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FEDERAL CIRCUIT DECLINES TO FIND PATENT CLAIMS INDEFINITE FOR BROAD DESCRIPTIVE WORDS (AND AN ODE TO 1L CIVIL PROCEDURE)

Niazi Licensing Corporation v. St. Jude Medical S.C., Inc.,
30 F.4th 1339 (Fed. Cir. 2022)♦

In a recent decision, the U.S. Court of Appeals for the Federal Circuit (“Federal Circuit”) handed down a ruling on the definiteness prong of patentability.¹ While the case tackled multiple issues on appeal, this Comment primarily focuses on two: whether claims are invalid for use of descriptive words or terms of degree, and whether sanctions are appropriate for failing to disclose predicate facts during discovery.² First, the panel unanimously disagreed with the district court’s analysis of claims containing two descriptive terms, “resilient” and “pliable,” and reversed the judgment holding claims indefinite for use of these terms.³ Ultimately, while the disputed terms were broad, they were not uncertain to a skilled artisan and did not amount to purely subjective terms that changed with a person’s opinion.⁴ Next, while the panel upheld the district court’s order of sanctions, Niazi missed an opportunity to have the panel weigh in on the appropriate test for the exclusion of previously undisclosed evidence.⁵ This outcome is an important reminder that procedural posture can have a ripple effect on downstream infringement claims.⁶

I. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiff-Appellant Niazi Licensing Corporation (“Niazi”) is the owner of U.S. Patent No. 6,638,268 (the “’268 patent”), titled “Catheter to Cannulate the Coronary Sinus.”⁷ Defendant-Appellee St.

♦ By Janelle Barbier, J.D. Candidate, Santa Clara University School of Law, 2023. I am forever grateful to my 1L civil procedure professor, Marina Hsieh, for my love of procedure.

¹ See *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1346 (Fed. Cir. 2022). Under the definiteness requirement, patent claims must particularly point out and distinctly claim the subject matter regarded as the invention. See 35 U.S.C. § 112 ¶2. The ’268 patent was issued in 2003 and is governed by the pre-AIA regime.

² See *Niazi*, 30 F.4th at 1346–47.

³ Judge Bryson, Judge Stoll, and Judge Taranto sat on the three-judge panel. See *id.* at 1342, 1346.

⁴ See *id.* at 1349–50.

⁵ See *id.* at 1354.

⁶ An analysis of how the procedural question could have affected Niazi’s claim of infringement is discussed *infra*, Section III.

⁷ *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 311 F. Supp. 3d 1078, 1079 (D. Minn. 2018).

Jude Medical S.C., Inc. (“St. Jude”) manufactures and sells medical devices, including a “telescoping catheter system” (the accused product).⁸ The ’268 patent is directed to resynchronization therapy—a method of treating heart failure that uses electrical leads to keep both sides of the heart consistently contracting together.⁹ The invention improves this therapy through the use of a double catheter—comprising an outer and inner catheter—that makes it easier to pass a lead into the veins of the heart.¹⁰

Claim 1 is directed to an apparatus and is representative of the claims on appeal for indefiniteness; the claim recites, in relevant part:

1. A double catheter, comprising:
 - an outer, *resilient* catheter having shape memory . . . ;
 - an inner, *pliable* catheter slidably disposed in the outer catheter¹¹

Claim 13—dependent on claim 1—further defines the outer catheter as having “sufficient stiffness”; other dependent claims provide exemplary resilient materials for constructing the outer catheter, such as “braided silastic.”¹²

The specification describes the outer catheter as having “sufficient shape memory to return to its original shape when undistorted” and a “braided design,” with resilience providing for “torque control and stiffness.”¹³ It also provides examples of materials that can be used to make the inner catheter, such as silicone; it further explains that the inner layer lacks longitudinal braiding, making it flexible, and that it is more flexible than the outer catheter.¹⁴

Claim 11 survived the invalidity challenge and is directed to a method of using the double catheter to place a lead in the coronary sinus vein.¹⁵ The claim recites, in relevant part:

11. A method . . . using a double catheter . . . comprising:
 - inserting the catheter* into the coronary sinus;

⁸ *Id.*

⁹ *Niazi*, 30 F.4th at 1343.

¹⁰ *Id.* (citing ’268 patent Abstract).

¹¹ *Id.* (citing ’268 patent col. 6 l. 62–col. 7 l. 9) (emphases added to disputed limitation).

