United States Court of Appeals for the Federal Circuit

KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC., KCI MEDICAL RESOURCES, KCI MANUFACTURING, AND MEDICAL HOLDINGS LIMITED,
Plaintiffs,

AND

WAKE FOREST UNIVERSITY HEALTH SCIENCES,
Plaintiff-Appellant,

v.

SMITH & NEPHEW, INC.,
Defendant-Appellee.

2011-1105

Appeal from the United States District Court for the Western District of Texas in case no. 08-CV-0102, Judge W. Royal Furgeson, Jr.

Decided: August 13, 2012

MATTHEW D. POWERS, Weil, Gotshal & Manges LLP, of Redwood Shores, California, argued for plaintiff-appellant. With him on the brief were ELIZABETH STOTLAND WEISWASSER, PETER SANDEL, JENNIFER H. WU,

DANIELLE ROSENTHAL and ERIN WIGGINS, of New York, New York. Of counsel was ANDREW SWANSON BROWN.

JOSEPH R. RE, Knobbe, Martens, Olson & Bear, LLP, of Irvine, California, argued for defendant-appellee. With him on the brief were JAMES F. LESNIAK, SHELIA N. SWAROOP and CHRISTY G. LEA. Of counsel on the brief was MARK J. GORMAN, Smith & Nephew, Inc., of Cordova, Tennessee.

Before BRYSON, DYK and O'MALLEY, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* O'Malley. *Circuit Judge* Dyk concurs in the result.

O'MALLEY, *Circuit Judge*.

Wake Forest University Health Sciences ("Wake Forest") appeals the district court's grant of judgment as a matter of law ("JMOL") of invalidity for obviousness. In granting Smith & Nephew, Inc.'s ("S&N") motion for JMOL, the district court overturned the jury's determination that S&N had failed to prove that the asserted claims of the patents in suit were obvious. We conclude that, on the basis of the jury's factual findings, S&N failed to establish by clear and convincing evidence that the claims were obvious. Accordingly, we reverse and remand.[1]

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[1] The concurrence raises, and then purports to resolve, issues that were neither raised nor discussed before the district court, and were not argued in this appeal. Because it is about matters not before us, we do not respond to the concurrence except to the extent our discussions of the patents and the prior art already do so.

BACKGROUND

I. Asserted Patents

Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., KCI Medical Resources, KCI Manufacturing, and Medical Holdings Limited (collectively "KCI") and Wake Forest brought suit against S&N, alleging infringement of U.S. Patent Nos. 7,216,651 ("'651 patent") and 5,645,081 ("'081 patent"). Wake Forest is the owner of the asserted patents, and KCI are the exclusive licensees of the patents. Both patents claim methods and apparatuses for treating difficult-to-heal wounds by applying suction or negative pressure, *e.g.*, '651 patent Abstract; '081 patent Abstract. Wake Forest and KCI asserted that S&N infringes apparatus claims 2 and 5 of the '081 patent and induces infringement of method claims 42, 109, 116, and 121 of the '651 patent.

As described by the asserted patents, medical "treatment of open wounds that are too large to spontaneously close" is difficult. '081 patent col.1 ll.11–12; '651 patent col.1 ll.29–30. "Wound closure requires that epithelial and subcutaneous tissue migrate from the wound border toward the wound." '081 patent col.2 ll.49–50. To facilitate such migration, doctors commonly use mechanical closures, such as sutures or staples. *Id.* at col.1 ll.24–25. Such mechanical closures create tension on the skin, which encourages epithelial migration. *Id.* at col.1 ll.25–28. "While suturing and stapling of wounds is widely practiced, it has a major drawback: the tensile force required to achieve closure with sutures or staples causes very high localized stresses at the suture insertion points, resulting in the rupture of the tissue at these points." *Id.* at col.1 ll.28–33. This rupturing inhibits healing of the wound. *Id.* at col.1 ll.33–35. Additionally, it is not feasi-

ble to suture some large open wounds. *Id.* at col.1 ll.28–33.

To address these shortcomings, the invention applies "negative pressure to a wound over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the wound, with the negative pressure being maintained for a time sufficient to facilitate closure of the wound." *Id.* at col.2 ll.45–49; '651 patent col.4 ll.18–23 ("[A] method of treating tissue damage is provided which comprises applying a negative or reduced pressure to a wound over an area sufficient to promote the migration of epithelial and subcutaneous tissue toward the wound and for a time period sufficient to facilitate closure of the wound."). Claim 2 of the '081 patent and claim 42 of the '651 patent are illustrative:

> 2. An apparatus for facilitating the healing of wounds, comprising:
> vacuum means for creating a negative pressure between about 0.1 and 0.99 atmospheres on the area of skin including and surrounding the wound;
> sealing means operatively associated with said vacuum means for maintaining said negative pressure on said wound by contacting the skin surrounding said wound; and
> open-cell polymer for positioning at the wound within the sealing means for preventing the over-growth of tissue in the wound.

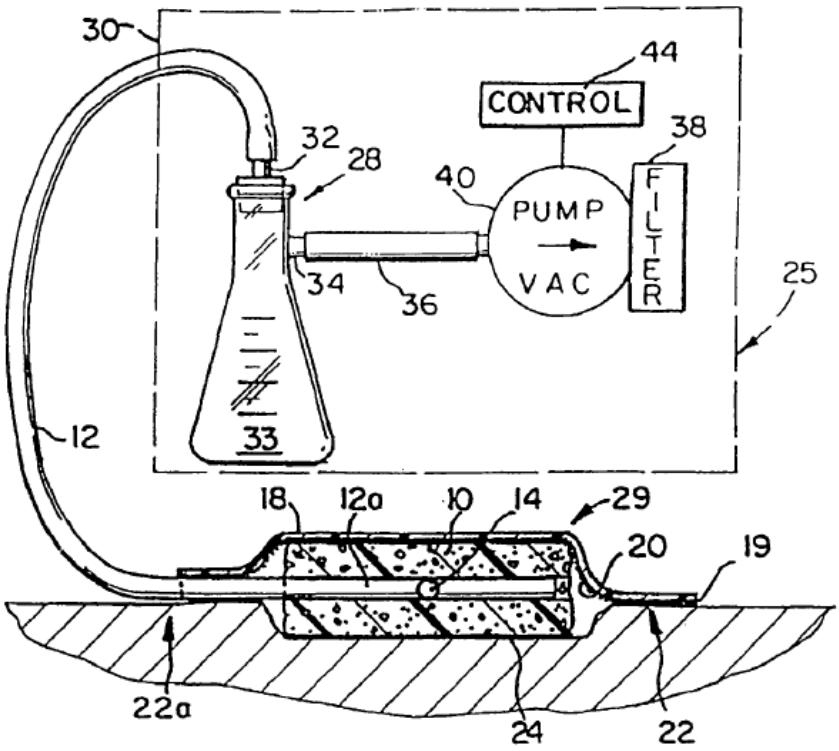
'081 patent col.9 ll.50–65.

> 42. A method of treating a wound comprising the steps of:
> i. providing a vacuum source capable of providing at least 0.11 atm of reduced pressure;

> ii. locating a flexible adhesive cover over the wound, said cover having a suction port;
> iii. locating a porous material comprising a synthetic polymer under said cover at the wound;
> iv. adhesively sealing and adhering the periphery of said cover to tissue surrounding the wound to form a continuous seal;
> v. operably connecting said suction port with said vacuum system for producing said reduced pressure;
> vi. interposing a fluid trap between said suction port and said vacuum source; and
> vii. maintaining reduced pressure of at least 0.11 atm at the
> wound until the wound had progressed toward a selected stage of healing.

