United States Court of Appeals for the Federal Circuit

2007-1340, -1341, -1342

KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC., and WAKE FOREST UNIVERSITY HEALTH SCIENCES,

Plaintiffs-Cross Appellants,

v.

BLUE SKY MEDICAL GROUP, INC.,

Defendant-Appellant,

and

RICHARD S. WESTON,

Defendant-Appellant,

and

MEDELA AG and MEDELA, INC.,

Defendants-Appellants.

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Appealed from: United States District Court for the Western District of Texas

Judge W. Royal Furgeson

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Defendants-Appellants.

Appeals from the United States District Court for the Western District of Texas in case no. 03-CV-0832, Judge W. Royal Furgeson, Jr.

DECIDED: February 2, 2009

Before BRYSON, DYK, and PROST, Circuit Judges.

Opinion for the court filed by Circuit Judge PROST. Dissenting opinion filed by Circuit Judge DYK.

PROST, Circuit Judge.

Defendants Medela, Inc. and Blue Sky Medical Group, Inc. appeal the denial of their motion for judgment as a matter of law on obviousness and their alternative motion

for a new trial on obviousness. They also appeal the district court's claim construction and failure to declare several claim terms indefinite. Plaintiff Kinetic Concepts, Inc. cross-appeals the denial of its motion for judgment as a matter of law on infringement and its alternative motion for a new trial on infringement.

For the reasons set forth below, we affirm.

I. BACKGROUND

Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health Sciences (collectively, "KCI") brought suit against Medela AG, Medela, Inc., Richard Weston, and Blue Sky Medical Group, Inc. (collectively, "Defendants"), alleging infringement of U.S. Patent Nos. 5,636,643 ("'643 patent") and 5,645,081 ("'081 patent"), as well as claims of false advertising, unfair competition, and conspiracy. Defendants responded with counterclaims alleging that the asserted patents were invalid and unenforceable. After a six week trial in the United States District Court for the Western District of Texas, the jury returned a verdict that the asserted patents were not shown to be invalid, unenforceable, or infringed. The jury also found against KCI on its false advertising, unfair competition, and conspiracy claims.

After trial, Defendants filed a motion for judgment as a matter of law ("JMOL") that the asserted claims are invalid as obvious under 35 U.S.C. § 103. In the alternative, Defendants requested a new trial on obviousness. KCI filed its own motion for judgment as a matter of law on infringement, or in the alternative, requested a new trial on infringement. The district court denied each of these motions.

Defendants now appeal the district court's denial of their JMOL motion on obviousness, arguing that under a proper claim construction no reasonable juror could

have found that the prior art did not render the asserted patents invalid. In the alternative, Defendants ask us to order a new trial on obviousness because the Supreme Court's decision in KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007), effected a supervening change in the law that retroactively rendered the jury instructions on obviousness erroneous. They also appeal the district court's determination that "selected stage of healing," "reduction in bacterial density in the wound by at least 50%," and "screen for prevention of overgrowth" are not indefinite claim limitations. KCI cross-appeals alleging that the district court erred by denying its motion for JMOL of infringement, and alternatively, requests a new trial on infringement because Defendants presented a "practicing the prior art" defense, compared the accused product to KCI's product, and engaged in "class warfare" before the jury.

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

A. The Asserted Patents

The patents at issue relate to treating difficult-to-heal wounds by applying suction, which is referred to in the patents as "reduced pressure" or "negative pressure." Claims 1 and 11 of the '643 patent, with emphases added, are illustrative:

> 1. An appliance for administering a reduced pressure treatment to a would [sic] comprising:
>
> (a) an impermeable cover adapted to cover and enclose the wound and adapted to maintain reduced pressure at the site of the wound;
>
> (b) a seal adapted to seal said cover to tissue surrounding the wound;
>
> (c) reduced pressure supply means for connection to a source of suction, said reduced pressure supply means cooperating with said cover to supply said reduced pressure beneath said cover; and
>
> (d) a screen adapted to prevent overgrowth of wound tissue, said screen being located between said wound and said cover.

11. A method treating a wound comprising the steps of:
    (a) applying a reduced pressure to the wound, wherein said applying step comprises the steps of:
        (i) placing a porous screen over the wound;
        (ii) locating an impermeable cover over the wound, said cover having a suction port;
        (iii) sealing the periphery of said impermeable cover to tissue surrounding the wound; and
        (iv) operably connecting said suction port with a vacuum system for producing said reduced pressure; and
    (b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing.

In addition to claims 1 and 11, KCI asserted claims 2, 3, 6, 7, 8, 12, 13, 14, 16, 26, 27, 28, 29, and 32 of the '643 patent. KCI also asserted claims 1, 3, 5, 8, 9, 11, 12, 13, 27, 31, 33, 36, 37, 54, 56, 58, 61, 62, 64, 65, and 66 of the '081 patent.

The issues on appeal focus on six limitations, at least one of which is present in each of the asserted claims. First, each of the asserted claims in both the '081 and '643 patents requires using "reduced" or "negative" pressure to "treat a wound" or "facilitate the healing of a wound," either as part of the preamble[1] or the body of the claim. Second, there is a "screen" or "screen means" limitation in each asserted claim of the '081 patent and claims 1, 2, 3, 11, and 12 of the '643 patent. Third, claims 12, 27, 33, 36, 37, 65, and 66 of the '081 patent and claims 13, 14, 28, and 29 of the '643 patent have limitations requiring the use of intermittent suction. Fourth, an "impermeable cover" limitation is present in claims 1, 2, 3, 6, 7, 8, 11, 12, 16, 26, 27, and 28 of the '643 patent.[2] Fifth, claims 11, 12, 29, and 32 of the '643 patent contain a limitation

[1] The parties concede that the preambles are limiting with respect to this limitation.

[2] Defendants argue that impermeable covers were well known by persons of ordinary skill in the art. However, as discussed below, KCI presented substantial evidence that the prior art did not teach or suggest the "treating a wound with negative

requiring treating toward a "selected stage of healing." Finally, claim 32 of the '643 patent recites "a reduction in bacterial density in the wound by at least 50%."

