

United States Court of Appeals for the Federal Circuit

2007-1560

DR. PETER RENTROP,

Plaintiff-Appellee,

v.

THE SPECTRANETICS CORPORATION,

Defendant-Appellant.

Marvin S. Gittes, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo P.C., of New York, New York, argued for plaintiff-appellee. With him on the brief was Timur E. Slonim.

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Appealed from: United States District Court for the Southern District of New York

Judge P. Kevin Castel

United States Court of Appeals for the Federal Circuit

2007-1560

DR. PETER RENTROP,

Plaintiff-Appellee,

v

THE SPECTRANETICS CORPORATION,

Defendant-Appellant.

Appeal from the United States District Court for the Southern District of New York in case no 04-CV-0101, Judge P Kevin Castel.

DECIDED: December 18, 2008

Before MICHEL, Chief Judge, FRIEDMAN, Circuit Judge, and WALKER^{*}, Chief District Judge.

WALKER, Chief District Judge.

Defendant-appellant The Spectranetics Corporation (“Spectranetics”) appeals from a final judgment of the district court awarding \$500,000 to plaintiff-appellee Dr Peter Rentrop. The judgment was based on a jury’s verdict that found claim 1 of Rentrop’s United States Patent No 6,673,064 (“the ’064 patent”) not invalid and infringed. After trial, the district court considered and rejected Spectranetics’s defense

* Honorable Vaughn R Walker, Chief Judge, United States District Court for the Northern District of California, sitting by designation.

of inequitable conduct, see Rentrop v Spectranetics Corp, 514 F Supp 2d 511 (SDNY 2007), and denied Spectranetics's motion for judgment as a matter of law on infringement. See Rentrop v Spectranetics Corp, 514 F Supp 2d 497 (SDNY 2007). On appeal, Spectranetics challenges the lower court's decisions on infringement and inequitable conduct and also argues that it is entitled as a matter of law to judgment of invalidity of claim 1 and other claims of the '064 patent. For the reasons discussed below, we affirm the judgment of the district court.

I

Dr Peter Rentrop is a cardiovascular interventionist with over thirty years of experience in medicine. He is chief of cardiovascular research at St Vincent's Hospital and Medical Center in New York City. Spectranetics is a Delaware corporation located in Colorado Springs, Colorado. It specializes in the design, marketing and sale of products for use in angioplasty (the widening of an obstructed blood vessel).

The '064 patent, issued to Rentrop on January 6, 2004, describes an "Excimer Laser Catheter." Excimer laser catheters are used to perform angioplasty procedures. The catheters deliver laser energy which penetrates arterial blockages, or occlusions, in order to enlarge the arterial channel for increased bloodflow or, in the case of the invention described by the '064 patent, to enlarge the channel sufficiently to allow other treatments, such as balloons or stents, to be administered.

Spectranetics is the only company with FDA approval to sell excimer laser catheters for use in human angioplasty in the United States. Rentrop became involved with Spectranetics when, from 1991 to 1996, he served as director of a cardiology symposium of which Spectranetics was a sponsor. When Spectranetics's first excimer

laser catheters became clinically available, Rentrop was trained in their use by Spectranetics, and Rentrop began using them routinely in 1995. At that time, Spectranetics sold excimer laser catheters in its “Extreme” catheter line with tip diameters of 1.4 mm, 1.7 mm and 2 mm.

In around 1996 or 1997, Rentrop began to disfavor use of the Extreme catheters, in part because he found them too inflexible to navigate bends in narrow arteries. Rentrop believed a smaller diameter laser catheter could be developed that would be useful in narrow arteries. In 1998, Rentrop communicated his idea for a 0.9 mm excimer laser catheter to Spectranetics. Over the course of twenty months of frequent communication with Kevin Taylor, Spectranetics’s director of engineering, Rentrop helped Spectranetics create a prototype of Rentrop’s proposed laser catheter. This involved an iterative process in which Kenneth Harlan, a Spectranetics technician, created prototypes of the proposed laser catheter and presented them to Rentrop, who inspected them and proposed modifications. After the final prototype was created, Rentrop conducted an animal study of the device in early 2000. A clinical trial followed, and Spectranetics gained FDA approval for and began marketing several models of 0.9 mm excimer laser catheters based on the prototype; these are the accused products in this patent litigation.

During their collaboration on development of the prototype, a disagreement arose between Rentrop and Spectranetics regarding financial recognition of Rentrop’s work. Rentrop and Spectranetics were not able to reach an agreement, so Rentrop sought to patent his invention. The ’064 patent, which is at issue in this appeal, was issued to

Rentrop on January 6, 2004. It is a continuation of and claims priority to a patent application filed January 4, 2000.

