United States Court of Appeals for the Federal Circuit

2007-1530

THE JOHNS HOPKINS UNIVERSITY
and ARROW INTERNATIONAL, INC.,

Plaintiffs-Appellees,

v.

DATASCOPE CORPORATION,

Defendant-Appellant.

Kenneth P. George, Amster, Rothstein & Ebenstein LLP, of New York, New York, argued for plaintiffs-appellees. With him on the brief were Ira E. Silfin, Marc J. Jason, and Rebecca R. Eisenberg.

Roy H. Wepner, Lerner, David, Littenberg, Krumholz & Mentlik, LLP, argued for defendant appellant. With him on the brief was Paul H. Kochanski.

Appealed from: United States District Court for the District of Maryland

Judge William D. Quarles, Jr.

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THE JOHNS HOPKINS UNIVERSITY and
ARROW INTERNATIONAL, INC.,

Plaintiffs-Appellees,

v.

DATASCOPE CORPORATION,

Defendant-Appellant.

Appeal from the United States District Court for the Northern Division of Maryland in consolidated case nos. 05-CV-00759 and 06-CV-02711, Judge William D. Quarles, Jr.

DECIDED: October 2, 2008

Before NEWMAN and SCHALL, Circuit Judges, and ZOBEL, District Judge.[*]

Opinion for the court filed by District Judge, ZOBEL. Dissenting opinion filed by Circuit Judge, NEWMAN.

Datascope Corporation ("Datascope") appeals from a final judgment of infringement and contributory infringement of claim 1 of United States Patent No. 5,766,191 ("the '191 patent"), claims 16-17, 27 and 34 of United States Patent No. 6,824,551 ("the '551 patent") and claims 1, 3-7 and 15-18 of United States Patent No. 7,108,704 ("the '704 patent"). Johns Hopkins Univ. & Arrow Int'l, Inc. v. Datascope Corp., 513 F. Supp. 2d 578 (D. Md.

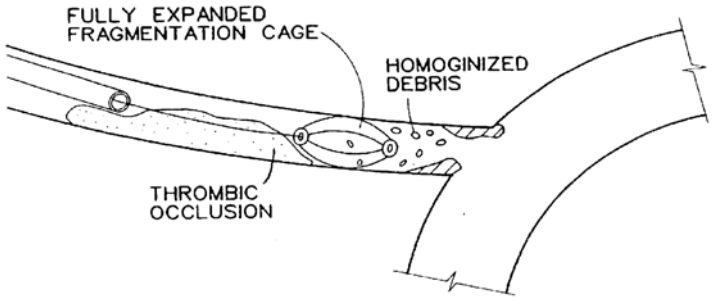
[*] Honorable Rya W. Zobel, District Judge, United States District Court for the District of Massachusetts, sitting by designation.

2007). For the reasons set forth below, we reverse the judgment of infringement of the asserted claims of the three patents-in-suit.

BACKGROUND

Johns Hopkins University ("Hopkins") is the owner and Arrow International, Inc. ("Arrow") the exclusive licensee of the '191, '551 and '704 patents, each titled "Percutaneous Mechanical Fragmentation Catheter System." All three patents are directed to methods for mechanically fragmenting blood clots, particularly thrombus material occluding synthetic vascular grafts, and all share a common specification.

The patented methods address the problem that patients undergoing chronic hemodialysis experience blockage of their dialysis access grafts approximately three or four times per year. In each of the claimed methods, a fragmentation catheter is introduced into the vascular conduit, typically through an outer sheath. Upon deployment, a fragmentation cage or basket at the distal end of the catheter expands to conform to the inner lumen of the vascular conduit (as shown in figure 11C reproduced below). After deployment, the fragmentation cage is rotated at a speed high enough to homogenize the thrombotic material obstructing the vascular conduit. The homogenized debris can then be safely flushed or aspirated.



Plaintiffs' complaint alleges that use of defendant's ProLumen device infringes the '191 and '551 patents. After the '704 patent issued, plaintiffs filed a second action alleging infringement of that patent as well. The two cases were consolidated and then bifurcated, with infringement and Datascope's affirmative defense of obviousness to be tried to a jury first and Datascope's affirmative defenses of inequitable conduct and unclean hands as to the '704 patent to be determined by the court after a later trial. On June 15, 2007, a jury found: (1) that Datascope indirectly infringed all asserted claims of the three patents; (2) that the asserted independent claim of each patent was not invalid and not obvious; and (3) that each plaintiff is entitled to damages, $460,583 to Arrow and $230,292 to Hopkins.