'651 patent col.25 ll.31–48.

Figure 1 of the '651 patent discloses the key components of the claimed apparatus:



As depicted in this figure, the claimed apparatus includes: (1) a vacuum pump (30) ; (2) tubing (12); (3) an open-celled foam wound screen (10); and (4) an adhesive seal (18). '651 patent col.6 ll.31–61; *see also* '081 patent col.2 ll.30–35 ("FlG. 1 shows a cross-sectional view of a negative pressure device comprising a open-cell polymer screen, a flexible hose connecting the foam section to a suction pump, and a flexible polymer sheet overlying the foam-hose assembly to provide the necessary seal."). To utilize the apparatus, "[f]irst, the open cell foam is cut to fit the shape of the wound and placed inside the wound. Then the adhesive seal is placed over the foam that is

inside the wound." *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, No. 08-cv-102, slip op. at 2 (W.D. Tex. Oct. 10, 2010) (order granting defendant's motion for judgment as a matter of law of invalidity for obviousness) (ECF No. 605) ("*JMOL Order*"). Once the seal is in place, "[o]ne end of the tubing is placed through the seal into the foam and the other end is attached to the vacuum pump. The vacuum pump is turned on and, because of the tight seal around the wound, the edges of the wound immediately begin to move together." *Id.*

II. Prior Art

In the present litigation, S&N asserted prior art that generally falls into three primary categories: (1) the Bagautdinov references; (2) the Zamierowski reference; and (3) the Chariker-Jeter references. On appeal, there is no dispute that these references are all prior art.

A. Bagautdinov References

The Bagautdinov references consist of two articles written by Dr. Bagautdinov. The first reference ("Bagautdinov I") was published in 1986. Joint Appendix ("J.A.") 10001–03. It discusses "a method for vacuum treatment of primary and secondary purulent wounds." J.A. 10002. The reference describes the method as follows:

> After surgical treatment of the purulent wound and hemostasis, a drain of polyurethane foam adapted in shape and size is placed on the surface (or in the cavity). The surrounding skin is smeared with sterile vaseline, antiseptic or inert salve on an oil base and covered with a polyethylene film. . . . Regardless of the method of sealing, a tube is hermetically installed onto the foam through a hole in the polyethylene made before-

> hand. The latter is connected to the vacuum pump through a collection vessel. At a vacuum of 10 to 60 mmHg the film clenches the wound strictly along its skin boundaries with uniform vacuum treatment of the walls only on the side of the cavity and elimination of exudate because of the porous structure of the drain. The duration of the treatment sessions depends on the degree of vacuum and ranges from 30 minutes to 2 hours, whereupon the polyethylene is removed and a gauze bandage emplaced. The sessions are conducted daily until the wound is clean. On average this procedure takes 3 to 4 days.

Id. Bagautdinov I notes that use of this method "inevitably obtain[s] acceleration of the healing periods and rehabilitation of the patients." J.A. 10003. The second reference ("Bagautdinov II") was also published in 1986. J.A. 10026–27. Bagautdinov II describes application of a method similar to that described in Bagautdinov I to 170 patients. J.A. 10026. The method employed requires that,

> [i]mmediately after surgical treatment of the infected area in the commonly accepted manner or using a Scalpel-1 laser, a drain made from polyurethane foam is placed in the wound. For sorption treatment, it is first filled with activated charcoal powder. The wound is sealed with polyethylene film in one of several ways, depending on the localization of the purulent focus. Vacuum aspiration is conducted through an aspiration tube using a constant suction pump. Thus, the polyethylene film "clenches" the wound strictly along its edges, and the sorbent makes secure contact with the walls. The porous structure of the drain allows for removal of exudate and vacuumi-

> zation of the wound only from the cavity side. The session lasts 1-2 hours with negative pressure of 10-40 mmHg, after which the isolation is removed. The drain is changed 1-2 times daily. Vacuum treatment was continued for 3-4 days.

J.A. 10026–27. As a result of this method, "[o]n average, the wound became clean by day 4-5, with the appearance of granulated tissue. . . . The average duration of in-patient treatment was 11.8 bed days, compared to 17.2 in the control group; 61.7% of the patients were released with healed wounds and did not require outpatient treatment." J.A. 10027.

B. Zamierowski Reference

The Zamierowski reference is a Patent Cooperation Treaty Application filed on April 3, 1990. J.A. 10057. The reference describes a "fluidic connection system . . . for draining liquids from and introducing liquids to patients." J.A. 10059. As described by the reference, the system, which amounts to a wound dressing, consists of:

> [A] semipermeable membrane including a pair of panels each having a perimeter and an edge strip. The membrane is formed by connecting the panel edge strips together to form a seam extending transversely across the membrane. The panels and the membrane include inner and outer surfaces. A tube opening extends through the seam between the panel edge strips and between the membrane inner and outer surfaces. The membrane inner surface is coated with an adhesive for attachment to the skin of a patient. A tube or sheath includes a proximate end extending through the tube opening and a distal end positioned in spaced relation from the membrane outer surface. . . . A passage extend[s] through the

> sheath between its ends. An inner conduit can be placed in the sheath passage and can include a connection seal assembly for forming a fluid-tight seal with the sheath. . . . When the fluidic connection system is used as a wound dressing, an intermediate layer of material can be applied between the wound and the cover membrane inner surface. Furthermore, the fluidic connection system of the present invention can be used to secure a percutaneous drainage tube within a patient, e.g. by inserting the percutanious tube through the sheath passage. . . . The cover membrane can be releasably, adhesively fastened to the skin around a periphery thereof. A tube fluidically communicates with the wound through an opening in the membrane. Fluids from a draining wound can be evacuated through the tube and liquid medication and irrigation can be introduced through the tube to the wound site. The fluid evacuation and introduction steps of the method can each be accomplished both actively and passively . . . .

J.A. 10061–63. The reference indicates that this wound dressing "promotes healing." J.A. 10063.

C. Chariker-Jeter References

The Chariker-Jeter references consist of two published articles ("Chariker-Jeter I" and "Chariker-Jeter II," respectively), J.A. 10044–47; J.A. 10050–56, and Dr. Chariker's 1989 public use of the system described in the articles on Gary Aderholt ("Chariker-Jeter public use"). Both Chariker-Jeter I and Chariker-Jeter II describe the same "closed wound drainage system." J.A. 10052. As described in Chariker-Jeter II, the drainage system is created by:

> 1. Irrigat[ing] the wound bed thoroughly with normal saline using a 30ml syringe with a 19-gauge needle.
> 2. Moisten one 2X2 gauze square with normal saline. Open completely and lay across the wound bed.
> 3. Place Jackson-Pratt drain in wound bed. Shorten the fenestrated drain as necessary so that the flat drain is confined to the wound bed. The drain is never placed in the fistula[2] tract. In the case of fistula drainage at skin level, the fenestrated portion of the drain is simply centered over the cutaneous opening. It may be helpful to encircle the cutaneous wound with a pectin-based skin barrier in order to create a "trough" in which to situate the fenestrated drain.
> 4. Saturate 4X4 gauze squares with normal saline. Open and fluff into wound to completely cover the drain and fill the defect to skin level. In the case of a cutaneous fistula, only enough moist gauze to cover the flat fenestrated drain is required.
> 5. Apply skin sealant (Bard Barrier Film, Skin-Prep, etc.) to all skin that will be covered by the film dressing. Allow to dry until slick.
> 6. Cut the film dressing or select a size to allow at least 1inch of intact skin beyond the wound edges. Place the film dressing over the packed wound. Carefully crimp the adhesive film dressing around the Jackson-Pratt tube to seal.
> 7. "Caulk" the tube exit site with a small amount of Stomahesive Paste where the film dressing is

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[2] A "fistula" is generally considered to be a hole in an organ. *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, 554 F.3d 1010, 1016 (Fed. Cir. 2009).