¹² *Id.* at 1349 (citing ’268 patent col. 8 ll. 13–27, 33–34).

¹³ *Id.* (citing ’268 patent col. 4 ll. 21–23, col. 5 ll. 4–6, col. 3 ll. 11–13).

¹⁴ *Id.* (citing ’268 patent col. 3 ll. 13–15, col. 5 ll. 13–18).

¹⁵ *Niazi*, 30 F.4th at 1344.

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 vein¹⁶

Niazi alleged that St. Jude’s products directly infringed the ’268 patent and that St. Jude’s instructions for use (“IFU”) induced its customers, mainly doctors, to infringe when performing resynchronization therapy.¹⁷ To support its allegations, Niazi submitted an expert report from its technical expert, Dr. Martin Burke, stating that Dr. Burke himself had directly infringed claim 11 when using St. Jude’s products.¹⁸

In 2017, Niazi sued St. Jude for direct and indirect patent infringement in the District of Minnesota.¹⁹ St. Jude’s claims for induced, contributory, and willful infringement all survived motions for dismissal; the claim for direct infringement was not challenged at this stage.²⁰ On cross-motions for summary judgment, the district court held that all but one of the asserted claims of the ’268 patent were indefinite—on the lone claim that survived, summary judgment of noninfringement was entered following resolution of evidentiary motions.²¹ As to direct infringement, the district court found that St. Jude’s instructions for use (“IFU”) did not direct users to complete steps in the same order required by claim 11.²²

During pre-trial proceedings in the district court, St. Jude moved to strike portions of Dr. Burke’s expert report on the basis that the report relied on facts not disclosed during discovery and that Niazi had not identified Dr. Burke as a potential fact witness.²³ The district

¹⁶ *Id.* at 1343–44 (citing ’268 patent col. 7 l. 63–col. 8 l. 9) (emphases added to disputed limitation).

¹⁷ *Id.* at 1344–45.

¹⁸ *Id.* at 1344.

¹⁹ *See id.* at 1342, 1344; *see also Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, No. 17-CV-5096, 2021 WL 4947712, at *1 (D. Minn. Oct. 25, 2021).

²⁰ *See Niazi*, 311 F. Supp. 3d at 1079.

²¹ *Niazi*, 30 F.4th at 1344–45 (citing *Niazi Licensing Corp. v. Bos. Sci. Corp.*, No. 17-CV-5094, 2019 WL 5304922, at *5–7 (D. Minn. Oct. 21, 2019), *aff’d in part, rev’d in part and remanded sub nom. Niazi*, 30 F.4th 1339 (district court’s ruling on indefiniteness); *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, No. 17-CV-5096, 2021 WL 1111074, at *8 (D. Minn. Mar. 23, 2021) (district court’s ruling on infringement)).

²² *Id.* at 1345.

²³ *Id.* at 1344.

court agreed with St. Jude, excluding the evidence under Rule 37 and precluding Dr. Burke from testifying as a fact witness.²⁴ The district court also assessed monetary sanctions against Niazi for failing to disclose predicate facts during discovery and excluded portions of its damages expert report as unreliable.²⁵

The Federal Circuit affirmed each of the district court's rulings, except on invalidity—the panel reversed the judgment on indefiniteness and remanded the case to determine the issue of infringement and to assess St. Jude's remaining invalidity defenses.²⁶

II. LEGAL ANALYSIS AND CONCLUSION

Niazi brought four issues on appeal. First, it challenged the district court's determination that the terms “resilient” and “pliable” rendered all but one claim indefinite.²⁷ Because all apparatus claims were invalidated for indefiniteness, Niazi could only pursue an indirect infringement claim for its remaining method claim.²⁸ Second, it contested the district court's ruling on induced infringement of Claim 11—the only claim to survive summary judgment—and disagreed that the elements of direct infringement and specific intent to encourage infringement were not proven.²⁹ Third, Niazi argued that the district court abused its discretion in assessing monetary sanctions and attorney fees against it, as well as excluding evidence that it submitted, for repeatedly failing to disclose facts during discovery.³⁰ Finally, Niazi disputed that its damages expert report was unreliable and speculative due to failure of its expert to apportion damages when calculating the royalty base.³¹

Writing for the panel, Judge Stoll first addressed the issue of definiteness—a statutory requirement under 35 U.S.C. § 112—by

²⁴ *Id.* at 1344–45. “Rule 37” refers to Federal Rule of Civil Procedure 37 in this Comment.