The following month, the district court held the bench trial on Datascope's defenses of inequitable conduct and unclean hands. It concluded that Datascope had not proven any misconduct by the attorney who prosecuted the '704 patent and therefore upheld the enforceability of the three patents against these defenses. Johns Hopkins Univ., 513 F. Supp. 2d at 584.

On the issues of infringement and obviousness, defendant moved pursuant to Rules 50 and 59 for judgment as a matter of law ("JMOL") or, in the alternative, a new trial. The district court denied both. On obviousness, the court noted that Datascope's evidence of prior art was presented through the testimony of its expert, Dr. Thomas Aretz. Id. Because the jury was free to determine the credibility of the witness and disbelieve his testimony, its verdict was not wrong as a matter of law and the court therefore denied the motion for JMOL. Id. at 584-85. The court also denied the motion for a new trial because Datascope's arguments did not address the grounds for a new trial under Fed. R. Civ. P. 59(a), as articulated by the Fourth Circuit. On infringement, the district court held that the

jury's conclusion was not against the clear weight of the evidence, and therefore denied the motion for JMOL or a new trial on that issue as well. Id. Finally, the court entered judgment in accordance with the jury's verdict and its own findings. Datascope filed a timely appeal from the judgment, and we have jurisdiction thereof under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I

We review the denial of JMOL without deference by applying the JMOL standard used by the district court. BBA Nonwovens Simpsonville, Inc. v. Superior Nonwovens, LLC, 303 F.3d 1332, 1336 (Fed. Cir. 2002). In the Fourth Circuit, "a motion for judgment as a matter of law should be granted if a district court determines, without weighing the evidence or considering the credibility of the witnesses, that substantial evidence does not support the jury's findings." Id. The denial of a motion for a new trial is reviewed for an abuse of discretion. Id. We review "[the] jury's conclusions on obviousness, a question of law, without deference, and the underlying findings of fact, whether explicit or implicit within the verdict, for substantial evidence." LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1353 (Fed. Cir. 2001). The determination of inequitable conduct is committed to the discretion of the district court and we review its decision for abuse of that discretion. Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V., 528 F.3d 1365, 1374 (Fed. Cir. 2008).

II

We hold that the jury's verdict of infringement of claim 1 of the '191 patent, claims 16-17, 27 and 34 of the '551 patent and claims 1, 3-7 and 15-18 of the '704 patent was not

supported by substantial evidence and that defendant's motion for JMOL should have been granted. We do not reach the other issues raised on appeal given Datascope's concession at oral argument that we need not reach a decision on invalidity if we find that its motion for JMOL was wrongly denied.

III

Each of the asserted independent claims in the patents-in-suit requires introducing, into a vascular conduit, a fragmentation catheter comprised either of a fragmentation member or an expanding distal end that automatically "expands to conform to the shape and diameter of the inner lumen" of the vascular conduit. Only claim 1 is asserted in the '191 patent. That claim provides in its entirety:

> A method for fragmenting thrombotic material in a vascular conduit comprising the steps of:
>
> introducing a fragmentation catheter in a vascular conduit to a thrombotic occlusion, wherein the fragmentation catheter comprises a fragmentation member at a distal end portion thereof that automatically expands to conform to the shape and diameter of the inner lumen of the vascular conduit upon deployment of the fragmentation member;
>
> deploying the fragmentation member; and
>
> rotating the fragmentation member at a speed to homogenize the thrombotic material.

'191 patent, col.8 ll.31-42 (filed Feb. 29, 1996) (emphasis added).

Asserted independent claim 16 of the '551 patent is identical to claim 1 of the '191 patent except that it does not require the "expands to conform" limitation to occur "upon deployment of the fragmentation member" and it does not include the second step requiring "deploying the fragmentation member." '551 patent, col.9 ll.44-54 (filed Dec. 3, 2002). Two of the other asserted claims of the '551 patent, 27 and 34, depend from four independent

claims, 1, 9, 16 and 19, of which 16 is the broadest, but all of which include the "expands to conform" limitation. Asserted claim 17 depends solely from claim 16.