> crimped around the tube. This ensures air-tight closure.
> 8. Reinforce this site with waterproof "pink tape" as illustrated.
> 9. Turn your attention now to the connection of the Jackson-Pratt to continuous suction. (Do not attempt to use the bulb of the Jackson-Pratt system.) With some brands of canister and tubing, all that is necessary is to cut the funnel end off the tubing and the small J-P tubing will fit snugly into the larger lumen tube. The junction should be taped securely with pink tape. Otherwise you may use small "Christmas tree" connector or cannibalize IV tubing to get a small plastic adapter to connect the tubing.
> 10. Turn on continuous suction to the upper range of the low setting (approximately 60 to 80 mmHg) and observe the wound site. The dressing should contract noticeably. If it does not, the system is not closed and wound drainage will not be efficiently removed. When this occurs, fistula drainage will accumulate, causing skin damage and leakage outside of the dressing. Another indication that you have not obtained a closed suction system is a whistling sound indicating that the dressing is not air-tight.

J.A. 10052 (footnote added). Chariker-Jeter II explains that "[o]ur clinical observations suggest that fistula effluent does inhibit wound healing. . . . By minimizing the inflammatory response [associated with the presence of effluent], fibroplasia is reduced. This, we believe, encourages rapid wound contraction and re-epithelialization." J.A. 10055.

Finally, with respect to the Chariker-Jeter public use, Dr. Chariker testified that he treated Mr. Aderholt in

1989 with his closed suction wound drainage system. "[Mr. Aderholt] was injured with a log chain that flew off another truck into his truck, entered his chest, his abdomen, ruptured his lung, his [diaphragm], his pancreas, his spleen, his stomach." J.A. 22032:8–11. With the aid of pictures of Mr. Aderholt's treatment, Dr. Chariker stated that his treatment was an example of the drainage system facilitating the healing of a wound on a patient without a fistula. J.A. 22035:6–38:11.

III. Prior Litigation

In 2003, Wake Forest and KCI sued Blue Sky Medical Group, Inc., ("Blue Sky") et al., alleging that its gauze based negative pressure wound therapy products infringed U.S. Patent No. 5,636,643[3] ("'643 patent") and the '081 patent. At trial, a jury found the patents were not infringed, not invalid, and not unenforceable. At the close of trial, defendants filed a motion for judgment as a matter of law, alleging that the asserted claims of the '643 and '081 patents were invalid as obvious under 35 U.S.C. § 103. The district court denied that motion.

On appeal, this court affirmed the jury's finding that invalidity was not established and that the asserted claims were not infringed. *Blue Sky*, 554 F.3d at 1025–26. In reaching that conclusion, however, we determined that the district court committed harmless error by failing to construe the term "wound." *Id.* at 1019. While we did not provide a definitive construction of "wound," we concluded that construing " 'wound' to include fistulae and 'pus pockets' would [] expand the scope of the claims far beyond anything described in the specification." *Id.* Significantly, for the present appeal, we also concluded that "wound," "as used in the asserted patents, does not cover

[3] KCI has not asserted this patent in the present litigation.

the fistulae described in the Chariker-Jeter publications . . . ." *Id.* at 1018.

IV. Present litigation

During the appeal in the prior litigation, S&N acquired Blue Sky. In December 2008, S&N announced it was launching a new foam-based negative pressure wound treatment product. Responding to this announcement, Wake Forest and KCI filed this suit, asserting that S&N's Renasys product infringed the asserted patents.

After conducting a *Markman* hearing, the district court construed various terms recited in the claims. For this appeal, the court's construction of only the term "wound" is relevant; it construed this term to mean: "tissue damage to the surface of the body, including the epithelial and subcutaneous layers, and excluding fistulae and pus pockets." *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, No. 08-cv-102, slip op. at 8 (W.D. Tex. Nov. 12, 2009) (claim construction order) (ECF No. 280) ("*Claim Construction Order*"); *see also JMOL Order* at 4.

Before the case was given to the jury for determination, the parties disagreed about the form and content of the jury instructions. Wake Forest and KCI had demanded a trial by jury. In response, S&N moved the district court to strike the jury demand with respect to questions of law, including the ultimate question of obviousness. Def.'s Mot. to Strike Pls.' Jury Demand on Questions of Law at 5–9, *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, 08-cv-102 (W.D. Tex. Jan. 21, 2010) (ECF No. 397) ("*Motion to Strike*"). Prior to ruling on the merits of the motion to strike, the district court conducted an on-the-record pre-trial hearing. During the hearing, S&N made clear that it wanted the jury to make findings with respect to the factors under *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), and reserve the

ultimate question of obviousness for the judge. Pre-Trial Conference Tr. at 16–22, *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, No. 08-cv-102 (W.D. Tex. Jan. 25, 2010) ("*Pre-Trial Conference Transcript*"). To facilitate this division of responsibility, S&N proposed a special interrogatory verdict form:

> [T]he way it's done and the way the models show . . . is the jury make[s] findings under *Graham v. John Deere*. If the jury is actually asked what is the level of skill in the art, that's one of the Graham findings. What is the scope and content of the prior art. . . . [W]e proposed and gave to KCI a two-page set of questions where we are specifically asking the jury to make findings as to whether or not the prior art contains a particular suggestion.

Id. at 16. Under this proposal, the trial judge would resolve the ultimate question of obviousness on the basis of the jury's factual findings as exemplified in their answers to the interrogatories.

Wake Forest and KCI expressed the belief that this proposal was "one of the worst ideas of all time" because it would make the process so complicated that the jury could not get it right, thereby "taking away from the jury the power they have been given by the constitution." *Id.* at 23. Highlighting their concern with S&N's proposed verdict form, Wake Forest and KCI explained that: "It's not two pages, but actually five pages of questions. Two pages that look like this of detailed questions about whether the prior art discloses teeny tiny aspects of the patent, and two questions that call for a narrative answer from the jury." *Id.* at 26. Responding to this criticism, the trial judge indicated that he was "very reluctant . . . to

give juries questions requiring narrative answers." *Id.* at 27.

The trial judge summarized the parties' arguments as both saying essentially the same thing: "[N]o matter how I present this to the jury I have to make a separate determination as to obviousness. Even if I were to submit this to the jury in a broad form submission – just is it obvious – regardless of what the jury said, my analysis would have to require that I do my own look at the matter from a legal point of view . . . ." *Id.* at 30. The trial judge concluded the discussion of the *Motion to Strike* by indicating that he would read the materials presented by the parties and consider using special interrogatories. He cautioned, however, that, "while I'm open to a special interrogatory presentation, I'm not open to a special interrogatory presentation that goes on and on and on." *Id.* at 30–31.

Four days after conducting the pre-trial hearing, the district court denied S&N's request that it not submit the ultimate question of obviousness to the jury. *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, No. 08-cv-102, slip op. at 4–5 (W.D. Tex. Jan. 29, 2010) (order granting in part and denying in part defendant's motion to strike plaintiff's jury demand on questions of law) (ECF No. 407). It concluded that "[t]he jury instructions shall explain the underlying factual issues that the jury must resolve as well as the legal standard for determining obviousness. Additionally, the jury verdict form shall specifically ask the jury to determine the underlying *Graham* factors, and make a final determination of obviousness that the court will consider as advisory." *Id.* at 5.