²⁵ *Id.* at 1344 (citing *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, No. 17-CV-5096, 2020 WL 1617879, at *1–3 (D. Minn. Apr. 2, 2020) (district court's ruling on sanctions); *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, No. 17-CV-5096, 2020 WL 5512507, at *9–11 (D. Minn. Sept. 14, 2020) (district court's ruling on damages report)).

²⁶ *See id.* at 1342–43.

²⁷ *Niazi*, 30 F.4th at 1344.

²⁸ “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 IFU for use (IFUs) for its CPS catheter.” *Id.* at 1345.

²⁹ *Id.* at 1345.

³⁰ *Id.* at 1353–56.

³¹ *Id.* at 1356–57.

laying out the *Nautilus* standard.³² This requirement serves the important policy goal of providing notice to the public of what is claimed and “mandates clarity, while recognizing that absolute precision is unattainable.”³³ When a patentee uses descriptive words or terms of degree in claim language, the key inquiry is whether the language provides objective boundaries to a skilled artisan when read in context of the invention.³⁴ And “a claim is not indefinite just because it is broad.”³⁵

Next, the panel recounted cases where the Federal Circuit decided the definiteness of descriptive words and terms of degree in claim language. Starting with cases where terms of degree were found to meet the definiteness standard, two cases were instructive.³⁶ First, the phrase “visually negligible,” in a claim element of a graphical indicator, was defined by the claim language itself—“whether it could be seen by the normal human eye.”³⁷ The prosecution history was also highly relevant; the examiner understood the meaning of the phrase through prosecution, as did both parties’ experts during the course of litigation.³⁸ Second, the term “not interfering substantially” was definite due to the written description and prosecution history providing examples with which a skilled artisan could compare an accused product to.³⁹

Turning to cases where terms of degree rendered claims indefinite, the predominant theme was that the intrinsic and extrinsic evidence “provided insufficient guidance as to any objective boundaries for the claims.”⁴⁰ The panel started with a classic example

³² See *id.* at 1346 (citing *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014)) (“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.’”).

³³ *Niazi*, 30 F.4th at 1346 (citing *Nautilus*, 572 U.S. at 910).

³⁴ *Id.* at 1347.

³⁵ *Id.*

³⁶ See *id.* at 1347–48.

³⁷ *Id.* at 1347 (citing *Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1371–73, 1378 (Fed. Cir. 2017)).

³⁸ *Id.* at 1348.

³⁹ In the disputed claim language, the term “not interfering substantially” applied to a chemical compound’s ability to associate with a nucleic acid, based on interference caused by a linkage group. *Niazi*, 30 F.4th at 1348 (citing *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1329, 1334–35 (Fed. Cir. 2010)).

⁴⁰ See *id.*

of a purely subjective term: “aesthetically pleasing.”⁴¹ In that case, nothing in the record supplied a standard for measuring the scope of the phrase—the scope changed depending on a person’s subjective determination.⁴² Similarly, the term “QoS requirements” was indefinite because it was defined by what characteristic was most important to a user, making it dependent “on the unpredictable vagaries of any one person’s opinion.”⁴³ In sum, the scope of a claim cannot be determined with reasonable certainty when it employs purely subjective terms.⁴⁴

As indefiniteness is reviewed *de novo*, the panel concluded by reviewing the evidence presented in the district court.⁴⁵ The intrinsic evidence, of the claim language read in light of the specification, was enough to resolve the issue.⁴⁶ Claim 1’s language conveyed that the resilient outer catheter must have “shape memory.”⁴⁷ And the written description provided exemplary materials for each catheter.⁴⁸ The panel found St. Jude’s reliance on a single sentence in the written description unpersuasive because the specification explained that each catheter must have degrees of stiffness and flexibility that were relative to each other.⁴⁹ Therefore, the claim terms at issue were not “purely subjective terms” and did not give rise to variable claim scope “depending on the particular eye of any one observer.”⁵⁰ In other words, taken as a whole, the intrinsic record provided a standard for measuring the scope of the terms.⁵¹

⁴¹ See *id.* (citing *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1345, 1349–56 (Fed. Cir. 2005)).

⁴² *Id.*

⁴³ *Id.* (citing *Intellectual Ventures I, LLC v. T-Mobile USA, Inc.*, 902 F.3d 1372, 1375–76, 1381–82 (Fed. Cir. 2018)).