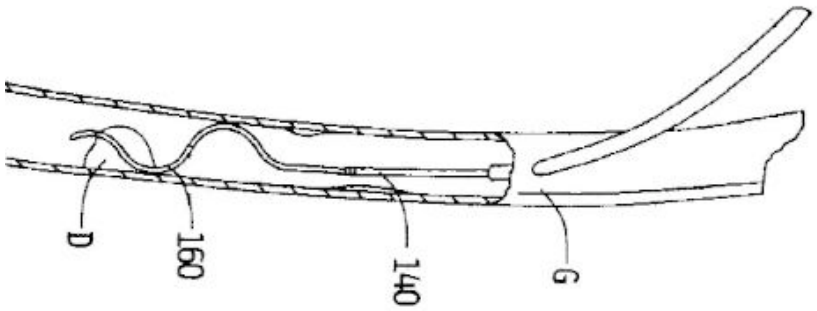
Claim 1 of the '704 patent is similar to the independent claims asserted in the other two patents except that it does not specifically require a fragmentation member. Rather, it requires only that the fragmentation catheter include an "expandable distal end." '704 patent, col.8 l.43 (filed Oct. 7, 2004). This claim also includes an additional limitation requiring "withdrawing the rotating expandable distal end through the thrombotic material in the vascular conduit." Id., col.8 ll.52-53. All of the asserted dependent claims of the '704 patent depend from independent claim 1.

The parties disagreed on the meaning of the phrase "expands to conform to the shape and diameter of the inner lumen" and the term "fragmentation member," used in the '191 and '551 patents. In its memorandum on claim construction, the district court held that the latter was a means-plus-function term and limited it to the wire cage or basket described in the specification, along with any equivalents. See 35 U.S.C. § 112, ¶ 6. As to the former, the court concluded that "diameter" referred to a "horizontal cross-section" of the vein "regardless of whether it forms a circle," while "shape" referred to the capability of the fragmentation member to "adjust to remain in contact with the sides of the inner lumen along its length." Johns Hopkins Univ. & Arrow Int'l, Inc. v. Datascope Corp., Nos. 05-CV-0759 and 06-CV-2711, 2007 WL 1575077, at *3 (D. Md. May 30, 2007). Based on this interpretation, the court instructed the jury as follows:

> The other term that is at issue here is the "expands to conform to the shape and diameter of the inner lumen." The claims at issue contain this phrase, which means that the fragmentation member in the '191 and '551 patents and the distal end in the '704 patent expands and adjusts to remain in contact with the inner lumen in three dimensions along its length and width.

(Trial Tr. vol. 3, 812, Jun. 14, 2007 ("Jury Instructions").)

In the place of a basket, defendant's device, the ProLumen, uses a single "S" shaped wire ("S-wire") which is rotated to break up thrombotic material (as shown below, 160 in figure 18 from United States Patent No. 7,037,316).[1]



The only evidence supporting plaintiffs' contention that use of the ProLumen literally meets the "expands to conform" limitation was presented through the testimony of their expert, Dr. Karim Valji ("Valji"). Valji opined that the S-wire in the ProLumen device expands and adjusts to remain in contact with the inner lumen in three dimensions along its length and width. He based this opinion on an animation Datascope produced showing the operation of the ProLumen and a demonstration of the deployment of the device before the jury. In each case he testified that as it is deployed, the S-wire "corkscrews" and expands in "both the shape and diameter of the inner lumen" as it exits its outer protective sheath:

> [A]s it's deployed, it travels in a spiral-type direction, so it's moving forward in one direction, and then it's also moving outwardly in the shape of a cylinder in the other two directions, much as a corkscrew would be used to remove a

[1] The fact that Datascope's device is separately patentable does not preclude a finding of infringement. See Nat'l Presto Indus. v. West Bend Co., 76 F.3d 1185, 1191 (Fed. Cir. 1996).

cork from a bottle of wine.

(Trial Tr. vol. 5, 277-78, Jun. 12, 2007.) While Valji agreed that the asserted methods also require that the fragmentation member or distal end remain in contact with the inner lumen in three dimensions even after deployment, the only basis he offered to support his opinion that the ProLumen met this limitation, even after it springs back to its original "S" shape, was his description of the Datascope animation:

> And we can see again that [the ProLumen is] expanding, it's filling the lumen in all three dimensions around the circumference of it, spinning around, breaking up the clot.