In accordance with this ruling, the parties began developing proposed joint jury instructions and a special verdict form. At the close of the presentation of evidence,

the parties were still developing the instructions and the verdict form. Jury Trial Tr. Day 10 at 2806, *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, No. 08-cv-102 (W.D. Tex. Feb. 23, 2010) ("*Day 10 Trial Transcript*"). Because the jury instructions and verdict form were not complete and there was some disagreement over the exact form the documents should take, the district court held a charge conference to resolve any remaining disputes, and finalize the instructions and the verdict form. At this stage in the proceeding, the obviousness verdict form proffered by S&N was eighteen pages in length, and Wake Forest and KCI's was slightly more than seven pages in length. *Id.* at 2969–70. Each of the proposed verdict forms contained specific questions addressing the differences, if any, between the asserted claims and the three categories of prior art discussed above. After reviewing the proposals, the judge stated, "I really can't give them this. . . . I may have to try to figure out something else to give them, but this won't work." *Id.* at 2985.

The judge explained his belief that, if the verdict form only posed the ultimate question to the jury, the court would be left with little guidance regarding the factual predicate for the jury's resolution of that issue. *Id.* at 2990–91. The district court, therefore, expressed its preference to ask the jury specific questions about the various *Graham* factors, in addition to asking the jury its view on the ultimate conclusion of obviousness. *Id.* at 2992–94.

After discussing the various options with the parties, the judge decided that the best option was to allow the parties to draft a 300-word description of what the parties asserted were the differences between the three main categories of prior art and each of the asserted claims. These "jury contentions" would be included in the jury instructions. Then the jury verdict form would ask what

differences, if any, the jury found between the given claim and the three main categories of prior art, providing space for the jury to list the differences in a narrative. *Id.* at 2997–3006.

With these guidelines, the judge dismissed the parties to finish drafting the jury instructions and verdict form, explaining that that they would meet that evening when the instructions and verdict form were complete. *Id.* at 3003–04. The judge advised the parties, however, that "if you've got any better idea on obviousness that you can agree to, I'll be glad to do it, but what you've come up with so far we're not going to do. And so, if you can't come up with anything, then you just have to do it the way I said, which I think is not optimal." *Id.* at 3062.

When the parties met that night with the judge, a court reporter was not present, so there is no record of the discussion. It is clear from looking at the jury instructions and the verdict form as presented to the jury, however, that the parties and the judge agreed to use a different format than suggested by the judge at the close of the charge conference. Although the jury instructions contain a discussion of the parties' contentions regarding the differences between the prior art and the claims, Jury Trial Tr. Day 11 at 3098–3102, *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, No. 08-cv-102 (W.D. Tex. Feb. 24, 2010) ("*Day 11 Trial Transcript*"), the verdict form did not allow the jury to provide a narrative about which differences they found to exist, nor did it pose questions regarding all of the *Graham* factors. J.A. 65–89. Instead, in questions 5(A)–(C), the jury was asked whether several enumerated differences between the prior art and the asserted claims were the only differences that existed. The jury was simply instructed to answer yes or no. In addition, in question 5(D), the verdict form contained a chart that allowed the jury to indicate whether they found

certain objective indicia of nonobviousness to be present with respect to each of the asserted claims. J.A. 70. Finally, in question 6, the verdict form asked the jury to decide whether S&N had proven that the asserted claims were obvious. J.A. 71.

The jury determined that the claims and the prior art exhibited differences in addition to those listed, J.A. 64–69, that most of the objective considerations favoring nonobviousness were present with respect to each claim, that infringement was proven, and that obviousness was not established. J.A. 62–63; 71. After the verdict was read to the parties, the district court indicated that the parties should prepare post-trial motions if they wished to challenge the jury's verdict. Jury Verdict Tr. at 12–13, *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, No. 08-cv-102 (W.D. Tex. Mar. 10, 2010) ("*Jury Verdict Transcript*").

Pursuant to Rule 50(b) of the Federal Rules of Civil Procedure, S&N moved for JMOL, arguing that all of the asserted claims of the '081 and '651 patents were obvious. In its motion, S&N asserted that substantial evidence did not support the jury's explicit findings that (1) additional differences between the prior art and the asserted claims existed, and (2) that multiple objective indicia of nonobviousness were present.

Responding to S&N's motion, Wake Forest and KCI argued that, in addition to the explicit jury findings, the jury's implicit findings necessary to determine the ultimate question of obviousness should be presumed to have been found in Wake Forest and KCI's favor. Furthermore, these findings, both explicit and implicit, should not be disturbed by the trial court unless they are not supported by substantial evidence. In light of this standard, Wake Forest and KCI asserted that substantial evidence

supported the jury's factual determinations: (1) that additional differences existed between the prior art and the asserted claims; (2) that objective indicia of nonobviousness were present; and (3) that teaching away was demonstrated with respect to the Bagautdinov and Chariker-Jeter references. On the basis of these findings, Wake Forest and KCI asserted that S&N's motion should be denied because it failed to establish that the asserted claims were obvious as a matter of law.

Replying to Wake Forest and KCI, S&N highlighted that the jury's verdict of nonobviousness was advisory only. Accordingly, it argued that there were no implicit factual findings in support of the advisory verdict on nonobviousness to which the court should defer. Instead, S&N asserted that "as the ultimate decision-maker on obviousness, th[e] [district] [c]ourt has the responsibility to make its own findings, based upon the current record, necessary to support its own legal conclusion regarding obviousness." Def.'s Reply in Supp. of its Renewed Mot. for J. as a Matter of Law of Invalidity for Obviousness and Mot. for New Trial at 1, *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, No. 08-cv-102 (W.D. Tex. May 12, 2010) (ECF No. 548). Based upon this understanding of how the jury's verdict should be reviewed by the district court, S&N argued that the asserted claims were obvious as a matter of law.

Prior to ruling on the merits of S&N's motion, the court conducted a hearing. S&N began by arguing that, because the jury's verdict on the ultimate question of obviousness was advisory, it is inappropriate to "just assume every finding of fact in favor of" the jury's nonobviousness verdict. Post-Trial Hr'g Tr. at 133, *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, No. 08-cv-102 (W.D. Tex. May 17, 2010) ("*Post-Trial Hearing Transcript*"). Indeed, S&N argued that implied findings of fact

only arose with respect to questions 5(A)–(C), regarding additional differences, and 5(D), regarding the existence of objective indicia of nonobviousness. *Id.* at 133–34, 36. "It is not simply enough to say the jury found obviousness, implied every finding of fact in our favor, which is what KCI is arguing, and therefore the verdict should be upheld. Not true. They are only entitled to implied findings to the extent they are encompassed by the Verdict Question 5, not 6." *Id.* at 136. S&N argued that substantial evidence did not support the jury's factual finding that additional patentably significant differences existed between the prior art and the asserted claims and that objective indicia of nonobviousness were present.

Wake Forest and KCI, on the other hand, argued that the jury's verdict on the ultimate question of obviousness is always advisory because, as a question of law, it must be determined by the court. *See id.* at 153. Nonetheless, "the case law is absolutely clear that . . . [w]hen the jury finds that [the claims] are not obvious, you have to assume that they find the right underlying facts, and then the test is substantial evidence" for the underlying factual findings. *Id.* at 155. Under this standard, Wake Forest and KCI argued that substantial evidence supported the jury's explicit and implicit factual findings, and that S&N's motion should have been denied.