B. Claim Construction

The parties have devoted significant attention to the construction of "treating a wound" and "facilitating the healing of wounds." Defendants argued before the first claim construction order that "treating a wound," as used in claim 13 of the '643 patent, should be construed as "giving medical care to an injury," or in the alternative, "giving medical care to (1) trauma to any of the tissues in the body, especially that caused by physical means and with interruption of continuity [or] (2) a surgical incision." Kinetic Concepts, Inc. v. Blue Sky Med. Corp., No. 03-CV-0832, at 5 (W.D. Tex. June 28, 2005) ("Order Construing Patent '643 Terms") (alteration in original). In response, KCI argued that "treating a wound" should be construed to mean "treating tissue damage to the surface of the body, including the epithelial and subcutaneous layers," or in the alternative, should not be construed because the jury would have no difficulty understanding the phrase's ordinary meaning. Id. at 5-6; Pl.'s Br. on Claim Construction 8-10, Kinetic Concepts, Inc. v. Blue Sky Med. Corp., No. 03-CV-0832 (W.D. Tex. Mar. 7, 2005). In its first claim construction order, the district court construed the term "according to its plain and ordinary meaning as 'giving medical care to an injury.'" Order Construing Patent '643 Terms at 7.

After a Markman hearing on November 14, 2005, the district court issued a second claim construction order construing terms from the '643 and '081 patents. Kinetic Concepts, Inc. v. Blue Sky Med. Corp., No. 03-CV-0832 (W.D. Tex. Jan. 24,

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pressure" limitation, which was present in each of the asserted claims. Therefore, it is

2006) ("Order Construing Patents '643 and '081 Claim Terms"). In this order, the court relied on its previous construction of "wound" as "injury" and construed "facilitating the healing of wounds" to mean "facilitating the healing of injuries." Id. at 9.

In the middle of the trial, however, the district court suggested vacating the construction of "wound" in light of the fact that the parties had yet to use the word "injury" in front of the jury. After clarifying on the record that neither party was waiving its right to appeal, the court issued an order vacating its construction of "wound." Kinetic Concepts, Inc. v. Blue Sky Med. Corp., No. 03-CV-0832 (W.D. Tex. June 29, 2006) ("Second Amended Order Construing Patent '643 and '081 Claim Terms"). As a result, "treating a wound" was construed to mean "giving medical care to a wound." Id. At trial, the jury was given this construction of "treating a wound," but was not instructed on the meaning of "facilitating the healing of wounds."

The construction of the "screen" limitation is also relevant to this appeal. The district court construed this term to mean "a porous material that applies a counter-acting force to granulation tissue to stop growth of granulation tissue above the level of skin surrounding the wound, the porous material being positioned at the wound within the sealing means." Order Construing Patents '643 and '081 Claim Terms at 16-17.

C. The Prior Art

At trial, Defendants presented several prior art references that are relevant to this appeal. These include the Chariker-Jeter publications, the Chariker-Jeter prior uses, the Svedman article, the Johnson article, and the Davydov publications. KCI distinguished each of these references by arguing to the jury that they did not teach

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unnecessary for us to address the "impermeable cover" limitation.

"treating a wound with negative pressure" and thus could not render the claimed invention obvious.

The Chariker-Jeter prior art presented at trial included a journal article, a book chapter, testimony from Dr. Chariker about public uses of the Chariker-Jeter system, and assorted presentation materials. The Chariker-Jeter system, as described by these references, was originally developed to treat certain wounds that were complicated by a hole in one of the patient's organs. Such a hole is commonly referred to as a "fistula." In broad terms, the system consists of lining the wound bed with gauze, placing one end of a tube in the wound, sealing a cover over the wound, and applying suction to the other end of the tube. Of the various Chariker-Jeter references, only one prior use, as described by Dr. Chariker in his testimony about the treatment of a patient, specifically disclosed using the Chariker-Jeter system on a wound that did not involve a fistula.

The second piece of prior art relied on by Defendants at trial was the Svedman article. This article describes placing a dressing over a wound, connecting a solution to a tube at one end of the dressing, and applying suction to a tube at the other end of the dressing. The effect is that the solution flows through the dressing and across the surface of the wound.

Defendants' third piece of prior art was the Johnson article, which describes anchoring a skin graft in place, cutting several "pie crust incisions" in the graft, covering the graft with gauze, inserting a suction drain, covering the entire area with a dressing, and applying suction.

The fourth and final piece of prior art was the Davydov reference, which consists of two articles that describe a treatment for infection in the mammary glands of nursing

women. The treatment method consists of making an incision in the breast, placing a glass cup over the incision, and applying suction to drain the pus and bacteria.

II. DISCUSSION

Defendants appeal the district court's denial of their motion for JMOL of obviousness, or in the alternative, their request for a new trial on obviousness. Defendants also appeal the district court's construction of "wound" and its failure to find several claim terms indefinite. KCI cross-appeals the district court's denial of its motion for JMOL of infringement, or, in the alternative, its request for a new trial on infringement. We address each issue in turn.

A. Defendants' Motion for JMOL of Obviousness

The denial of a motion for JMOL is reviewed "under the law of the regional circuit where the appeal from the district court normally would lie." z4 Techs., Inc. v. Microsoft Corp., 507 F.3d 1340, 1346 (Fed. Cir. 2007) (quotations omitted). In the Fifth Circuit, JMOL "is appropriate only when a 'reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue.'" Cambridge Toxicology Group, Inc. v. Exnicios, 495 F.3d 169, 179 (5th Cir. 2007) (quoting Fed. R. Civ. P. 50(a)(1)). "We must affirm unless there is no legally sufficient evidentiary basis for the jury's verdict." Lane v. R.A. Sims, Jr., Inc., 241 F.3d 439, 445 (5th Cir. 2001) (internal quotations omitted).