⁴⁴ The Federal Circuit “drew a similar conclusion as to the claim phrase ‘unobtrusive manner that does not distract the viewer.’” *Id.* (citing *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371–74 (Fed. Cir. 2014)).

⁴⁵ See *Niazi*, 30 F.4th at 1345 (“Definiteness is a question of law that we review *de novo*.”), 1349.

⁴⁶ See *id.* at 1349.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ St. Jude argued that *Niazi* was inconsistent in its description of the terms at issue, pointing to a sentence in the written description that stated that both catheters “preferably have a predetermined shape and a certain degree of stiffness to maintain such shape . . . but still flexible enough to bend when required.” The panel responded that “the outer catheter has a greater degree of stiffness and less flexibility compared to the inner catheter.” See *id.* at 1350 (citing *Niazi*, 2019 WL 5304922, at *6).

⁵⁰ *Id.* at 1349–50.

⁵¹ *Niazi*, 30 F.4th at 1349.

Moreover, the extrinsic evidence of dictionary definitions buttressed the panel’s conclusion on definiteness, illustrating that the plain language would have understood meanings by skilled artisans.⁵² The panel held that the claims using the terms “resilient” and “pliable” were not indefinite because the “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.”⁵³

Moving to the issue of infringement on claim 11, the panel began with the first part of an infringement analysis: claim construction.⁵⁴ The panel agreed 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)”; thus, direct infringement could not be proven.⁵⁵ Because an essential element of indirect infringement was lacking, the panel declined to reach the issue of whether Niazi presented evidence that St. Jude acted with the requisite specific intent to support the claim.⁵⁶

The remaining issues were reviewed under an abuse of discretion standard.⁵⁷ In sum, the panel concluded that the court did not abuse its discretion in any of its decisions regarding the evidentiary motions and sanctions.⁵⁸

But hiding in this pile of motions was an interesting question on civil procedure: whether the Eighth Circuit’s four-factor test for exclusion of previously undisclosed evidence had survived Rule 37’s enactment.⁵⁹ Consistent with Federal Circuit precedent, the panel reviewed the district court’s decision to issue sanctions under Rule 37 under the law of the Eighth Circuit, which employs an abuse of discretion standard.⁶⁰ Niazi argued that the district court abused its discretion in applying the four-factor test.⁶¹ However, as the panel pointed out, the district court did not rely on the four factors; instead,

⁵² See *id.* at 1350 (quoting Dictionary.com) (explaining that “‘resilient’ is defined as ‘returning to the original form or position after being bent, compressed, or stretched’” and that “‘pliable’ [] is defined as ‘easily bent, flexible, supple’”).

⁵³ See *id.*

⁵⁴ See *id.* at 1350–53.

⁵⁵ See *id.* at 1353.

⁵⁶ See *id.* at 1351.

⁵⁷ See *Niazi*, 30 F.4th at 1353, 1356.

⁵⁸ See *id.* at 1353, 1355, 1358.

⁵⁹ See *id.* at 1354 n.4.

⁶⁰ See *id.* at 1353 (citing *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1370–71 (Fed. Cir. 2002); *Vanderberg v. Petco Animal Supplies Stores, Inc.*, 906 F.3d 698, 702 (8th Cir. 2018)).

⁶¹ *Id.* at 1354.

it analyzed whether Niazi's failures were "substantially justified or harmless" under Rule 37(c)(1).⁶² And because Niazi did not challenge the actual basis for the district court's conclusion—nor the court's determination that it need not consider the four-factor test—the Federal Circuit declined to reweigh the factors on appeal.⁶³

Moreover, even assuming, without deciding, that the four-factor test was controlling, the panel found that Niazi had not identified a legal or factual error in the district court's decision to not analyze the factors.⁶⁴ Because of this omission by Niazi, the panel affirmed the district court's rulings without reaching the procedural question.⁶⁵

III. DISCUSSION

There are two important takeaways from this case. First, the case summarizes nicely what to do—and what not to do—to avoid an indefiniteness holding when drafting claims with terms of degree. If possible, define the terms in the claim language itself. In the case of "resilient," for example, the term could almost be seen as superfluous, given that its definition was contained in the same claim. Recall that claim 1 recited "a resilient catheter having shape memory."⁶⁶ And the dictionary definition—provided by the Federal Circuit—specified that "resilient" meant "returning to its original form or position after being [manipulated]."⁶⁷ Thus, "resilient" likely could have stood on its own because its standard definition mirrored that intended by the claim language. This point is illustrated in the term "pliable" being defined by its plain and ordinary meaning despite that term standing alone in the claim language.