Ultimately, the district court indicated that it would "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." *JMOL Order* at 8. After thoroughly summarizing the relevant prior art, the district court concluded that, contrary to the jury's explicit findings, "the differences between the claimed invention and the prior art, if any, are minimal." *Id.* at 18. Indeed, the district court concluded that the differences were so minor

that "such minimal variations would have been apparent to one having ordinary skill in the art . . . ." *Id.* at 34. The court concluded, therefore, that "the evidence is clear and convincing that there is no legally sufficient basis on the record to conclude that all asserted claims of the patents in suit were not obvious." *Id.* The fact that the jury also found that several objective indicia of nonobviousness were present did not alter the district court's conclusion because, it said, "the Court is not convinced that they overcome the strong case of obviousness established by the teaching in the prior art." *Id.* at 35. Accordingly, the court granted S&N's motion and entered judgment in its favor. *Id.* at 37.

Wake Forest timely appealed.[4] We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review a district court's grant of JMOL de novo, applying the law from the regional circuit, the Fifth Circuit in this case. *Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241, 1248 (Fed. Cir. 2005). In the Fifth Circuit, JMOL may be granted by the trial court only if "the facts and inferences point so strongly and overwhelmingly in favor of one party that the Court believes that reasonable men could not arrive at a contrary verdict . . . . On the other hand, if there is substantial evidence opposed to the [grant of JMOL] . . . [it] should be denied." *Broussard v. State Farm Fire & Cas. Co.*, 523 F.3d 618, 624 (5th Cir. 2008) (quoting *Brown v. Bryan Cnty.*, 219 F.3d 450, 456 (5th Cir. 2000)). When evaluating the district court's grant of JMOL, consideration is given to "all of the evidence, drawing all reasonable inferences and resolving all credibility determinations in the light most favorable to

[4] KCI did not appeal this judgment and is not, therefore, an appellant before this court.

the non-moving party." *Id.* (quoting *Brown*, 219 F.3d at 456. Because obviousness is a mixed question of law and fact, "[w]e first presume that the jury resolved the underlying factual disputes in favor of the verdict [] and leave those presumed findings undisturbed if they are supported by substantial evidence. Then we examine the [ultimate] legal conclusion [of obviousness] de novo to see whether it is correct in light of the presumed jury fact findings." *Jurgens v. McKasy*, 927 F.2d 1552, 1557 (Fed. Cir. 1991) (internal citations omitted); *see also Bos. Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 990 (Fed. Cir. 2009) ("When we consider that, even in light of a jury's findings of fact, the references demonstrate an invention to have been obvious, we may reverse its obviousness determination." (citing *Richardson-Vicks, Inc. v. Upjohn Co.*, 122 F.3d 1476, 1479 (Fed. Cir. 1997))).

In the face of what amounts to well settled law, S&N argues that, because the jury's verdict in this case was "advisory," "no factual findings implied within the advisory verdict are binding . . . ." Appellee's Br. at 39. S&N asserts, therefore, that we should review only the jury's explicit factual findings with respect to questions 5(A)–(D) for substantial evidence. Because the jury's advisory verdict on the ultimate question of obviousness gave rise to no implied factual findings, S&N contends the district court was free to make its own findings of fact with respect to all issues not submitted to the jury. *Id.* at 39–40. According to S&N, we should review these factual findings for clear error. Finally, S&N argues that the district court's ultimate conclusion regarding obviousness should be reviewed de novo in light of the factual findings we find to be supported by the evidence. We disagree.

Although S&N is correct that the district court repeatedly referred to the jury in this case as "advisory," S&N is wrong about the implications use of that term

carries. We first address the ways in which the phrase "advisory jury" is used by trial courts.

The term is sometimes used to refer to Rule 39(c)(1) juries. Fed. R. Civ. P. 39(c)(1) ("In an action not triable of right by a jury, the court, on motion or on its own: may try any issue with an advisory jury . . . ."). Under Rule 39(c)(1), when an "advisory jury" is used, no jury findings – either explicit or implicit – are binding on the trial court and the court is obligated to make independent findings of fact and conclusions of law on the issue presented to the jury. S&N first claims that the district court submitted the matter to the jury under Rule 39(c)(1) and that accordingly, neither the trial court nor we are bound by the jury's factual findings. We disagree.

We do not believe that the district court intended to invoke Rule 39(c)(1) when it referred to an "advisory jury." First, a Rule 39(c)(1) advisory jury is available only in an action not triable by right to a jury. *Id.* But, patent infringement actions must be tried to a jury if demanded by a party. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 377 (1996). Second, S&N did not ask and the district court did not make special findings that Rule 52 requires in all actions tried "with an advisory jury." Fed. R. Civ. P. 52 ("[T]he court must find the facts specially and state its conclusions of law separately."); *see also Transmatic, Inc. v. Gluton Indus., Inc.*, 53 F.3d 1270, 1275 (Fed. Cir. 1995) ("When, as here, trial is held before the district court with an advisory jury, the court must find the facts specially just as it would when conducting a bench trial without an advisory jury." (citing *In re Incident Aboard the D/B Ocean King*, 758 F.2d 1063, 1072 (5th Cir.1985))). And, rather than filing a motion to have the judgment amended under Rule 52(b), which applies to actions tried before a Rule 39(c)(1) advisory jury, S&N filed a motion pursuant to Rule 50, which governs "judg-

ment as a matter of law in a jury trial."[5] Fed. R. Civ. P. 50. Finally, S&N concedes that the district court, and we, must defer to the jury's explicit factual findings, a concession that is inconsistent with its reliance on Rule 39(c)(1). It is clear, therefore, that the court did not use the term "advisory jury" to denote a Rule 39(c)(1) jury.[6]

As a consequence, all of the cases cited by S&N for the proposition that there are "no factual findings implied

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[5] During oral argument, S&N argued that this court's decision in *Goodwall Construction Co. v. Beers Construction Co.*, 991 F.2d 751 (Fed. Cir. 1993) required it to file its motion under Rule 50 and not Rule 52(b). Oral Argument at 30:12–30:49, *Kinetic Concepts, Inc., v. Smith & Nephew, Inc.*, No. 2011-1105, *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/2011-1105/all. *Goodwall* does not address this issue, however. Instead, it addresses whether a motion on an issue unresolved by the jury, which utilized a Rule 49(a) special verdict form, is a motion for judgment under Rule 49(a) or Rule 50(b). 991 F.2d at 756–57. We held that it was a motion under Rule 49(a). *Id.* at 757.

[6] To the extent S&N argues that KCI waived its right to a jury trial, and agreed to use a Rule 39(c)(1) jury, we find no merit in this argument. Waiver of the right to a jury trial cannot be assumed under circumstances in which a party continually requests a jury trial and the district court never referenced Rule 39 or waiver of the right to a jury trial when it referred to an "advisory jury." *See Jennings v. McCormick*, 154 F.3d 542, 545 (5th Cir. 1998) ("The right to jury trial is too important and the usual procedure for its waiver is too clearly set out by the Civil Rules for courts to find a knowing and voluntary relinquishment of the right in a doubtful situation." (citation omitted)); *McDonald v. Steward*, 132 F.3d 225, 229 (5th Cir. 1998) ("Waiver should not be found in a doubtful situation." (internal quotation and citation omitted)); *McAfee v. Martin*, 63 F.3d 436, 437 (5th Cir. 1995) ("[C]ourts should indulge every reasonable presumption against waiver." (internal quotation and citation omitted)).

within the advisory verdict [that] are binding on the district court" are irrelevant because all of the cases involved actions that are not triable to a jury by right and all addressed Rule 39(c)(1) advisory juries. *E.g.*, *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1333 (Fed. Cir. 2011) ("Inequitable conduct is equitable in nature, with no right to a jury, and the trial court has the obligation to resolve the underlying facts of materiality and intent." (citation omitted)); *Sheila's Shine Prods., Inc. v. Sheila Shine, Inc.*, 486 F.2d 114, 122 (5th Cir. 1973). Whether the jury's verdict on obviousness gave rise to implied factual findings is not, therefore, controlled by these cases.