(Id. at 272.) However, each of the asserted independent claims in the three patents requires the "expands to conform" limitation to be met prior to rotation. The '191 and '704 patents require the limitation to be met "on deployment" and they each include, as a separate step, "deploying the fragmentation member/expandable distal end" prior to the rotation step. '191 patent, col.8 ll.37, 39; '704 patent, col.8 ll.46, 48. Asserted claim 16 of the '551 patent does not include a separate deployment step. However, it still requires introduction of "a fragmentation member at a distal end portion thereof that automatically expands to conform to the shape and diameter of the inner lumen of the vascular conduit" prior to the rotation step. '551 patent, col.9 ll.50-52. The "expands to conform" limitation is separate from the rotation element, therefore the distal end of the fragmentation member must meet the "conforms to" requirement whether it is rotating or not. Valji's testimony, that the S-wire fills the lumen in all three dimensions as it rotates does not address the requirement that the fragmentation member or distal end remain in contact with the inner lumen in three dimensions before rotation. In addition, the fact that the S-wire sweeps

through a volume, i.e. that it fills the lumen as it rotates, is not evidence that it makes contact with the inner lumen in three dimensions at any particular instant in time.

Indeed, on cross-examination Valji testified repeatedly that the ProLumen only contacts the lumen at two points, even while rotating:

> Q. Is it your testimony that, when the S wire of the ProLumen is deployed, the wire, at any time, makes the same kind of helical wraparound contact with the inside of the lumen – continuous contact, so to speak? Does it ever do that?
>
> A. It – the device does make continuous contact with the lumen at certain points.
>
> Q. At certain points. How many points?
>
> A. Two.
>
> Q. Two and only two, right?
>
> A. Right.

(Trial Tr. vol. 5, 304, Jun. 12, 2007.)

> Q. Now, let me ask you this: When [the ProLumen] rotates, if you were to take a very fast camera and take a stop action kind of shot at any given millisecond or whatever, what would you see in the tube?
>
> A. You would see the stationary wire.
>
> Q. The S wire making contact at only two points, correct?
>
> A. Correct.

(Id. at 314; see also id. at 318 ("There are two points of contact . . ."); id. at 324 (Valji describing the contact of the S wire with the vessel wall as "the two-point contact").)[2]

[2] Plaintiffs assert that "[t]he evidence included the testimony by Dr. Valji that 'when the ProLumen is rotated, there are effectively infinite numbers of contact . . . .' (A477), not just the two points of contact as contended by Datascope." (Pls' Brief at 35.) First, this is an equivalency argument; Valji's use of "effectively" acknowledges that there are not literally an infinite number of contacts. Yet, in the next sentence, plaintiffs assert

The video animation demonstrating the operation of the ProLumen device and relied on by Valji provides no evidence to support his opinion that the "expands to conform" limitation is literally met; rather, it is in agreement with his factual testimony. It clearly shows that, at deployment and prior to rotation, the S-wire fragmentor contacts the lumen at only two points along the longitudinal axis of the vessel. On rotation, the S-wire blurs to effectively fill the lumen and rout out the clot as the catheter is moved along the longitudinal dimension of the vessel, but there is no evidence to suggest that at any instant there are more than two points of contact with the inner wall of the lumen.

In reviewing the district court's denial of JMOL, we must "assume that testimony in favor of the non-moving party is credible, unless totally incredible on its face . . . ." Cline v. Wal-Mart Stores, Inc., 144 F.3d 294, 301 (4th Cir. 1998) (internal quotation marks and citation omitted). Here, accepting as true Valji's factual testimony, that the ProLumen device at all times after deployment only contacts the inner lumen at two points, his opinion

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that "the evidence presented to the jury was that this claim term was met literally." (Id.) Second, plaintiffs' selective editing obfuscates the meaning of Valji's testimony, which, taken in context, actually supports Datascope's contention:

> Q. Okay. With the ProLumen, the S-shaped wire, again there are only two points of contact; is that right?
>
> A. There are only two points of contact, but that's not where the work is being done – not at the points of contact.
>
> Q. Okay.
>
> A. And, when it's rotated, there are effectively infinite numbers of contact with the clot.