The claim at issue in this appeal is claim 1 of the '064 patent. It states:

An excimer laser catheter, comprising:
a catheter shaft containing optical fibers in a concentric arrangement, a tip extending from the catheter shaft and having a diameter that is smaller than that of the catheter shaft, the tip having a length of at least 1 cm and a diameter less than 1 millimeter, each of the optical fibers extending through a full length of the tip and a full length of the catheter shaft, the catheter shaft being configured to be stiffer and less flexible than the tip so as to be pushable to push the tip into a desired site even though the tip negotiates arterial bends to reach the desired site.

'064 patent col 4, ln 60 – col 5, ln 4 (emphasis added).

On January 6, 2004, Rentrop filed a complaint alleging that Spectranetics's accused products infringed various claims, including claim 1, of the '064 patent. Spectranetics asserted defenses including obviousness and inequitable conduct and counterclaimed to, among other things, correct inventorship of the '064 patent. A jury trial was held and on December 8, 2006, the jury returned its verdict that the accused products infringed claim 1, but not claim 2, 3 or 7, of the '064 patent, that the '064 patent was not invalid, and that Rentrop was the sole inventor of the '064 patent.¹ After trial, Spectranetics filed a renewed motion for judgment as a matter of law on infringement, which the district court denied on August 23, 2007. Rentrop, 514 F Supp 2d at 499. Spectranetics did not challenge the jury's validity determination in the trial court. The

¹ The parties stipulated that the jury's verdict on infringement and validity of: (a) claim 1 also will apply to claims 8, 15, 16 and 17; (b) claim 2 also will apply to claims 9 and 18; (c) claim 3 also will apply to claims 4, 10, 11, 19 and 20; and (d) claim 7 also will apply to claims 14 and 23.

district court also considered and rejected Spectranetics's defense of inequitable conduct. Rentrop, 514 F Supp 2d 511.

Spectranetics timely appealed. We have jurisdiction pursuant to 28 USC § 1295(a)(1).

II

We turn first to Spectranetics's argument regarding obviousness. Spectranetics cannot, of course, attack the basis for the jury's obviousness verdict directly as it did not move for judgment as a matter of law on obviousness. Rather, Spectranetics argues that claim 1 of the '064 patent was so clearly obvious based on the prior art presented to the jury that the only possible explanation for the jury not finding the claim to be obvious was that the district court gave a rigid "teaching, suggestion or motivation" jury instruction in violation of the Supreme Court's recent decision in KSR Int'l Co v Teleflex Inc, 550 US 398 (2007).

Rentrop argues that Spectranetics waived its argument based on KSR because Spectranetics did not bring this argument to the district court's attention before entry of judgment. We agree. KSR was decided on April 30, 2007. The jury returned its verdict on December 8, 2006, and briefing on post-trial motions was completed by February 20, 2007 — over two months before KSR was decided. The district court, however, did not decide the post-trial motions until August 23, 2007, and judgment was not entered until August 24, 2007, almost four months after the decision in KSR.

In Sage Products, Inc v Devon Industries, Inc, 126 F3d 1420 (Fed Cir 1997), we had occasion to discuss why we do not allow new arguments to be presented for the first time on appeal:

This is an appellate court. By and large, it is our place to review judicial decisions—including claim interpretations and grants of summary judgment—reached by trial courts. No matter how independent an appellate court's review of an issue may be, it is still no more than that—a review. With a few notable exceptions, such as some jurisdictional matters, appellate courts do not consider a party's new theories, lodged first on appeal. If a litigant seeks to show error in a trial court's overlooking an argument, it must first present that argument to the trial court. In short, this court does not “review” that which was not presented to the district court.

Id, 126 F3d at 1426. Although Sage Products involved new arguments presented on appeal of summary judgment of non-infringement that were not based on an intervening change in the law, its reasoning applies here. Where possible, every legal argument should be presented first to the trial court. KSR was decided almost four months before the trial court entered judgment, giving Spectranetics ample time to bring that decision to the trial court's attention. Had Spectranetics done so, the trial court — if it agreed that the jury instructions on obviousness were incorrect under KSR — could have taken appropriate action and possibly obviated the need for this appeal. Spectranetics points out that we have taken up the KSR jury instruction issue several times where it had not been brought before the district court first, but in the cases Spectranetics cites, judgment was entered by the district court before KSR was decided. See Cordis Corp v Medtronic AVE, Inc, 511 F3d 1157 (Fed Cir 2008); Black & Decker, Inc v Robert Bosch Tool Corp, 260 Fed App'x 284 (Fed Cir 2008).