The term "advisory jury" can also be used to denote a jury's resolution of a legal issue that the court can permissibly give to the jury to decide, but whose ultimate determination is reserved for the court. *See e.g.*, *Spectralytics, Inc. v. Cordis Corp.*, 649 F.3d 1336, 1341–42 (Fed. Cir. 2011); *R.R. Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1515 (Fed. Cir. 1984). As we have explained:

> [I]t is neither error nor dangerous to justice to submit legal issues to juries, *the submission being accompanied by appropriate instructions on the law from the trial judge*. The rules relating to interrogatories, jury instructions, motions for directed verdict, JNOV, and new trial, and the rules governing appeals following jury trials, are fully adequate to provide for interposition of the judge as guardian of the law at the proper point and when necessary. There is no question that the judge must remain the ultimate arbiter on the question of obviousness. He or she exercises that role first in exercising the judge's duty of giving proper instructions on the law to the jury before it considers its verdict. The judge exercises control

> on the question again when presented with a motion for JNOV or new trial. In no sense need the judge abdicate the guardianship role.

R.R. Dynamics, 727 F.2d at 1515. This appears to be the manner in which the district court used the term "advisory jury." *Pre-Trial Conference Transcript* at 16–22 ("[N]o matter how I present this to the jury I have to make a separate determination as to obviousness."). This conclusion is buttressed by the fact that the Patent Case Management Judicial Guide, which the district court explained it reviewed with respect to this issue, suggests this use of the term "advisory jury." Peter S. Menell et al., *Patent Case Management Judicial Guide* 8-32 (2009) ("[T]he court can submit only the relevant *Graham* factors to the jury for its determination through special interrogatories, with or without an advisory verdict on the legal question of obviousness, and then determine the ultimate question of obviousness itself based on the jury's factual determinations.").

With this understanding of the district court's use of the term "advisory jury," we now address S&N's remaining argument regarding the standard of review. S&N asserts that the district court utilized a Rule 49(a) special interrogatory verdict form. Based on this contention, S&N asserts that there are no implied factual findings to which deference is due because a party waives its right to a jury trial on factual issues for which the party did not demand a special interrogatory and "factual issues not submitted to the jury as special interrogatories are deemed decided by the district court in accordance with the court's judgment." Appellee Br. at 40.

S&N is incorrect. First, a court employing a Fed. R. Civ. P. 49 special verdict form can only require the jury to return such findings as to "each issue of fact." Rule

49(a)(1). Because the ultimate conclusion of obviousness is a legal question, there is strength to the argument that by including that question on its verdict form the court chose to employ a general verdict with answers to written questions governed by Rule 49(b). It is clear that factual findings in support of the general verdict are implied when a verdict form under Rule 49(b) is used. *See Quaker City Gear Works, Inc. v. Skil Corp.*, 747 F.2d 1446, 1453 (Fed. Cir. 1984) (explaining that when a Rule 49(a) verdict form includes a legal question, "since the answer to the legal question necessarily resolves any disputed underlying factual issues, we have undertaken to review the factual findings on which the legal conclusion is based, applying the substantial evidence standard." (citation omitted)). Furthermore, we have indicated that, while it is not error to submit legal questions to the jury as part of a Rule 49(a) special verdict form, "since the answer to the legal question necessarily resolves any disputed underlying factual issues," the court must accept implicit factual findings upon which the legal conclusion is based when they are supported by substantial evidence. *Id.* (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1550 (Fed. Cir. 1983)); *see also Gia Techs. Inc. v. Recycled Prods. Corp.*, 175 F.3d 365, 371 (5th Cir. 1999) ("Rule 49(a) does not permit a district court to make findings contrary to the jury verdict."). In essence, because the district court included the ultimate question of obviousness on the special verdict form, all of the factual determinations underlying the ultimate question were implicitly put to the jury for resolution. Wake Forest did not, therefore, waive a jury trial on any factual issue not submitted to the jury in an interrogatory, and the district court was required to accept all implicit factual findings supporting the jury's conclusion with respect to the ultimate conclusion of obviousness that were supported by substantial evidence.

Accordingly, we review all of the jury's explicit and implicit factual findings for substantial evidence. We then examine the legal conclusion of obviousness de novo to determine whether it is correct in light of the factual findings that we find adequately supported. *Jurgens*, 927 F.2d at 1557.

I.

A patent is obvious, and, therefore, invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). Obviousness is a question of law based on underlying factual findings: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness. *Graham*, 383 U.S. at 17–18. A party seeking to invalidate a patent on the basis of obviousness must "demonstrate 'by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.' " *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (quoting *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007)). While an analysis of any teaching, suggestion, or motivation to combine elements from different prior art references is useful in an obviousness analysis, the overall inquiry must be expansive and flexible. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 415, 419 (2007).

This court has explained, moreover, that the obviousness inquiry requires examination of all four *Graham*

factors. *E.g.*, *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1375 (Fed. Cir. 2012). Indeed, courts must consider all of the *Graham* factors prior to reaching a conclusion with respect to obviousness. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1076–77 (Fed. Cir. 2012) (collecting cases). At all times, the burden is on the defendant to establish by clear and convincing evidence that the patent is obvious. *Id.* at 1077–78.

Because Wake Forest asserts that the district court erred by granting judgment as a matter of law overturning the jury's verdict, we must determine which of the jury's explicit and implicit factual findings with respect to the *Graham* factors are supported by substantial evidence. Each of the *Graham* factors is addressed in turn below.

A. Scope and Content of the Prior Art

The parties agree on which references are prior art. On appeal, S&N focuses its obviousness analysis on the Bagautdinov references, Zamierowski reference, and the Chariker-Jeter references. With respect to these references, the parties dispute their content,[7] namely, whether the prior art discloses the treatment of wounds with negative pressure. This is the central issue on appeal because all of the asserted claims, covering either the method or apparatus, require the use of negative pressure to either "treat a wound" or "facilitate the healing of

[7] While the district court stated that the parties did not contest the content of the prior art, this statement was incorrect. *JMOL Order* at 7. Whether the prior art disclosed the treatment of wounds with negative pressure was a key dispute between the parties, *see id.* at 21, and the district court resolved the issue in its JMOL order. *Id.* at 25, 27–28, 33.

wound."[8] The district court concluded that there was no support for the proposition that these primary references did not disclose the treatment of wounds utilizing negative pressure. *JMOL Order* at 25, 27–28, 33. As explained below, this was error: substantial evidence supports the jury's implied factual finding that none of these references disclosed the treatment of wounds using negative pressure.

1. Content of the Bagautdinov References

The Bagautdinov references disclose a device for draining fluid from purulent wounds. The device involves placement of a polyurethane foam in the purulent wound, attaching the foam to a pump, and covering the apparatus and the wound with a polyethylene film secured to the skin with vaseline oil. J.A. 10002.

The jury was presented with conflicting evidence regarding whether the references treated wounds as construed by the district court, and if they did, whether they treated wounds with negative pressure. S&N's experts contended that the references disclosed the treatment of wounds within the meaning of the asserted claims. *See* J.A. 22345:13–17 (testimony of Dr. Gordon, S&N's expert, stating that Bagautdinov I disclosed the use of negative pressure to treat a wound). In addition, Dr. Bagautdinov displayed the method disclosed in the references to the jurors with the aid of a manikin. J.A. 22204–05.