(Trial Tr. vol. 5, 318, Jun. 12, 2007 (emphasis added).) The claimed methods, however, require three dimensional contact with the inner lumen, not the clot.

that it remains in contact with the inner lumen in three dimensions along its length and width is incredible because it is impossible for use of this device to meet this limitation. As a matter of geometry, the two points of contact of the ProLumen S-wire can describe a two-dimensional plane along the length of the lumen, but cannot contact the inner lumen in three dimensions as required by the district court's claim construction. We therefore do not accept Valji's opinion in deciding whether substantial evidence exists to support the jury's finding of infringement. See Wechsler v. Macke Int'l Trade, Inc., 486 F.3d 1286, 1294 (Fed. Cir. 2007) (expert opinion contrary to the factual evidence need not be credited).

Substantial evidence is "more than a mere scintilla" and is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." z4 Techs., Inc. v. Microsoft Corp., 507 F.3d 1340, 1353 (Fed. Cir. 2007) (quoting Consol. Edison Co. v. NLRB, 305 U.S. 197, 229 (1938)). If, "after reviewing all of the evidence in a light most favorable to the prevailing party, this court is convinced that a reasonable jury could not have found in that party's favor, we must reverse the denial of a motion for judgment as a matter of law." Akamai Techs., Inc. v. Cable. & Wireless Internet Servs., Inc., 344 F.3d 1186, 1192 (Fed. Cir. 2003) (citation omitted). We have carefully considered plaintiffs' evidence that the S-wire expands and adjusts to "remain in contact with the inner lumen in three dimensions along its length and width." (Jury Instructions.) Here, no reasonable jury could have found that the ProLumen device literally met this limitation based on Valji's opinion, given his contradictory testimony that the device only contacts the vessel in two places.[3] See Hewlett-Packard Co. v. Mustek Sys., Inc., 340 F.3d 1314, 1321 (Fed. Cir.

[3] This is not to say that the jury in this case necessarily acted unreasonably.

2003) (holding that verdict of literal infringement was unsupported by substantial evidence because the accused device did not perform the required function as defined in the jury instruction). The district court's denial of JMOL on the issue of infringement was, therefore, in error.

IV

In view of our disposition of the case we need not reach the issues of obviousness or inequitable conduct nor consider defendant's alternative request for a new trial.

CONCLUSION

Because the jury's finding of infringement was not supported by substantial evidence, we reverse the court's denial of Datascope's motion for JMOL of non-infringement and remand to the district court for entry of a final judgment in favor of Datascope consistent with this opinion.

COSTS

While the judge instructed the jury on the doctrine of equivalents with respect to the fragmentation member, he did not explicitly limit the jury's consideration of the doctrine to that term. Valji testified that when the ProLumen's S-wire was rotated, it filled the lumen in three dimensions and effectively created an infinite number of contacts. In addition, Valji described to the jury a chart Datascope had submitted to the Food and Drug Administration ("FDA") showing that the ProLumen was equivalent to plaintiffs' device in terms of its safe and effective use in humans. In conjunction with Valji's generalized testimony as to the similarity between the claims and the function of the ProLumen, the jury may have concluded that the regulatory submission was evidence of equivalency, even though FDA equivalence is irrelevant to patent law because it involves fundamentally different inquiries. However, even if the jury did base its finding on equivalency rather than literal infringement, our conclusion would not change, as plaintiffs did not present the particularized testimony and linking argument necessary to support a jury finding of infringement on the basis of the doctrine of equivalents. See, e.g., Lear Siegler, Inc. v. Sealy Mattress Co., 873 F.2d 1422, 1426 (Fed. Cir 1989); Comark Communs. v. Harris Corp., 156 F.3d 1182, 1189 (Fed. Cir. 1998); see also Pls.' Br. at 35 ("the evidence presented to the jury was that [the expands to conform] claim term was met literally").

Each party shall bear its own costs.

REVERSED and REMANDED.

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NEWMAN, Circuit Judge, dissenting.

I respectfully dissent, for substantial evidence supported the jury verdict, as was recognized by the district court in denying judgment as a matter of law. My respected colleagues on this panel have not shown the absence of such evidence; indeed, they appear to recognize that it was present. There is no sufficient ground for this court's independent appellate trial of the factual issues that were decided by the jury and sustained by the district court.