In addition to clear claim language, use the specification to resolve any doubts of ambiguity. Providing examples gives a person skilled in the art a reference point for which to compare accused products and allows that person to opine on claim scope with reasonable certainty, as required under *Nautilus*. A patent's written description can also be used to compare claim elements—it is not necessary to venture outside the invention as comparing elements within a claim can provide a reference range. Utilizing the specification in this manner provides the objective standard with which to measure a claim's scope by—the gold standard in an indefiniteness

⁶² See *id.* The district court relied on the principles articulated in *Vanderberg v. Petco*, discussed *infra*. See *Niazi*, 2020 WL 1617879, at *2.

⁶³ See *Niazi*, 30 F.4th at 1354 n.4.

⁶⁴ See *id.*

⁶⁵ See *id.* at 1354.

⁶⁶ See *id.* at 1343 (citing '268 patent col. 6 l. 62–col. 7 l. 9).

⁶⁷ See *id.* at 1350.

analysis.⁶⁸ Finally, dictionary definitions can bolster the interpretation of claim language, especially when the meaning ascribed by a patent owner aligns with the plain and ordinary meaning of the term in everyday use.

A Note For Civil Procedure Nerds

Finally, the case is a reminder that it is important to preserve, and articulate, objections based on civil procedure as much as with issues concerning substantive patent law. This is especially salient under the deferential abuse of discretion standard.⁶⁹ The remainder of this Comment analyzes the procedural question alluded to by the Federal Circuit—whether the Eighth Circuit’s common law tests remain viable in light of Rule 37—and whether preserving the issue for appeal would have changed the outcome for Niazi. On appeal, Niazi would need to show two things to prevail: (1) the district court abused its discretion; and (2) that error resulted in prejudice to Niazi.⁷⁰

As a threshold matter, for procedural issues that are not intertwined with substantive patent law, the law of the regional circuit governs.⁷¹ In addition, this issue presents a classic preemption question on whose rules control procedure in federal court. At first blush, the *Erie* doctrine may come to mind; law students and practitioners alike will almost certainly recall this doctrine which permeates much of the

⁶⁸ Indeed, the Federal Circuit has repeatedly referred to the need to define a claim’s “objective boundaries.” See, e.g., *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1364 (Fed. Cir. 2018) (finding claims indefinite for use of the term “minimal redundancy” because they lacked objective boundaries); *Guangdong Alison Hi-Tech Co. v. Int’l Trade Comm’n*, 936 F.3d 1353, 1360 (Fed. Cir. 2019) (finding claims definite because the written description provided objective boundaries for the claim term “lofty . . . batting”).

⁶⁹ “The question, of course, is not whether this Court, or whether the Court of Appeals, would as an original matter have dismissed the action; it is whether the District Court abused its discretion in so doing.” *Nat’l Hockey League v. Metro. Hockey Club, Inc.*, 427 U.S. 639, 642 (1976) (explaining that the record supported the district court’s decision to issue sanctions under Rule 37).

⁷⁰ See *Wegener v. Johnson*, 527 F.3d 687, 690 (8th Cir. 2008) (explaining that even if a district court abuses its discretion, the appellant must also show that affirming the error would result in “fundamental unfairness”); see also *Petrone v. Werner Enterprises, Inc.*, 940 F.3d 425, 436 (8th Cir. 2019) (“Notwithstanding the district court’s error, we will affirm unless Defendants can show the error was not harmless.”).

⁷¹ The Federal Circuit “review[s] procedural matters, that are not unique to patent issues, under the law of the particular regional circuit court where appeals from the district court would normally lie.” See *Panduit Corp. v. All States Plastic Mfg. Co.*, 744 F.2d 1564, 1574–75 (Fed. Cir. 1984).

civil procedure curriculum.⁷² As a refresher, *Erie* says that federal courts must apply state substantive law and federal procedural law when sitting in diversity.⁷³

True, this is not a diversity case. But as commentators have pointed out, “in instances in which the relevant regional circuit has not addressed the particular procedural issue before the Federal Circuit,” the court’s choice of law process “strikingly resembles the methodology federal courts undertake” when applying the *Erie* doctrine.⁷⁴ In this situation, the court seeks to step into the shoes of the regional circuit.⁷⁵ Moreover, when it comes to interpreting the Federal Rules of Civil Procedure, the Federal Circuit has indicated that generally, it defers to the regional circuit.⁷⁶ And the court has previously addressed Rule 37 in a panoply of cases.⁷⁷

Armed with this choice of law framework, we can analyze the facts in this case. When determining whether to exclude previously undisclosed evidence, the Eighth Circuit has traditionally relied on two different tests.⁷⁸ Niazi focused on one of the tests which consists of

⁷² The *Erie* doctrine originated from *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938).