Wake Forest presented conflicting testimony, however. It proffered expert testimony that the purulent wounds described in the Bagautdinov references are in fact abscess or pus pockets not within the district court's

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[8] While the district court indicated in the *JMOL Order* that it was not sure the claims contained this limitation, as explained below, they do. *See infra* p. 30.

construction of the term "wound." J.A. 22871:19–21 ("Dr. Bagautdinov is using a variant, or modification of a technique, to aspirate, or to suck out, pus from a purulent wound, which is a pus pocket."); J.A. 21431:15–23 (discussing how Bagautdinov treated pus pockets by lancing and then draining them with the disclosed method). In addition, Wake Forest's expert testified that the Bagautdinov references indicate that use of the device is discontinued when the purulent wound has been cleaned of infection, whereas the patented method and apparatus are utilized only after a wound has been cleaned of infection. J.A. 22878:7–80:16. S&N's expert conceded, moreover, that the Bagautdinov articles were "particularly concerned about the problems related to putting negative pressure on the area of skin surrounding the wound and the risk of spreading infection, causing tissue damage . . . ." J.A. 22343:5–8. In other words, the Bagautdinov references explain that use of negative pressure on or surrounding a wound is dangerous to the patient. This amounts to teaching away. *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1332 (Fed. Cir. 2008) (quoting *In re Kahn*, 441 F.3d 977, 990 (Fed. Cir. 2006) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.")).

Finally, Wake Forest presented testimony that the method disclosed in the Bagautdinov references could not create an adequate seal, J.A. 21437:25–38:2; J.A. 21433:2–15, and did not treat wounds through negative pressure because the pressure was not sustained for a long enough period of time. J.A. 21433:18–34:11; J.A. 21437:19–38:2. Indeed, Dr. Bagautdinov admitted that he only used his device to treat "infected wounds," J.A.

22312:15–22, and that he "never considered using [his] technique to treat wounds until closure." J.A. 22310:17–21.

Because of this conflicting expert testimony, the jury was free 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). In light of the jury's determination that S&N failed to prove obviousness, we must infer that the jury found Wake Forest's experts to be credible and persuasive on this point. *Broussard*, 523 F.3d at 624; *Jurgens*, 927 F.2d at 1557. Crediting their testimony over that of S&N's expert, there is substantial evidence supporting the factual finding that the Bagautdinov references do not disclose: (1) the treatment of "wounds" as described in patents; or (2) use of negative pressure to treat wounds. There is also substantial evidence to support the finding that the references teach away from maintaining negative pressure on a wound for extended periods of time because of the perceived problems associated with doing so.

2. Content of the Zamierowski Reference

The parties agree that the Zamierowski reference's method is utilized on "wounds" within the district court's construction, and discloses placing a screen means into a wound, sealing the wound by placing a membrane with an adhesive coating over the wound, and connecting a tube from under the membrane to a vacuum source. J.A. 28. This system can then be used to either drain from or inject fluid into the wound. J.A. 10063. S&N argues, and the district court found, that the Zamierowski reference also disclosed treating wounds with negative pressure. *JMOL Order* at 27–28.

During trial, Wake Forest argued that this reference does not disclose healing wounds with negative pressure

because it neither disclosed a seal capable of maintaining negative pressure on a wound, nor disclosed treating the wound towards a selected stage of healing as required by the asserted method claims.

The district court concluded that Wake Forest's first argument was incorrect because it found that the patent claims do not require healing to be accomplished by negative pressure. *Id.* at 27. In the alternative, the district court concluded that the Zamierowski reference met this requirement because fluid is removed from the wound with negative pressure and removal of fluid enabled healing, so "healing" was "accomplished by the negative pressure." *Id.* at 27–28.

The district court was incorrect with respect to its determination that the claims of the asserted patents do not require wounds to be healed by negative pressure. First, in the *Blue Sky* appeal, we concluded that all of the claims of the '081 patent asserted in the present litigation require the use of negative pressure to treat a "wound." 554 F.3d at 1015 ("[E]ach 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 . . . ."). Thus, we have already construed the claims to include this limitation and that legal conclusion was binding on the district court and is binding on this panel. The specifications of both the '081 and '651 patents support our conclusion in *Blue Sky*, moreover. *E.g.*, '081 patent col.2 ll.45–49 ("The present invention includes . . . applying a negative pressure to a wound over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the wound, with the negative pressure being maintained for a time sufficient to facilitate closure of the wound."); '651 patent col.2 ll.61–64 ("[A] wound treatment apparatus is provided for treating a wound by applying reduced pressure . . . to the wound

. . . ."). And, before the PTO, the patentees distinguished their claims from the prior art by asserting that references "do not disclose or suggest 'an appliance for administering a reduced pressure treatment to a wound'; 'an apparatus/method for treating a wound' with reduced pressure." J.A. 5501 ('651 patent); *see also* J.A. 5502 ('651 patent); J.A. 8267 ('081 patent) (Unlike the prior art, "[the] claimed invention is directed to a device configured to create and maintain negative pressure on a wound site . . . for the purpose of administering a negative pressure treatment to the wound."). Finally, S&N never argued before the district court that the asserted claims did not require this limitation. In light of our prior holding in *Blue Sky*, the language of the specification, and the patentee's statements made during reexamination, we find that each of the asserted claims requires the use of negative pressure to heal or treat wounds.

With respect to the district court's alternative holding, whether the prior art discloses the limitations of a particular claim is a question of fact to be determined by the jury, and Wake Forest presented ample evidence that the Zamierowski reference does not disclose the use of negative pressure to heal wounds. J.A. 21453:19–25; J.A. 22667:24–70:10; J.A. 22866:19–68:12.

In support of its argument that the Zamierowski reference does not disclose a seal capable of maintaining negative pressure, Wake Forest presented testimony that the reference does not create a seal within the meaning of the patent because it uses only a tight liquid seal that has air gaps. J.A. 21472:19–73:11; J.A. 22668:25–69:4. This testimony is consistent with the reference, which indicates that the dressing material is "breathable semipermeable" and the seal is "relatively liquid-tight." J.A. 10068; J.A. 10070. With respect to the contention that "healing" is not accomplished as contemplated by the

patents, Wake Forest's expert testified that the Zamierowski reference failed to disclose maintaining negative pressure until the wound has progressed to a selected stage of healing. J.A. 22456:24–58:1; J.A. 22669:5–8. Zamierowski, instead, uses a tubing system to medicate and drain wounds, and thereby "promote[ ] healing" generally, J.A. 10061–63; J.A. 10074; it does not disclose the use and maintenance of negative pressure on a wound site to facilitate wound closure and thereby promote wound healing, as do the patents. And, unlike the system specified in the patents, Zamierowski's system is to be removed once the process of medication and draining has been completed. J.A. 10073. Indeed, the inventor of the Zamierowski device testified that the inventors of the '651 and '081 patents invented the use of negative pressure for wound therapy and that he had not. J.A. 22571:13–17; *see also* J.A. 22571:10–12 (Zamierowski inventor indicating that his contribution to the commercial embodiment of the asserted patents is primarily the methods of attaching the "the rigid conduit to the flimsy film").

Because the jury concluded that S&N failed to establish that the patents were obvious, we must assume that the jury found Wake Forest's expert to be credible and persuasive on this point. In light of this assumption, there is substantial evidence to support the factual finding that the Zamierowski reference does not disclose a sealing means capable of maintaining negative pressure, or maintenance of pressure until the wound has progressed toward a selected stage of healing.

3. Content of the Chariker-Jeter References

The Chariker-Jeter references, as explained above, disclose a system for treating wounds that are complicated by a fistula. J.A. 10043. The parties dispute whether these references disclose the treatment of a

wound within the meaning of the patents, and if it does disclose treatment of such wounds, whether the disclosed device used negative pressure to treat the wounds. With the exception of the Chariker-Jeter public use, the two Chariker-Jeter publications indisputably deal only with the treatment of "[p]atients with draining wounds and fistulae." J.A. 10050.