We hold that when there is a relevant change in the law before entry of final judgment, a party generally must notify the district court; if the party fails to do so, it waives arguments on appeal that are based on that change in the law. Spectranetics did not bring KSR to the attention of the district court and therefore has waived its

arguments based on KSR. The jury's determination that the '064 patent is not invalid will not be disturbed.

Although we hold that Spectranetics waived its arguments based on KSR, we note that the jury instructions on obviousness in this case appear to be consistent with KSR. KSR — a case in which jury instructions were not at issue — rejected a “formalistic conception of the words teaching, suggestion and motivation.” KSR, 127 S Ct at 1741. The Court held that the commonly used teaching, suggestion and motivation (“TSM”) test provides a “helpful insight,” noting that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” Id. But the Court held that applying the TSM principle as a rigid rule is error. Id.

Spectranetics challenges the jury instruction because it stated:

In evaluating the scope and content of the prior art, you should keep in mind that there must have been some suggestion for a person skilled in the art to make the combination covered by the claims of the patent in issue in order for the claims to have been obvious.

In other words, a claim in a patent is not obvious and invalid, simply because the claim combines elements that can all be found among the prior art references. It must have been a motivation or a suggestion to combine the limits in a manner disclosed by the patent.

While this instruction might violate KSR if it were the only instruction, the district court went on to define motivation for the jury: “The motivation may arise from common knowledge, or common sense of the person of ordinary skill in the art, without any specific hint or suggestion in a particular reference.”

Thus, the court instructed the jury on the TSM principle, but described it in unrigid terms. These instructions on the TSM principle are similar to the instructions in Cordis, 511 F3d at 1172, where we held the instructions at issue did not conflict with KSR.

Spectranetics also challenges the jury instructions as impermissibly prohibiting an “obvious to try” inquiry. In KSR, the Court held it was error to conclude that a “patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try.” KSR, 127 S Ct at 1742 (internal quotation omitted). But the portion of the jury instructions Spectranetics challenges reads:

You must also keep in mind that the test for obviousness is not whether or not it would have been obvious to try to make the invention, but rather whether or not the inconvenience [sic] would have been obvious to a person of ordinary skill in the inventor’s field at the time the invention was made.

Read in context, this instruction states, correctly, that the test for obviousness is not whether it would be obvious to try to solve the problem that the invention solves. The instruction does not imply that a showing that the specific combination of elements was obvious to try is insufficient to find obviousness.

Even if Spectranetics had not waived its KSR argument, it appears that it would not have been entitled to relief from the jury’s finding of nonobviousness.

III

We turn next to Spectranetics’s appeal from the district court’s denial of judgment as a matter of law on infringement.

The Federal Circuit “defers to the law of the regional circuits on matters of procedural law that do not implicate issues of patent law.” Duro-Last, Inc v Custom Seal, Inc, 321 F3d 1098, 1106 (Fed Cir 2003). “Thus for questions relating to Rule 50

motions generally, this court has applied regional circuit law.” *Id.* The Second Circuit has stated that a “Rule 50 motion may be granted only when, considering the evidence in the light most favorable to the non-moving party and drawing all reasonable evidentiary inferences in that party’s favor, there was ‘no legally sufficient evidentiary basis for a reasonable jury to find’ in favor of the non-moving party.” Nimely v City of New York, 414 F3d 381, 390 (2d Cir 2005) (quoting Fed R Civ P 50(a)). We agree with the district court that sufficient evidence was presented to sustain the jury’s finding that Spectranetics’s accused products infringed claim 1 of the ’064 patent.

Spectranetics’s non-infringement argument centers on the claim term “tip.” The district court construed “tip” as “that which serves as the end, cap or point of an object.” While Spectranetics’s accused products have a component that has all the characteristics of the “tip” described in claim 1, the accused products also have a hard glue and platinum band at the very end of the device. This hard band, Spectranetics argues, is the “tip” of their accused products. Because claim 1 of the ’064 patent requires that “the catheter shaft be[] configured to be stiffer and less flexible than the tip,” Spectranetics argues that its products’ hard and stiff “tip” is not covered by the claim.

Rentrop’s infringement expert, Dr Edward Sinofsky, explained, however, that the hard glue and platinum band, a radiopaque feature included so the device would be visible on a scanning machine, was not the entire tip of the accused products (the entire tip of the accused products being more flexible and less stiff than the catheter shaft). Spectranetics argues that Sinofsky’s testimony was not based on the court’s construction of “tip” and that therefore his testimony was confusing to the jury.