⁷³ See *id.* at 78 (“Except in matters governed by the Federal Constitution or by acts of Congress, the law to be applied in any case is the law of the state.”), 92 (Reed, J., concurring in part) (“no one doubts federal power over procedure”).

⁷⁴ See Jennifer E. Sturiale, *A Balanced Consideration of the Federal Circuit’s Choice-of-Law Rule*, 2020 UTAH L. REV. 475, 487 (2020).

⁷⁵ See *id.* (citing *Panduit*, 744 F.2d at 1575) (explaining that the Federal Circuit seeks to “predict how that regional circuit would have decided the issue in light of the decisions of that circuit’s various district courts, [and] public policy”). The court also considers “whether there is a consensus among the regional circuits, the need to promote uniformity in patent law, and the nature of the legal issue involved”—it generally conforms its law “to that of the regional circuits when there exists expressed uniformity among the circuits.” *Id.* at 490 (citing *Manildra Milling Corp. v. Ogilvie Mills, Inc.*, 76 F.3d 1178, 1181 (Fed. Cir. 1996)).

⁷⁶ However, deference to regional circuit law is inappropriate in some cases. See *Manildra*, 76 F.3d at 1181–82.

⁷⁷ See *Biodex Corp. v. Loredan Biomedical, Inc.*, 946 F.2d 850, 857 n.10 (Fed. Cir. 1991) (collecting cases) (describing cases where the Federal Circuit reviewed district courts’ application of Rule 37).

⁷⁸ See *Marti v. City of Maplewood, Mo.*, 57 F.3d 680, 683 (8th Cir. 1995) (“Two similar tests, or sets of factors, have been used by this court to determine whether a witness’s testimony should be excluded if that witness was not named in the pretrial order.”).

four factors.⁷⁹ The second test used by the Eighth Circuit also consists of four factors.⁸⁰ Under such tests, application of the factors is “within the sound discretion of the district court.”⁸¹

Apart from these common law tests, the Federal Rules of Civil Procedure—under Rule 37—allow for “a self-executing sanction for failure to make a disclosure required by Rule 26(a).”⁸² The Eighth Circuit has summarized Rule 37 by explaining that if a party does not satisfy the disclosure requirements, “the undisclosed information or expert is excluded unless the failure was substantially justified or harmless.”⁸³ District courts in the Eighth Circuit are split on whether Rule 37 mandates exclusion when an exception does not apply—the appellate court has not opined on this question.⁸⁴

Here, the district court explained that the Eighth Circuit has been silent on whether a common law test has survived Rule 37’s enactment, going so far as to state that “contrary to [Niazi]’s argument, there is no such four-factor test.”⁸⁵ Although the Eighth Circuit has explained that it is not error for district courts to consider this balancing test in evaluating the admissibility of undisclosed evidence, the district court reasoned that the circuit’s opinion predated the effective date of Rule 37.⁸⁶ The district court went on to cite an Eighth Circuit case that

⁷⁹ See *Niazi*, 30 F.4th at 1354. The factors are: “(1) the reason the party fails to name the witness; (2) the importance of the testimony; (3) the amount of time the opposing party needs to properly prepare for the testimony; and (4) whether a continuance would in some way be useful.” *Citizens Bank of Batesville, Arkansas v. Ford Motor Co.*, 16 F.3d 965, 966 (8th Cir. 1994).

⁸⁰ The factors are: “(1) the prejudice or surprise in fact of the party against whom the excluded witness would have testified; (2) the ability of that party to cure the prejudice; (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court; and (4) bad faith or willfulness of the party failing to comply with the court’s order.” *Marti*, 57 F.3d at 683 (citing *Morfeld v. Kehm*, 803 F.2d 1452, 1455 (8th Cir.1986)).

⁸¹ *Niazi*, 30 F.4th at 1354 n.4 (citing *Citizens*, 16 F.3d at 967).

⁸² FED. R. CIV. P. 37(c) advisory committee’s note to 1993 amendment.