Defendants allege several errors in the district court's treatment of its obviousness contentions. First, Defendants argue that the court's failure to construe "wound" prevented the jury from properly assessing whether the prior art was within the scope of the asserted claims. Second, Defendants argue that the district court erred by

finding that substantial evidence supported the jury's finding that the patents were not obvious. Finally, Defendants contend that the district court was required to conduct its own independent obviousness analysis and erred by simply reviewing the jury's verdict for substantial evidence. We address each argument in turn.

1. Construction of "Wound"

Defendants argue that the district court erred by vacating its construction of "wound" when the term's meaning was critical to the obviousness inquiry. According to Defendants, this error allowed KCI to improperly avoid the prior art by arguing claim construction to the jury. Specifically, Defendants take issue with KCI's characterization at trial of the Chariker-Jeter, Svedman, Johnson, and Davydov references as "draining fistulae," "irrigating wounds," "immobilizing skin grafts," and "draining bodily fluids," respectively, as opposed to "treating wounds with negative pressure." Defendants' expert testified that under the plain and ordinary meaning of "wound," each of the prior art references disclosed "treating a wound with negative pressure." The effect of this, according to Defendants, was that the jury was improperly forced to choose between competing claim constructions offered by the experts.

Defendants ask us to adopt their proposed "plain and ordinary meaning" construction, taken from Stedman's Medical Dictionary: "(1) trauma to any of the tissues of the body, especially that caused by physical means and with interruption of continuity [or] (2) a surgical incision." They argue that the specification's use of broad language when describing the wounds that can be treated shows that the ordinary meaning, as defined in the dictionary, was intended. See '643 patent col.12 ll.41-42 ("Negative pressure appliances are useful for treating a variety of wounds."); id. col.13

ll.24-25 ("The present invention also includes a method of treating damaged tissue . . . ."). Additionally, Defendants cite the numerous examples in the '643 patent's specification that describe open wounds, infected wounds, burn wounds, skin graft and skin flap wounds, decubitus ulcer wounds, incisional wounds, chronic open wounds secondary to stasis ulcers, and wounds which respond to increased blood flow, to support their proposed construction.

KCI responds that any error resulting from the district court's failure to construe the "wound" phrases is harmless because Defendants' proposed construction is incorrect as a matter of law and the jury's verdict demonstrates that it adopted the correct construction. According to KCI, the correct construction of "wound" is "tissue damage to the surface of the body, including the epithelial and subcutaneous layers." KCI argues that while the specification may refer to a "variety of wounds," each and every example specifically described is a skin wound. Therefore, KCI alleges, the Stedman's Medical Dictionary definition is broader than the scope of the specification and cannot be used to define "wound" as used in the claims. Further, KCI notes that under Defendants' proposed construction, "wound" would include, in addition to fistulae, "conditions such as ruptured appendices and stomach ulcers" that the specification in no way suggests can be treated according to the claimed invention. Appellee's Br. 53.

As a threshold matter, it appears that the parties' dispute over the construction of "wound" only affects the Chariker-Jeter and Davydov references. At trial, KCI did not contest that "wounds" were the subject of both the Svedman and Johnson articles. For example, KCI's expert, Dr. Orgill, testified that, in the Johnson reference, "[t]he skin graft is closing the wound." J.A. 204,899. Similarly, Dr. Orgill described the Svedman article

as teaching "irrigation of a wound." J.A. 204,923. Therefore, the effect of any error in the failure to construe "wound" is limited to the Chariker-Jeter and Davydov references.[3]

We agree with KCI that "wound," as used in the asserted patents, does not cover the fistulae described in the Chariker-Jeter publications and the "pus pockets" described in the Davydov references. As this court held in Phillips v. AWH Corp., "the specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). All of the examples described in the specification involve skin wounds. See id. at 1321 ("Properly viewed, the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent."). To construe "wound" to include fistulae and "pus pockets" would thus expand the scope of the claims far beyond anything described in the specification. See Nystrom v. TREX Co., 424 F.3d 1136, 1145 (Fed. Cir. 2005) ("[I]n the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to the public—i.e., those of ordinary skill in the art—that the inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the context of the intrinsic record, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source.").

[3] Defendants also argue that KCI improperly distinguished the prior art on the ground that it did not "treat" wounds. However, Defendants have not alleged error in the district court's construction of "treating" as "giving medical care to," nor have they asked us for a construction of "facilitating the healing of." See Second Amended Order Construing Patent '643 and '081 Claim Term at 2. Therefore, we confine our inquiry to the construction of "wound."

We further conclude that the district court's failure to instruct the jury on the construction of "wound" in this case was harmless.[4] See B. Braun Med., Inc. v. Abbott Labs., 124 F.3d 1419, 1423 (Fed. Cir. 1997) (holding that the district court's pre-Markman failure to instruct the jury on the construction of a means-plus-function limitation was harmless because the jury adopted the correct construction). Because the jury's verdict is supported under the proper construction, and because we perceive no danger under the circumstances of this case that the jury may have used an incorrect construction of "wound" that might have prejudiced Defendants, there is no need to remand for a new trial.

2. Substantial Evidence of Nonobviousness

Defendants next argue that regardless of which claim construction is used, the prior art references disclose "treating wounds with negative pressure." In support of this, Defendants cite the Chariker-Jeter publications that describe treatment of wounds complicated by fistulae, Dr. Chariker's testimony about the use of that method on a wound that did not include a fistula, the Svedman article, the Johnson article, and the Davydov articles.

The scope and content of the prior art are factual questions to be determined by the jury. Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 17 (1966). This court reviews these factual determinations, "whether explicit or implicit within the verdict, for

[4] While O2 Micro International, Ltd. v. Beyond Innovation Technology Co., 521 F.3d 1351 (Fed. Cir. 2008), permits a remand for further claim construction, it does not require one. Remanding is particularly unnecessary in this case, where claim construction was briefed before the district court and the disputed term was initially construed but later vacated because the parties did not use the construction in front of the jury. See id. at 1363 (remanding because "the district court is in the best position to determine the proper construction of this claim term in the first instance").

substantial evidence." LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1353 (Fed. Cir. 2001).