Spectranetics relies on the following exchange during the cross-examination of Sinofsky:

Q. Dr Sinofsky, when you gave your opinion on infringement, did you take into account the Court's Markman ruling?

A. I'm not sure what that is.

Q. All right. So you don't know what I'm talking about?

A. I've heard of the Markman ruling, but I don't know what it is.

Spectranetics is overreaching. The exchange above demonstrates only that Sinofsky was unfamiliar with the legal term "Markman hearing," not that he was unaware of the court's construction of "tip." Indeed, on redirect examination, Sinofsky testified that he had heard of and understood the district court's definition of "tip."

Sinofsky's identification of the tip of Spectranetics's accused products and his explanation of how the tip read on claim 1 of the '064 patent were consistent with the court's claim construction, and the jury was entitled to credit them. Spectranetics is not entitled to judgment as a matter of law of noninfringement of claim 1 of the '064 patent.

IV

Finally, we turn to Spectranetics's appeal of the district court's determination that Spectranetics failed to establish the affirmative defense of inequitable conduct.

"To prove that a patent is unenforceable due to inequitable conduct, the alleged infringer must provide clear and convincing evidence of (1) affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information and (2) an intent to deceive." Impax Labs, Inc v Aventis Pharm Inc, 468 F3d 1366, 1374 (Fed Cir 2006). A fact is material if it is material

under either PTO Rule 56 or the “reasonable examiner” standard. Digital Control Inc v Charles Machine Works, 437 F3d 1309, 1316 (Fed Cir 2006).

PTO Rule 56 states that:

[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim, or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

37 CFR § 1.56(b) (2008).

“Under the earlier ‘reasonable examiner’ standard, ‘information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.’” Cargill, Inc v Canbra Foods, Ltd, 476 F3d 1359, 1364 (Fed Cir 2007) (quoting 37 CFR § 1.56(a) (1991)).

The intent element requires that “the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.” Impax Labs, 468 F3d at 1374-75. Intent need not be proven by direct evidence; it is usually inferred from the facts and circumstances surrounding the conduct at issue. Id at 1375.

If a district court finds materiality and intent by clear and convincing evidence, it must “balance the equities to determine whether the patentee has committed inequitable conduct that warrants holding the patent unenforceable.” Id. “The more material the omission or the misrepresentation, the lower the level of intent required to

establish inequitable conduct, and vice versa.” Critikon, Inc v Becton Dickinson Vascular Access, Inc, 120 F3d 1253, 1256 (Fed Cir 1997).

We review the district court’s findings on the issues of materiality and intent for clear error. Impax Labs, 468 F3d at 1375. The ultimate decision regarding inequitable conduct is reviewed for abuse of discretion. Id.

In this case, Spectranetics argues that the district court erred by not finding inequitable conduct based on Rentrop’s nondisclosure or inadequate disclosure of several items of prior art and his minimization of the role of Spectranetics in the development of the invention disclosed by the ’064 patent. But the district court considered these arguments and addressed each of them in a well-reasoned opinion. See Rentrop, 514 F Supp 2d at 525-30. For only one of the alleged failures to disclose material information (regarding Spectranetics technician Harlan’s performance of a “chicken bone” test of the device that was referenced in the patent) did the district court find even a weak inference of intent to deceive, and in that case, the district court found the nondisclosure to be not highly material. Id at 529. In no other instance of non-disclosure did the district court find even a threshold level of intent. Rather, it determined that Rentrop’s testimony was “credible in all material respects.” To establish that the district court abused its discretion when it balanced the equities and held that the low materiality and weak inference of intent to deceive regarding the “chicken bone” experiment did not warrant finding the ’064 patent unenforceable or that it clearly erred by not finding clear and convincing evidence of materiality and intent to deceive for the other alleged nondisclosures, Spectranetics would need to provide

compelling evidence of materiality and intent to deceive. It has not done so, and it is not entitled to reversal of the district court's rejection of the inequitable conduct defense.

CONCLUSION

For the reasons discussed above, we conclude that Spectranetics waived its challenge to the jury instructions on obviousness, that the jury's verdict of infringement was supported by legally sufficient evidence and that the district court's determination that Spectranetics did not establish an inequitable conduct defense was not an abuse of discretion or based on clearly erroneous findings of fact. Accordingly, we affirm the judgment of the district court.

AFFIRMED

No costs.