the exclusion order was clear: "Dr. Burke was precluded from offering testimony of fact in this case because he was not timely disclosed as a fact witness." J.A. 219 (Hr'g Tr. 62:7-11). As a sanction for violating the order, the magistrate judge awarded St. Jude attorney fees and costs associated with bringing

⁽explaining that it was not error for district court to consider the "balancing test we previously found helpful to evaluate the admissibility of evidence a party did not properly disclose"))—Niazi has not mounted a meaningful challenge on appeal. Application of these factors is within the sound discretion of the district court. Because Niazi has not identified any legal error or clear factual error, we will not reweigh these factors on appeal. *See Citizens Bank*, 16 F.3d at 967 (declining "to second-guess the [d]istrict [c]ourt's exercise of discretion" in applying these four factors).

the motion to strike. On review of Niazi's objections to this decision, the district court determined that the imposition of sanctions against Niazi for "willful violation" of the magistrate judge's "clear[] and unambiguous[]" order was neither clearly erroneous nor contrary to law, and it accordingly agreed with the magistrate judge's award. *Sanctions Op. II*, 2020 WL 3638771, at *4.

Rule 37(c)(1)(A) allows courts to impose "reasonable expenses, including attorney [] fees" for failure to "provide information or identify a witness as required by Rule 26(a) or (e)," specifying that "the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial unless the failure was substantially justified or is harmless." Here, the court specifically found a violation of Rule 26(a) and (e)'s disclosure requirements and sanctioned Niazi by excluding that evidence as a result of the failure to disclose. Rule 37(c)(1)(A) contemplates monetary sanctions in a situation such as this, where Niazi attempted to circumvent an already-imposed Rule 37 sanction of exclusion by using the excluded evidence in connection with its summary judgment motion. Indeed, even absent a court order excluding the nondisclosed information, where a party has failed "to provide information or identify a witness as required by Rule 26(a) or (e)," Rule 37(c)(1)(A) permits a court to impose monetary sanctions "caused by the failure" to disclose.

Here, the sanctions the court imposed were specifically keyed to St. Jude's expenses in moving to strike the already-excluded evidence from consideration at summary judgment. We see no abuse of discretion in the district court's decision to award monetary sanctions.

We are not persuaded by Niazi's arguments to the contrary. First, Niazi argues that the magistrate judge's initial exclusion order only precluded Dr. Burke from testifying that he had directly infringed claim 11. Appellant's Br. 49–51. Niazi contends that it cannot be

sanctioned for Dr. Burke's inclusion of other factual assertions in his declaration because the magistrate judge's order was not clear and unambiguous. The magistrate judge, in awarding sanctions, construed her own prior exclusion order as prohibiting Dr. Burke from presenting fact testimony, period. J.A. 164–67 (Hr'g Tr. 7:16–10:10). This, she said, was a "clear" ruling. J.A. 219 (Hr'g Tr. 62:7–11). The district court, on review of Niazi's objections, agreed. Sanctions Op. II, 2020 WL 3638771, at *3-4 & n.2. We see no abuse of discretion in this determination. Review of the magistrate judge's ruling, which refers to precluding Dr. Burke as a fact witness, fully supports the magistrate judge's and district court's conclusion. See, e.g., J.A. 140 (Hr'g Tr. 95:17-18 ("St. Jude also seeks to preclude Dr. Burke from testifying as a fact witness due to late disclosure.")); J.A. 152 (Hr'g Tr. 107:15–19 (finding there was "unfair surprise as far as the disclosure of Dr. Burke as a fact witness is concerned" and that "a continuance will not cure the problem created by [Niazi's] own doing")).

Second, Niazi argues that monetary sanctions are not justified in light of the magistrate judge's finding that Niazi did not act in bad faith. According to Niazi, under Eighth Circuit precedent, "[a] bad faith finding is specifically required in order to assess attorney [] fees." Appellant's Br. 48 (second alteration added) (citing Stevenson v. Union Pac. R.R. Co., 354 F.3d 739, 751 (8th Cir. 2004)). But Stevenson involved attorney fees awarded under the court's inherent power to impose sanctions, not Rule 37. Niazi cites no cases or other authority to suggest that bad faith is required under Rule 37. Rather, First American State Bank v. Continental Insurance Co. suggests otherwise, finding no abuse of discretion in a district court's award of monetary sanctions against trial counsel under Rule 37(b), such sanctions being "precipitated by substantially unjustified and willful non-compliance with several discovery orders." 897 F.2d 319, 331-32 (8th Cir. 1990). Here, the magistrate judge specifically found Niazi's

violation of the exclusion order willful, *see* J.A. 219–20 (Hr'g Tr. 62:17–63:3), and the district court agreed, *see Sanctions Op. II*, 2020 WL 3638771, at *3. We see no abuse of discretion in the court's decision to award sanctions in the form of costs and attorney fees under Rule 37 for willful violation of its prior order. Accordingly, we affirm.

IV

Niazi's final argument on appeal challenges the district court's order excluding as unreliable Mr. Carlson's expert report on damages for infringement of claim 11. We review a district court's decision to exclude expert testimony for an abuse of discretion. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 142, 152–53 (1999).