Defendants primarily rely on the Chariker-Jeter references, including the publications and Dr. Chariker's testimony at trial. However, KCI distinguished these references in front of the jury and presented substantial evidence that these references did not disclose "treating wounds with negative pressure." For example, Dr. Argenta, a witness for KCI and one of the named inventors on the asserted patents, testified that the Chariker-Jeter system is "totally different" from the claimed invention. Specifically, Dr. Argenta stated that the Chariker-Jeter method was designed for draining the effluent from fistulae, not treating a wound in order to increase granulation. Additionally, KCI's expert, Dr. Orgill, testified that the Chariker-Jeter references "deal[] with draining fistulas only, no[t] healing of the wound." With respect to Dr. Chariker's testimony about the use of the method on a patient whose wound did not include a fistula, KCI purports to have impeached Dr. Chariker's testimony about this patient with contradictory deposition testimony. The jury was correctly instructed, however, that it was the "sole judge[] of credibility" and that it must decide which witnesses to believe. Moreover, Fifth Circuit law dictates that "in case[s] of conflicting expert testimony, the jury is entitled to make credibility determinations and believe the witness it considers more trustworthy." Streber v. Hunter, 221 F.3d 701, 726 (5th Cir. 2000) (quotations omitted). Based on our review of the record, we find that the testimony of KCI's witnesses was sufficient to allow the jury to reach the conclusion that the Chariker-Jeter method was not used to "treat a wound with negative pressure" as required by the claims.

We reach the same conclusion regarding the Svedman, Johnson, and Davydov articles. Dr. Orgill distinguished the Svedman technique on two grounds. First, Dr. Orgill told the jury that Svedman taught an irrigation device, not a device for treating a wound with negative pressure. Second, Dr. Orgill explained that the Svedman technique could not maintain negative pressure on the wound because the Vaseline between the dressing and the wound would become viscous when warmed by contact with human skin. With respect to the Johnson article, Dr. Orgill told the jury that the skin graft, not the negative pressure, was treating the wound. According to Dr. Orgill, the Johnson article simply described one of many ways to immobilize a skin graft to a wound. Finally, Dr. Orgill testified that Davydov did not teach treatment of a "wound" with negative pressure. Rather, Dr. Orgill explained, the Davydov method was used to treat a "pocket of pus" that was "enclosed within the breast." According to Dr. Orgill, the only wound disclosed in the Davydov articles was the incision made to gain access to the "pocket of pus," which did not begin to heal until the suction device was removed.

Thus, KCI addressed each of Defendants' prior art references and provided the jury with a basis for determining that they did not teach or suggest "treating a wound with negative pressure," a limitation found in every asserted claim. We conclude that this was sufficient to support the jury's verdict of nonobviousness.[5]

3. The District Court's Review of the Jury's Verdict on Obviousness

[5] While this appeal was pending, claim 13 of the '643 patent was rejected during reexamination as obvious in view of two other Svedman references that were not relied on by Defendants in this appeal. Because those references were not argued before us, the results of the reexamination have no effect on this appeal.

Defendants' final argument with respect to its JMOL motion is that the district court erred by failing to conduct its own obviousness analysis. Defendants do not argue that submitting the question of obviousness to the jury is error. However, they assert that the district court strayed by "treat[ing] the obviousness conclusion as a pure factual question" and simply reviewing the jury's verdict for substantial evidence. Appellant's Br. 54. Because of this, Defendants argue, the district court never considered which Graham factors justified a nonobviousness verdict. Defendants allege that had such an analysis occurred, the district court would have concluded that the asserted patents were obvious.

Defendants' obviousness argument at trial relied heavily on the prior art references, the scope and content of which are factual questions to be determined by the jury. See Graham, 383 U.S. at 17. As discussed above, KCI presented substantial evidence to support its interpretation of the references. Thus, we must assume that the jury found that the prior art does not disclose "treating a wound with negative pressure" within the meaning of the patents. See Arsement v. Spinnaker Exploration Co., 400 F.3d 238, 249 (5th Cir. 2005) (on appeal of a motion for JMOL, "the evidence, as well as all reasonable inferences from it, are viewed in the light most favorable to the verdict" (quotations omitted)). In light of this, we conclude that Defendants failed to establish that the asserted claims were obvious as a matter of law.

B. Defendants' Request for a New Trial on Obviousness

In the alternative to their request for JMOL of obviousness, Defendants seek a new trial on obviousness because of alleged errors in the jury instructions. At trial, the jury was instructed that:

> In order to prove obviousness, [Defendants] must prove by clear and convincing evidence that one of ordinary skill in the art at the time would have found in the prior art some teaching, suggestion or incentive to combine the prior art in the way [KCI] did in its invention.

J.A. 235 (emphasis added). Defendants concede that they stipulated to this instruction, but argue that a supervening change in the law resulting from KSR justifies their raising this issue for the first time on appeal. KCI responds that because Defendants stipulated to the instruction, any error was "invited" and is thus unreviewable. For the purpose of this review, we assume arguendo that Defendants did not invite the alleged error in the jury instructions.

Challenges to jury instructions are reviewed "under the law of the regional circuit where the district court sits." Voda v. Cordis Corp., 536 F.3d 1311, 1328 (Fed. Cir. 2008). In the Fifth Circuit, an objection to the jury instructions first raised on appeal must "meet the exacting requirements of plain error." Tompkins v. Cyr, 202 F.3d 770, 784 (5th Cir. 2000). "To overturn a verdict for plain error in the instructions, we must find an obviously incorrect statement of law that was probably responsible for an incorrect verdict, leading to substantial injustice." Id. (citations and quotations omitted).