⁸³ See *Vanderberg*, 906 F.3d at 702–03.

⁸⁴ *Id.* at 703 n.3.

⁸⁵ See *Niazi*, 2020 WL 1617879, at *7.

⁸⁶ See *id.* at *7 n.2 (citing *Carmody v. Kansas City Bd. of Police Comm’rs*, 713 F.3d 401, 405 (8th Cir. 2013)). Rule 37 was first enacted in 1937. Presumably, the district court was referring to the FRCP’s most recent amendment which occurred in 2015. However, Rule 37(c)(1) was not changed in 2015. This alone may be sufficient proof that the Eighth Circuit has not discarded its factored analysis. See FED. R. CIV. P. 37 advisory committee’s note to 2015 amendment; see also J. Ben Segarra, *2015 Amendments to the*

referred to a mixture of factors taken from both tests, explaining that the factors apply when fashioning an alternative to Rule 37's exclusion sanction, but *only* upon motion from the aggrieved party.⁸⁷

At the heart of the issue is whether Rule 37(c) mandates exclusion. But even assuming, *arguendo*, that Rule 37's exclusion sanction is compulsory, there is still a question of whether the Rule applies in a particular case. A review of recent Eighth Circuit cases reveals that the circuit still considers the factors enumerated in its precedential cases. For example, in *Wegener v. Johnson* (cited to by the district court), the appellate court looked at the importance of the evidence and the effect that its admission would have on scheduling.⁸⁸ This compels the conclusion that—if Rule 37 must be imposed for disclosure failures that are not harmless nor substantially justified—the tests are alive and well. In other words, the circuit observes both Rule 37 and its common law precedent—it applies its common law factors to decide whether a failure to disclose evidence was harmless or substantially justified.⁸⁹

Federal Rules of Civil Procedure, AM. BAR ASS'N PRAC. POINTS (Jan. 23, 2017).

⁸⁷ See *Niazi*, 2020 WL 1617879, at *7 n.2 (citing *Wegener*, 527 F.3d at 692) (explaining that courts should consider “the reason for noncompliance, the surprise and prejudice to the opposing party, the extent to which allowing the information or testimony would disrupt the order and efficiency of the trial, and the importance of the information or testimony”). Whether *Niazi* was required to file a motion to request an alternative sanction is outside the scope of this Comment and is separate from the purported misapplication of the four-factor test. However, the Eighth Circuit has said that “[w]here a party fails to make a timely disclosure, Federal Rule of Civil Procedure 37(c)(1) provides the district court with the authority to exclude the late-disclosed materials or to fashion a lesser penalty than total exclusion.” *Vogt v. State Farm Life Ins. Co.*, 963 F.3d 753, 771 (8th Cir. 2020), *cert. denied*, 141 S. Ct. 2551 (2021).

⁸⁸ See 527 F.3d at 692 (“a continuance would have postponed a much-delayed trial, and the testimony was offered to prove a point upon which a substantial amount of other evidence was presented to the jury”); see also *Hillesheim v. Holiday Stationstores, Inc.*, 903 F.3d 786, 790 (8th Cir. 2018) (assessing surprise to the opposing party and the usefulness of a continuance); *Jackson v. Allstate Ins. Co.*, 785 F.3d 1193, 1204 (8th Cir. 2015) (finding that the opposing party failed to demonstrate surprise); *Doe v. Young*, 664 F.3d 727, 735–36 (8th Cir. 2011) (explaining that a continuance is more appropriate than exclusion to cure unfair surprise); *Davis v. U.S. Bancorp*, 383 F.3d 761, 765 (8th Cir. 2004) (agreeing with the district court that there was no unfair surprise to the opposing party).

⁸⁹ Interestingly, the magistrate judge (whose exclusion order was adopted by the district court) relied on an opinion that used this exact framework, albeit from a district court in a different appellate jurisdiction. See *Dedmon v. Cont'l*

This brings us to the million-dollar question—would a proper objection by Niazi have made a difference? The Eighth Circuit makes clear that if a district court errs in its legal conclusion, it abused its discretion.⁹⁰ As explained above, concluding that the factored tests were dead was likely legal error. In fact, the Federal Circuit touched on this oversight.⁹¹ But Niazi could not rely solely on the district court’s error—it would also need to show that affirming the error would result in “fundamental unfairness.”⁹²

Niazi likely could have demonstrated resulting prejudice from the district court’s refusal to analyze the appropriateness of sanctions under the factored tests. Notably, the Eighth Circuit’s factors weigh the harm caused to each party by excluding or admitting the evidence.⁹³ By not using this approach, the district court focused mainly on the harm that would result to St. Jude if Niazi’s evidence was admitted.⁹⁴ However, as described below, the harm to Niazi resulting from *not* admitting the evidence was arguably greater.