Mr. Carlson concluded that a royalty rate of 14.6% "is the minimum reasonable royalty" rate for infringement of claim 11, directed to a procedure for implanting an electrical lead into a lateral branch of a coronary sinus vein using a double catheter. J.A. 728. He further opined that certain qualitative factors "would support a higher royalty rate." *Id.* As for the royalty base, he opined that the royalty base for infringement of claim 11 includes an outer catheter, an inner catheter, a guide wire, and a lead, because: (1) the method claims recite these elements; and (2) this court "has recognized that in some instances, a royalty based upon actual use of a method – as opposed to a royalty applied to the sale of a device that practices the method - is impractical in view of real-world considerations." J.A. 727 (citing Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1334 (Fed. Cir. 2009)).

Mr. Carlson did not explain why a royalty based on the alleged use of the method would be impractical in this case. Instead, Mr. Carlson stated merely that because claim 11 requires an outer catheter, an inner catheter, a guide wire, and a lead, these components comprise the smallest saleable component used by an electrophysiologist to practice the claimed method. Accordingly, Mr. Carlson concluded

that the royalty base should include all sales of these components. The district court excluded Mr. Carlson's expert opinion as legally insufficient because Mr. Carlson failed to "apportion" between infringing and noninfringing uses and because he could not properly include leads in the royalty base. *Daubert Op.*, 2020 WL 5512507, at *10–11. We affirm the district court's exclusion.⁵

Mr. Carlson did not even attempt to explain why a royalty based on use of the method would be impractical in this case. He did not attempt to value any efficiencies or patient health advantages gained by practicing the patented method compared to non-patented methods or explain why this could not be done. Nor did he identify any other evidence relating to the value of the claimed method relative to other methods or explain why such a valuation would not be possible.

In addition, Mr. Carlson included in his damages calculations sales of all of St. Jude's outer catheters, inner catheters, guide wires, and leads, even though it was undisputed that not all of those sold devices had been used to practice the claimed method. Appellant's Br. 56 (noting that claim 11 is the "predominant" method). Whether one refers to this as failure to "apportion" as the parties and district court did or as failing to limit damages to a reasonable approximation of actual infringing uses of the claimed method, Mr. Carlson's failure to account for noninfringing uses of the sold devices was legally improper. In this regard, we disagree with Niazi's carefully worded assertion on appeal that apportionment does not apply to method claims. Damages should be apportioned to separate out noninfringing uses, and patentees cannot recover damages

⁵ We address this issue notwithstanding our affirmance of summary judgment of noninfringement of claim 11 because method claims 24–27 remain at issue on remand.

based on sales of products with the mere capability to practice the claimed method. Rather, where the only asserted claim is a method claim, the damages base should be limited to products that were actually used to perform the claimed method. *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348, 1358–59 (Fed. Cir. 2009).

It is true that "we have never laid down any rigid requirement that damages in all circumstances be limited to specific instances of infringement proven with direct evidence." Lucent, 580 F.3d at 1334. But Mr. Carlson did not address or rely on any evidence-such as testimony of electrophysiologists, other anecdotal testimony, or survey evidence—that estimated the amount or percentage of sold devices that were actually used to infringe the claimed method. Niazi asserts in its appeal brief that the claimed method was the "predominant method" and that, therefore, because damages do not have to be more than a reasonable approximation, it was reasonable to include all sales. First, the appendix page that Niazi cites for this "predominant method" assertion, J.A. 716, says nothing about frequency of use and does not support its assertion. Second, even assuming that the record supported the notion that the claimed method was the "predominant" method, predominant is a broad word that merely means "most frequent" or "common." Such a broad, unsupported, and conclusory assertion does not reliably establish how often the patented method was used by doctors to allow a reasonable approximation of the damages base.

We are also not persuaded by Niazi's argument that Mr. Carlson properly included leads in his calculation of the royalty base because he accounted for apportionment in the royalty rate. Appellant's Br. 54–55 (citing *Exmark*, 879 F.3d at 1348). We do not see any apportionment analysis—either in calculating the base or calculating the rate—in the portions of Mr. Carlson's report provided to this court. There is simply no explanation of how (or even whether) he apportioned to account for unpatented uses

when selecting the minimum royalty rate of 14.6%. And the explanation provided in Niazi's brief—that Mr. Carlson selected a range of rates from 6.0% to 16.63%, Appellant's Reply Br. 30—is contradicted by the report itself. Mr. Carlson did not provide a range of reasonable royalty rates; rather, he concluded that a royalty rate of 14.6% "is the *minimum* reasonable royalty [rate] under [his] quantitative analysis." J.A. 728 (emphasis added); *see also* J.A. 726 (opining that a "reasonable royalty rate is 14.60%, and that [Niazi] and St. Jude would have reasonably entered into a license at that rate"); J.A. 729 (indicating 14.6% is the reasonable royalty rate).

For at least these reasons, we see no abuse of discretion by the district court in excluding Mr. Carlson's conclusory and legally insufficient analysis.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the foregoing reasons, we reverse the district court's determination that claims 1, 10, 13–15, 18–19, and 23–27 are invalid as indefinite and remand for further proceedings. As to claim 11, we affirm the district court's summary judgment of no induced infringement. Finally, we affirm the district court's exclusion of portions of Dr. Burke's and Mr. Carlson's expert reports for failure to disclose predicate facts during fact discovery; its award of monetary sanctions for violating that exclusion order; and its exclusion of Mr. Carlson's damages expert report as unreliable.

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

COSTS

No costs.