As discussed above, substantial evidence supports a finding that the Chariker-Jeter, Svedman, Johnson, and Davydov prior art references do not "treat wounds with negative pressure" as claimed in the asserted patents. The alleged error in the jury instruction relates to the "teaching, suggestion, or incentive to combine the prior art."

Based on our conclusion that there was substantial evidence that none of the prior art references "treat wounds with negative pressure," we are not persuaded that the instruction on obviousness was "probably responsible for an incorrect verdict." See id.; see also z4 Techs., 507 F.3d at 1355 (affirming denial of a new trial on obviousness after KSR because defendants failed to identify evidence establishing a prima facie case of obviousness). Accordingly, we affirm the district court's denial of Defendants' request for a new trial.

C. Defendants' Indefiniteness Arguments

The definiteness analysis requires a determination of "whether one skilled in the art would understand the bounds of the claim when read in light of the specification." Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n, 161 F.3d 696, 705 (Fed. Cir. 1998) (quoting Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 875 (Fed. Cir. 1993)). "If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." Exxon Res. & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Definiteness is a question of law, which we review de novo. Id. at 1376.

Defendants first argue that "selected stage of healing" is indefinite because the specification does not explain how the selected stage is to be determined for particular wounds at particular times. Further, Defendants argue that whether a wound has progressed to a selected stage of healing is wholly subjective. However, KCI points out that the specification of the '643 patent provides several examples of selected stages of healing. '643 patent col.12 ll.47-54. Additionally, KCI submitted a declaration from one

of the named inventors of the asserted patents explaining that a doctor of ordinary skill in the art would understand how the selected stage of healing may vary from wound to wound. While it may be true that the patentee's ability to "articulate a definition supported by the specification . . . does not end the inquiry," Defendants have not shown in this case that a person of skill in the art would be unable to ascertain the meaning of the term. See Halliburton Energy Servs. v. M-I LLC, 514 F.3d 1244, 1251 (Fed. Cir. 2008). Accordingly, we conclude that "selected stage of healing" is not "insolubly ambiguous." See Exxon, 265 F.3d at 1375.

Relying on Honeywell International, Inc. v. International Trade Commission, 341 F.3d 1332, 1339-40 (Fed. Cir. 2003), Defendants also argue that "reduction in bacterial density in the wound by at least 50%" is indefinite because there are several methods for measuring bacterial density, each of which may yield a drastically different result, and a person of ordinary skill in the art would not know which method to use. However, KCI responds that a person of ordinary skill in the art would know which method to use because Example 2 of the '643 patent describes a particular method. '643 patent col.15 ll.58-65. We agree with KCI that Honeywell does not control where, as here, several methods for calculating reduction in bacterial density are available but the specification discloses one particular method. Thus, we conclude that "reduction in bacterial density in the wound by at least 50%" is not indefinite.

Finally, Defendants argue that the claims reciting a "screen" are indefinite because a person of skill in the art would not know what "overgrowth of tissue in the wound" is or how a "screen" could prevent it. Defendants point to several parts of the record that allegedly present conflicting definitions of "preventing overgrowth," such as

"preventing loculation," "removing bacteria," "removing dead tissue that sticks to the screen," and "preventing the formation of scar tissue." KCI argues in response that one of the named inventors defined overgrowth as "[g]rowth of granulation tissue above the surrounding uninjured tissue" and explained that the screen prevented this by "distribut[ing] the pressure" within the wound. KCI also asserts that the allegedly conflicting definitions are not definitions of "overgrowth" at all. Instead, KCI argues, Defendants are pulling quotes from the inventors' deposition testimony about various complications of wound healing and attempting to mischaracterize them as definitions of "overgrowth." In light of KCI's explanation of the record before us, we are not persuaded that this claim term is "insolubly ambiguous." See Exxon, 265 F.3d at 1375. Accordingly, we find no error in the district court's failure to find the term indefinite.

D. KCI's Motion for JMOL of Infringement

We turn now to KCI's cross appeal on infringement. While several infringement theories were presented at trial, KCI limits its cross appeal to Blue Sky Medical Group, Inc.'s ("Blue Sky") alleged direct and induced infringement resulting from its sale of Versatile kits. Blue Sky assembles and sells several Versatile kits, each of which includes a Versatile pump and a combination of various "convenience items." The most basic kits include a Versatile pump, tubing, and a drain. Other kits include items such as Aquaphor gauze, adhesive dressing, scissors, and gloves. KCI alleges that Blue Sky's sale of certain kits directly infringed the asserted apparatus claims of the '081 patent and induced infringement of both the '081 claims and several method claims of the '643 patent. The jury rejected these contentions and the district court denied KCI's motion for JMOL.

1. Direct Infringement

KCI first argues that the undisputed evidence proved that two of Blue Sky's Versatile kits, "Chariker-Jeter Plus" and "Complete," directly infringed each of the twenty-one asserted claims of the '081 patent. According to KCI, the only disputed limitation in these claims was the requirement of a screen for preventing overgrowth of tissue in the wound. KCI alleges that it was undisputed that the Aquaphor contained in both kits satisfied this limitation. KCI relies primarily on the testimony of its expert, Dr. Orgill, who argued that Aquaphor "looks like a screen," "has the semi-rigid properties described in the patent," and is used "to restrain overgrowth of granulation tissue and help provide even distribution of the suction." According to KCI, a reasonable jury could not have found for Blue Sky because Blue Sky never presented any evidence that Aquaphor does not prevent overgrowth.

Blue Sky responds with two grounds on which we could affirm the district court's denial of KCI's motion for JMOL. First, it argues that KCI accused eighteen products, six of which did not contain Aquaphor or anything else alleged to have satisfied the screen limitations, but then stipulated to a verdict form that did not differentiate between the various kits. Blue Sky contends that KCI thus treated infringement as an "all or nothing matter" and cannot now complain about the lack of specificity in the verdict. We need not decide the viability of this "all or nothing" theory, which is contested by KCI, because Blue Sky's second argument, that there was indeed a dispute over whether Aquaphor served to prevent overgrowth, is determinative.