Niazi could have taken aim at the district court’s ruling by showing that the excluded evidence had strong probative value.⁹⁵ In that sense, its exclusion was not harmless—at least not to Niazi. At the Federal Circuit, Niazi argued that “St. Jude admits that Dr. Burke’s testimony as a direct infringer was important, which weighs against exclusion.”⁹⁶ Indeed, the Eighth Circuit has placed great weight on the

Airlines, Inc., No. 13-CV-0005-WJM-NYW, 2015 WL 4639737, at *1–5 (D. Colo. Aug. 5, 2015).

⁹⁰ See *Union Elec. Co. v. Energy Ins. Mut. Ltd.*, 689 F.3d 968, 970 (8th Cir. 2012) (“A district court abuses its discretion when it applies an incorrect legal standard[.]”). While a district court has discretion over evidentiary rulings, the Eighth Circuit exercises de novo review over “whether the district court applied the correct legal standard in exercising that discretion[.]” See *Sherman v. Winco Fireworks, Inc.*, 532 F.3d 709, 714 (8th Cir. 2008).

⁹¹ See *Niazi*, 30 F.4th at 1354 n.4 (“Niazi does not challenge the district court’s legal determination that it need not consider these factors.”).

⁹² See *Wegener*, 527 F.3d at 690. It is possible that the Eighth Circuit would view exclusion of evidence, based on “an erroneous view of the law,” as giving rise to fundamental unfairness. See *Davis*, 383 F.3d at 765.

⁹³ Indeed, the Eighth Circuit has referred to the four-factor test as a “balancing test.” See *Carmody*, 713 F.3d at 405.

⁹⁴ See *Niazi*, 2020 WL 1617879, at *3 (“NLC’s failure to timely produce such discovery evidence is not harmless simply because any prejudice can be remedied by a continuance and additional depositions”).

⁹⁵ See *Wegener*, 527 F.3d at 694.

⁹⁶ See Reply Brief of Plaintiff at *23, *Niazi*, 30 F.4th 1339 (No. 2021-1864).

importance of evidence targeted for exclusion.⁹⁷ Furthermore, the circuit instructs that “[w]here the exclusion of evidence is tantamount to dismissal, a district court may need to first consider the possibility of lesser sanctions.”⁹⁸

Given that Dr. Burke’s testimony was integral—perhaps even tantamount—to Niazi’s success on the merits of its infringement claim, its exclusion surely prejudiced Niazi.⁹⁹ And because the Federal Circuit would seek to resolve the issue by predicting how the Eighth Circuit would decide the issue, the importance of this testimony would weigh strongly against exclusion.¹⁰⁰ The matter became even more critical because Niazi succeeded in obtaining a reversal of the district court’s indefiniteness ruling, giving Niazi another chance to prove infringement.

To be sure, even if Niazi had identified a cognizable legal or factual error on the exclusion issue, along with resulting prejudice, that would not equate with an automatic win on its infringement claim. But it would have earned Niazi a remand; in other words, Niazi would have lived to fight another day, bringing with it evidence of direct infringement. And another day in the world of patent litigation is priceless.

⁹⁷ See, e.g., *Wegener*, 527 F.3d at 693 (explaining that “supplemental testimony, though relevant, was not that important to [plaintiff]’s case because it was offered to prove a point in support of which a substantial amount of other evidence was presented to the jury”).

⁹⁸ See *Vanderberg*, 906 F.3d at 704–05.

⁹⁹ 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.’” *Niazi*, 30 F.4th at 1354.

¹⁰⁰ See *MLC Intell. Prop., LLC v. Micron Tech., Inc.*, 10 F.4th 1358, 1370–73 (Fed. Cir. 2021) (analyzing a district court’s ruling to exclude evidence under Rule 37 by looking to the law of the regional circuit); see also *Askan v. FARO Techs., Inc.*, 809 F. App’x 880, 884 (Fed. Cir. 2020) (“We apply regional circuit law when we review a district court’s decision to sanction a litigant pursuant to Federal Rule of Civil Procedure 37.”).