In reviewing a jury verdict, the court must draw all reasonable inferences in favor of the verdict, without making credibility determinations and without reweighing the evidence. See, e.g., Reeves v. Sanderson Plumbing Products, Inc., 530 U.S. 133, 150 (2000) ("although the court should review the record as a whole, it must disregard all evidence

favorable to the moving party that the jury is not required to believe."). When reviewing a jury verdict, it is impermissible for the appellate court to substitute its own findings based on the evidence that was before the jury, for "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

The device that is shown in the Hopkins patent fragments blood clots through the rotation of a wire structure at the end of a lumen inserted into the blood vessel. This structure is claimed as a "fragmentation member," for when rotated the wires fragment the blood clot, scouring the blood vessel. No fragmentation occurs until the structure is rotated. The accused device also fragments blood clots through the rotation of a wire structure at the end of a lumen inserted into the blood vessel. This structure consists of a single S-shaped wire, not a group of wires as shown by Hopkins. When rotated, the S-shaped wire fragments the blood clot, scouring the blood vessel. No fragmentation occurs until the structure is rotated. A reasonable jury could have found that this wire structure is a "fragmentation member" of the claims, for both the Hopkins device and the Datascope device fragment the blood clot through the action of rotating wires.

Another claim limitation is that the fragmentation member "expands to conform" to the blood vessel. The wire structure at the end of the Hopkins lumen spreads, after release from the end of the lumen by which it is inserted, to contact the clot material in the blood vessel. The S-shaped wire structure at the end of the Datascope lumen also spreads, after release from the end of the lumen by which it is inserted, to contact the clot material in the blood vessel. When rotated, both structures conform to the size of the blood vessel where they are rotating.

The Hopkins evidence presented to the jury stressed the similarities of the wire

structures and their fragmentation action. The Datascope evidence presented to the jury stressed the differences of the wire structures and their fragmentation action. Datascope showed an animation of the accused device and both experts testified as to that animation. The jury saw the competing devices, and their operation was explained. Hopkins' expert Dr. Valji testified that the S-shaped wire at the end of the lumen in the accused device is a fragmentation member in that when it rotates it fragments the clot by wire action, like the wires at the end of the lumen in the Hopkins device. In considering the "wire cage or basket" shape of the Hopkins device, the jury heard Dr. Valji's testimony that "when . . . in . . . operable position, this S-shaped wire takes on the configuration essentially of a basket." Record at A445. Dr. Valji also testified that the accused device "when allow[ed] . . . to expand by deployment, will expand both the shape and diameter of the inner lumen of . . . the graft" meeting the "expands to conform" claim limitation. Record at A436. Datascope made contrary arguments, urging opposite conclusions.

The jury found infringement, on instructions that were agreed by the parties. The district court, denying Datascope's JMOL motion, stated that "[t]he jury's finding was certainly not against the clear weight of the evidence." Indeed, there was substantial evidence in support of the verdict. Whether or not there was also substantial evidence on the other side, "[a]n appellate court cannot substitute its interpretation of the evidence for that of the trial court simply because the reviewing court 'might give the facts another construction, resolve the ambiguities differently, and find a more sinister cast to actions which the District Court apparently deemed innocent.'" Inwood Laboratories, Inc. v. Ives Laboratories, Inc., 456 U.S. 844, 857-58 (1982) (quoting United States v. Real Estate Boards, 339 U.S. 485, 495 (1950)). I do not disagree that there was evidence and argument on Datascope's side. However, it is not our province to reweigh the evidence,

when there was substantial evidence by which a reasonable jury could have reached its verdict. See Tennant v. Peoria & Pekin Union Ry. Co., 321 U.S. 29, 35 (1944) ("Courts are not free to reweigh the evidence and set aside the jury verdict merely because the jury could have drawn difference inferences or conclusions or because judges feel that other results are more reasonable."); DMI, Inc. v. Deere & Co., 802 F.2d 421, 427 (Fed. Cir. 1986) ("When . . . there are conflicting elements in the evidence, neither the trial court on JNOV nor this court may substitute its choice for that of the jury.").

As the district court explained, a reasonable jury could have reached the verdict of infringement. I must, respectfully, dissent.