Blue Sky cites the testimony of co-founder Tim Johnson, who explained to the jury that Aquaphor is a "soft, flexible, conforming gauze." Blue Sky also points out that

the jury observed Aquaphor gauze and had the opportunity to assess its rigidity. Additionally, Blue Sky cites testimony that the purpose of the Aquaphor was to prevent granulation tissue from attaching to either the foam screen or fluffed gauze that was placed in the wound, which allowed the jury to infer that Aquaphor did not prevent overgrowth. Finally, Blue Sky asserts that the jury was not required to accept Dr. Orgill's "wholly conclusory" testimony.

We decline to require the jury to accept the testimony of KCI's lone infringement witness, Dr. Orgill. The jury was instructed that it was not required to accept any particular witness's testimony, and the Fifth Circuit has made clear that the jury is entitled to disbelieve a party's expert if it chooses. See Streber, 221 F.3d at 726. Additionally, while Defendants' evidence may not have been overwhelming, it was nonetheless sufficient to support the jury's conclusion that KCI failed to meet its burden of proving that the Aquaphor prevented overgrowth.

2. Induced Infringement

KCI also appeals the denial of its motion for JMOL that Blue Sky induced infringement of claims 13, 14, and 29 of the '643 patent, each of which is a method claim that recites the use of intermittent suction. Importantly, none of these claims require a screen for the prevention of overgrowth. KCI points out that the Versatile manual explains that it "is designed for operation in two suction modes—continuous and intermittent." Additionally, KCI alleges, Blue Sky told customers that "pressure can be altered . . . to an intermittent setting" and gave express instructions to "[s]elect continuous or intermittent suction mode." KCI cites testimony from a Blue Sky witness that "[m]any of our patients have pain with the intermittent use" as further proof that

customers actually followed these instructions. Finally, at trial, KCI presented a statement from one of Blue Sky's distributors that Blue Sky told it that intermittent pressure was "[s]ometimes successful."

Blue Sky does not dispute that the Versatile is capable of using intermittent suction. Instead, Blue Sky argues that the jury's verdict is correct because KCI failed to prove both actual direct infringement and that Blue Sky had the requisite intent for inducement. With respect to direct infringement, Blue Sky argues that when the testimony KCI relies on—"many of our patients have pain with intermittent use"—is read in context, it is unclear whether the witness, a nurse with thirty years of experience using negative pressure wound therapy, was referring to use of the Versatile or use of KCI's commercial embodiment, the VAC. According to Blue Sky, such ambiguous testimony cannot support, let alone require, an inference of direct infringement. Blue Sky also argues that the product manuals and other circumstantial evidence, without more, are insufficient to prove infringement as a matter of law under Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1272 (Fed. Cir. 1986). Finally, Blue Sky argues that testimony from its principals, Tim Johnson and Richard Weston, provided substantial evidence to support the jury's finding that Blue Sky lacked the level of intent necessary for inducement.

To prove induced infringement, the plaintiff must prove both direct infringement and "that the defendant possessed specific intent to encourage another's infringement." DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc in relevant part). We conclude that substantial evidence supports a finding that Blue Sky lacked the necessary intent. Tim Johnson testified that Blue Sky never intended to infringe

KCI's patents. Richard Weston testified that he thought that because the Versatile simply performed the Chariker-Jeter method, which was in the public domain, KCI's patents could pose no barrier to Blue Sky entering the market. KCI may be correct that "practicing the prior art" is not a defense to patent infringement. See Ecolab Inc. v. Paraclipse, Inc., 285 F.3d 1362, 1377 (Fed. Cir. 2002). However, it does not follow that a defendant's belief that it can freely practice inventions found in the public domain cannot support a jury's finding that the intent required for induced infringement was lacking. The jury heard Blue Sky's founders explain why they did not believe they were infringing and had the opportunity to assess their credibility. We find no basis to overturn the jury's decision with respect to inducement.

E. KCI's Motion for a New Trial

In the alternative to its motion for JMOL, KCI requests a new trial on infringement. In the Fifth Circuit, the district court's denial of a motion for a new trial is reviewed for abuse of discretion. Industrias Magromer Cueros y Pieles S.A. v. La. Bayou Furs Inc., 293 F.3d 912, 924 (5th Cir. 2002).

KCI alleges that Defendants' "practicing the prior art" defense, comparisons of the Versatile to the VAC, and "blatant class-warfare arguments," including references to KCI's wealth and the need for an inexpensive alternative to the VAC, prejudiced the jury and resulted in an incorrect verdict.

Blue Sky responds that any comparisons between the Versatile and the Chariker-Jeter prior art references were relevant to rebut KCI's allegations of copying and willful infringement, to prove lack of intent to induce infringement, and to impeach KCI's expert's unsubstantiated distinctions between the gauze in the prior art and the

gauze used with the Versatile. Similarly, Blue Sky asserts that the comparisons between the VAC and the Versatile were relevant in response to KCI's allegations that Blue Sky blatantly copied the VAC. Finally, Blue Sky argues that its references to KCI's wealth were relevant to prove the bias of KCI's witnesses and respond to KCI's arguments that Blue Sky was more interested in profits than patients.

We agree with Defendants and the district court that the arguments to which KCI objects had proper uses or were made in response to issues raised by KCI. The district court expressly found that Defendants' arguments did not amount to class warfare. Additionally, the jury was specifically instructed that it should not treat anyone unfairly based on wealth. Accordingly, we find no abuse of discretion in the court's denial of KCI's motion for a new trial.

III. CONCLUSION

For the foregoing reasons, we affirm the district court's denial of Defendants' motion for JMOL of obviousness and its determinations that certain claim terms were not indefinite. We also deny Defendants' request for a new trial on obviousness. With respect to KCI's cross-appeal, we affirm the district court's denial of KCI's motion for JMOL of infringement and its request for a new trial on infringement.

AFFIRMED

United States Court of Appeals for the Federal Circuit

2007-1340, -1341, -1342

KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC.,
and WAKE FOREST UNIVERSITY HEALTH SCIENCES,

Plaintiffs-Cross Appellants,

v.

BLUE SKY MEDICAL GROUP, INC.,

Defendant-Appellant,

and

RICHARD S. WESTON,

Defendant-Appellant,

and

MEDELA AG and MEDELA, INC.,

Defendants-Appellants.

Appeals from the United States District Court for the Western District of Texas in case no. 03-CV-0832, Judge W. Royal Furgeson, Jr.

DYK, Circuit Judge, dissenting.

I respectfully dissent from the majority's holding that affirms the judgment that the claims are nonobvious. In my view, the majority improperly holds that the claim term "wound" can be limited to the disclosed embodiments in the specification, and, having done so, then misreads the specification as showing only embodiments treating harm to the surface of the body or skin wounds. Under the correct construction of this claim

term, the asserted claims of U.S. Patent Nos. 5,636,643 ("'643 Patent") and 5,645,081 ("'081 Patent") would have been obvious.[1]

I

The proper construction of the term "wound" was extensively disputed pre-trial. Defendants Medela AG and Medela, Inc. ("Defendants") argued that "wound" should be construed according to its plain meaning as "injury." Defendants alternatively argued that "wound" should be construed as found in Stedman's Medical Dictionary (26th ed.): "(1) trauma to any of the tissues of the body, especially that caused by physical means and with interruption of continuity [or] (2) a surgical incision."

Plaintiffs Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health Sciences ("Plaintiffs") argued that "treating a wound" should not be construed at all because it is well within the common experience and understanding of every juror. Plaintiffs argued in the alternative that "wound" should be construed as "tissue damage to the surface of the body, including the epithelial and subcutaneous layers." Although both parties introduced expert reports on claim construction to the district court, neither party relies on these expert reports on appeal.

Initially, the district court construed "wound" as "injury." Kinetic Concepts, Inc. v. Blue Sky Med. Corp., No. 03-CV-0832, at 5 (W.D. Tex. June 28, 2005) ("Order Construing Patent '643 Terms"). However, after approximately ten days of trial, the district court decided sua sponte that it would adopt the Plaintiffs' approach and not instruct the jury on the proper construction of "wound." Kinetic Concepts, Inc. v. Blue

[1] The asserted claims are claims 1-3, 6-8, 11-14, 16, 26-29, and 32 of the '643 patent, and claims 1, 3, 5, 8, 9, 11-13, 27, 31, 33, 36, 37, 54, 56, 58, 61, 62, and 64-66 of the '081 patent.

Sky Med. Corp., No. 03-CV-0832 (W.D. Tex. June 29, 2006) ("Second Amended Order Construing Patent '643 and '081 Claim Terms").

At trial, Plaintiffs argued the definition of "wound" to the jury in an effort to distinguish the prior art, particularly the public uses of Chariker and Jeter that involved applying negative pressure to surgical incisions including both a hole in the skin and a "fistula" or hole in an internal organ. Plaintiffs argued to the jury that a "fistula" was distinct from a "wound," and that the purpose of the public uses of Chariker and Jeter was "fistula drainage" as opposed to "wound healing."[2]

[2] In opening and closing arguments, Plaintiffs attempted to distinguish the public uses of Chariker and Jeter by focusing on the fact that the method was usually used when there was a fistula: "this [Chariker-Jeter] is about fistulas, not about the wounds that we are talking about," J.A. 200862; "Remember Chariker-Jeter is healing – is drainage, not healing. Chariker-Jeter is fistula only," J.A. 205656; "Now, let's talk about Chariker-Jeter and I will repeat myself 400 times and I will shut up. Chariker-Jeter, fistulas, fistulas, fistulas, fistulas. It's about drainage," J.A. 205665. The testimony of Plaintiffs' expert witness on validity, Dr. Orgill, is also illustrative:

> Q: Is that wound healing?
>
> A: No. That's fistula drainage.
>
> Q: And why isn't that wound healing?
>
> A: Well, Chariker-Jeter describes that they stop this device when the fistula closes. And usually these devices take about 16 days, that's what they describe in their article, for this nasty fluid to stop coming out. And after that, when the fistula closes, then that's when the wound healing or the rest of the wound can start to heal.

J.A. 204932-35. Cross-examination on the definition of wound included an answer from this witness that "[v]ery often people with the definition of tissue would separate tissues from organs, so, in other words, many people in their definition of tissue might not consider, for example, a kidney to be a tissue. I understand some people would, but some people would separate organ from tissues." J.A. 205092. Testimony by an inventor also focused on this distinction: "It's totally different. They're treating drainage. We're treating a wound. . . . We're treating to close a wound. They're treating to control the fistula."

II

The district court's failure to construe the term "wound" was a clear error. We have held that "[w]hen the parties raise an actual dispute regarding the proper scope of [the patent] claims, the court, not the jury, must resolve that dispute." O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1360 (Fed Cir. 2008). It is improper to argue claim construction to the jury because the "risk of confusing the jury is high when experts opine on claim construction." CytoLogix Corp. v. Ventana Med. Sys., Inc., 424 F.3d 1168, 1172-73 (Fed. Cir. 2005); see Sundance, Inc. v. Demonte Fabricating Ltd., No. 2008-1068, slip op. at 11-12 n.6 (Fed. Cir. Dec. 24, 2008). In this case, the definition of the term "wound" was central to the case and a primary focal point of the Markman hearing; as a result, the court should have construed the term "wound."

The appellees do not dispute that it was error to fail to construe wound, instead claiming that the issue "need not be resolved, however, since any error was harmless" under the claim construction now adopted by the majority. Appellee's Br. 51. The majority agrees. However, there is no suggestion by either the majority or the appellees that the verdict could be sustained under the appellants' proposed construction. Thus, the crucial question is whether the majority's claim construction is correct. In my opinion it is not.

III

The majority construes "wound" to mean "tissue damage to the surface of the body, including the epithelial and subcutaneous layers" because "[a]ll of the examples described in the specification involve skin wounds." Maj. op. at 9-11. It is the words of the claim that define the scope of the patent. See Phillips v. AWH Corp., 415 F.3d

1303, 1312 (Fed. Cir. 2005) (en banc). The words are generally construed according to their ordinary and customary meaning, that is, "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Id. at 1313. This meaning is to be interpreted in the context of the entire patent, including the specification. Id. However, it is improper to import limitations from the specification into the claims where there is no indication that the specific examples in the specification are intended to be strictly coextensive with the claim. Id. at 1323.

The majority holds that the term "wound" should be understood as limited to damage to tissues near the surface of the body, particularly the skin, and should not include damage to organs. The majority points to no medical dictionary or other extrinsic evidence supporting this claim construction. The specification does not define "wound" or provide any examples of the types of harms that would not qualify as wounds under the claim terms. Nor does the specification state that the examples listed in the specification were intended to describe the entire invention. See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1343-44 (Fed. Cir. 2001) (specification described "all embodiments of the present invention"). Nonetheless, the majority concludes that, because the specification examples supposedly only include descriptions of damage to the skin, the specification limits the kinds of wounds encompassed by the claim. In my view, our decision in Phillips bars us from construing the claims as limited by the specification examples, and the majority's approach is without support in our post-Phillips cases.

But even if the examples could limit the claims, in my view the examples here are not limiting, and indeed the specifications confirm the inappropriateness of the majority's

construction. The specifications of both patents make clear that the examples are merely "illustrative."[3] The specifications also state that the invention is "useful for treating a variety of wounds." '643 Patent col.12 ll.41-42. "Wounds that have exhibited positive response to treatment by the application of negative pressure include infected open wounds, decubitus ulcers, dehisced incisions, partial thickness burns, and various lesions to which flaps or grafts have been attached." '643 Patent col.2 ll.58-62. (emphasis added). The use of the illustrative and open language of "include" demonstrates that there may be other types of wounds that the specification does not expressly point out, but that would nonetheless be covered by the claim term "wound." See SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1284 (Fed. Cir. 2005); Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1344-45 (Fed. Cir. 2003). Throughout the specifications, the term "wound" is used only in this broad and inclusive way. See, e.g., '643 Patent col.13 ll.23-29.

Moreover, the majority is incorrect in asserting that "[a]ll of the examples described in the specification involve skin wounds." Maj. op. at 11. In fact, a number of examples illustrate that the wounds at issue are not merely skin wounds but deep wounds that include damage to more than the skin, such as wounds in which bone was exposed, '643 Patent col.19 ll.35-39, col.20 ll.23-27, large quantities of fluid were draining, '643 Patent col.19 ll.23-26, surgical incisions cut through the abdominal wall

[3] The '081 Patent specification states: "[t]hese examples are provided for illustrative purposes only and are not to be taken as limiting," col.5 ll.47-49, and "[t]he foregoing examples are illustrative of the present invention, and are not to be construed as limiting thereof," col.9 ll.46-48. See also '643 Patent col.21 ll.43-45 ("The terms and expressions which have been employed are used as terms of description and not of limitation.").

and did not heal, '643 Patent col.19 ll.55-65, or bone was infected, '643 Patent col.20 ll.49-61. See also '081 Patent col.8 ll.58-67, col. 9 ll.19-27, ll.35-41. These examples disclose wounds with far more than mere "damage to the epithelial and subcutaneous layers," suggesting that other kinds of damage, including fistulae caused by surgical incision, would be within the definition of "wound" as used in the claim. These examples explicitly identify benefits achieved in the healing of interior tissue. For example, '643 Patent col.19 ll.55-65 and '081 Patent col.8 ll.60-65 describe increased healing of the abdominal wall by granulation tissue in and through Prolene mesh, and '643 Patent col.19 ll.23-26 and '643 Patent col.20 ll.25-35 describe draining fluid from interior infections.[4]

In view of the inclusive language and examples of the specification, I would find a dictionary frequently used by a person of ordinary skill in the art significant in understanding the meaning of "wound" in the claim. See Phillips, 415 F.3d at 1322-23 ("[J]udges are free to consult dictionaries and technical treatises . . . when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." (quoting Vitrionics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996))). The definition of "wound"

[4] To be sure, one of the identified purposes of the invention applies only to the skin. See '643 Patent col.1 ll.20-25 (describing the "zone of stasis" in which blood flow to the skin around a wound is restricted as a problem addressed by the invention). However, we have held that "[t]he court's task is not to limit claim language to exclude particular devices because they do not serve a perceived 'purpose' of the invention. . . . An invention may possess a number of advantages or purposes, and there is no requirement that every claim directed to that invention be limited to encompass all of them." E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1370 (Fed. Cir. 2003).

provided by Stedman's, an accepted medical dictionary,[5] includes "trauma to any of the tissues of the body" and "surgical incision." In light of the disclosures of the specifications and the additional support of the dictionary, in my view the term "wound" as used in the claim includes fistulae caused by surgical incision.

IV

The uncontroverted evidence demonstrates obviousness under the construction that I would adopt. Extensive evidence was presented at trial of public uses to heal fistula's caused by surgical incisions, by both Dr. Chariker and Dr. Jeter.[6] There was no testimony to the contrary, nor is there any contention that the claims would be nonobvious if "wound" were construed as I suggest. Under the correct claim construction the undisputed evidence demonstrates that the claims would have been obvious.

For the foregoing reasons, I respectfully dissent.

[5] Plaintiffs' expert witness testified that Stedman's is a medical dictionary used in the profession. Plaintiffs even referenced the definition of wound provided by Stedman's in filings to the FDA describing the full scope of wounds that could be treated by their device.

[6] The parties do not dispute that this evidence meets the definition of a prior art public use under 35 U.S.C. § 102(b).