In *Blue Sky*, we held that the term wound, as used in these patents "does not cover the fistulae described in the [Chariker-Jeter] publications . . . ." 554 F.3d at 1018. Despite our conclusion that the injuries treated in the Chariker-Jeter publications are not "wounds" within the meaning of these patents, S&N presented testimony attempting to establish that the references disclosed such treatment. J.A. 22348:1–49:12; J.A. 22028:7–30:6. Regarding the Chariker-Jeter public use, which was not addressed in *Blue Sky*, S&N proffered the testimony of Dr. Chariker who, while he was a resident, helped treat Mr. Aderholt with the system disclosed in the Chariker-Jeter publications. In this testimony, Dr. Chariker testified that he used the system to heal Mr. Aderholt with negative pressure. J.A. 22032:2–38:11.

Wake Forest presented testimony to contradict S&N's evidence. Its expert testified that all of the patients mentioned in the Chariker-Jeter publications had fistulae, and therefore, that the publications do not disclose the treatment of wounds within the district court's construction. J.A. 21441:1–7; J.A. 22672:11–23. In fact, on cross examination Dr. Chariker admitted that neither of the Chariker-Jeter publications discloses wounds not involving a fistula. J.A. 22045:15–25. Wake Forest's experts testified, moreover, that the device disclosed in the Chariker-Jeter references did not use negative pressure to treat wounds. J.A. 22671:12–91:24; J.A. 21439:1–41:22; J.A. 22869:13–70:21. And, Wake Forest's expert

testified that the Chariker-Jeter publications actually taught to limit granulization, which is directly contrary to the purpose of the '651 and '081 patents. J.A. 21441:12–19 ("So according to their document, they seem to want to limit granulation tissue formation."); J.A. 22673:11–12 ("[Drs. Chariker and Jeter] actually wanted to inhibit granulation tissue.").

Significantly, Dr. Chariker conceded that he "didn't publish anything about negative pressure wound therapy regarding fistulas or nonfistulas." J.A. 22046:8–9. Similarly, Dr. Jeter admitted on cross examination that she never suggested using the disclosed device if there was nothing to drain. J.A. 22147:8–11.

With respect to the Chariker-Jeter public use, Wake Forest offered testimony that Mr. Aderholt's wound involved a fistula, so it was not a wound within the meaning of the patents. J.A. 22696:4–13; J.A. 22698:22–99:5; J.A. 22898:22–99:8. On cross examination, moreover, Dr. Chariker refused to say that Mr. Aderholt did not have a fistula; he only stated that one was never diagnosed. J.A. 22057:23; J.A. 22058:4; J.A. 22085:2–6. In addition, Wake Forest's expert testified that, based on his reading of Mr. Aderholt's operative notes and pictures of his treatment, the system used on Mr. Aderholt was not the system disclosed in the Chariker-Jeter publications. J.A. 22714:25–15:9. Wake Forest's expert also testified that the Chariker-Jeter public use did not have a seal capable of maintaining negative pressure because Mr. Aderholt's skin had several sump drains that freely let air flow. J.A. 2900:14–02:14. In other words, his wound was not healed with negative pressure. J.A. 2712:13–14:19.

Finally, Wake Forest's experts testified that use of the drainage system disclosed in the Chariker-Jeter publications was discontinued when the fistula closed or substan-

tial drainage from the fistula stopped, irrespective of the state of any wound healing. J.A. 22869:20–70:12; J.A. 21438:13–39:18; J.A. 22672:24–74:4; J.A. 22870:3–5 ("In every single case, every single case that they show in the book chapter and in the article, the minute the fistula stopped draining, they got rid of their device."). Dr. Chariker conceded this fact on cross examination. J.A. 22062:17–20. This, again, reasonably could be deemed a teaching away from continued long-term use of the device, as directed by the '081 and '651 patents.

Again, because of the procedural posture of this case, we must assume that the jury found Wake Forest's experts credible and persuasive. Rather than credit this testimony, however, the district court impermissibly reweighed witness credibility, concluding that Wake Forest's expert's testimony that Mr. Aderholt had a fistula was "completely unsupported by the evidence." *JMOL Order* at 32. This was error. *See Blue Sky*, 554 F.3d at 1020. On the basis of this credited testimony, there is substantial evidence to support the finding that: (1) none of the Chariker-Jeter references discloses treatment of a wound within the meaning of the patents (as distinct from a fistula or pus pocket); (2) the Chariker-Jeter references do not disclose use of negative pressure to heal or treat wounds[9]; (3) the Chariker-Jeter publications teach away from promoting healing by using negative pressure; (4)

[9] This is the same conclusion we reached in *Blue Sky* with respect to the Chariker-Jeter references. 554 F.3d at 1020 ("[W]e 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."). On this point, the evidence presented in this case by Wake Forest and KCI was just as strong as the evidence presented in *Blue Sky*. We, of course, base our conclusion on the evidence in the current record.

the Chariker-Jeter public use did not involve the device disclosed in the Chariker-Jeter publications; and (5) the public use did not involve a seal capable of maintaining negative pressure. Finally, with respect to the method claims, substantial evidence supports the finding that negative pressure was not maintained until the wound progressed toward a selected stage of healing.

B. Level of Ordinary Skill in the Art

Although the parties did not stipulate the level of ordinary skill in the art, S&N's expert testified that the level of ordinary skill in the art "would include health care professionals, for example physicians or nurses, but it could be a podiatrist or somebody else, who has additional training or knowledge about wound care. It could also be engineers with experience operating or designing equipment used in conjunction with wound care." J.A. 22340:8–13. According to the district court, Wake Forest asserted that the level of skill was higher. J.A. 393. Because it is generally easier to establish obviousness under a higher level of ordinary skill in the art, *Innovention Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011) ("A less sophisticated level of skill generally favors a determination of nonobviousness, and thus the patentee, while a higher level of skill favors the reverse." (citation omitted)), we must assume that, in light of the jury's verdict, it adopted the lower level of skill proposed by S&N.

C. Differences Between the Claimed Invention and the Prior Art

The jury explicitly found that the prior art and the asserted claims exhibited several differences, which S&N conceded existed. J.A. 65–69. In addition, the jury stated that each of the prior art references exhibited additional differences from those explicitly mentioned on the verdict

form, although they were not asked to and, thus, did not identify those additional differences.

Although there are many differences between the primary prior art references and the asserted claims, for the purpose of this appeal, we need only focus on three. As discussed above, substantial evidence supports the finding that none of the references discloses treating wounds with negative pressure as required by the patents. Nor do the Bagautdinov and Chariker-Jeter references relate to the treatment of wounds described in the patents, as construed by this court in *Blue Sky* and the district court here. Finally, the Bagautdinov references and the Zamierowski reference do not disclose a seal capable of maintaining negative pressure. Accordingly, none of the references discloses healing or treatment with negative pressure. Only the Zamierowski reference discloses treating or healing wounds and only the Chariker-Jeter printed publications disclose a seal that is capable of maintaining pressure.

Even if the references disclosed all of the limitations of the asserted claims, which they do not, S&N still needed to proffer evidence indicating why a person having ordinary skill in the art would combine the references to arrive at the claimed invention. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008) (holding that post-KSR "some kind of motivation must be shown from some source, so that the jury can understand why a person of ordinary skill would have thought of either combining two or more references or modifying one to achieve the patented [invention]." (citation omitted)). Significantly, whether there is a reason to combine prior art references is a question of fact. *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1303 (Fed. Cir. 2010) (citing *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1352 (Fed. Cir.

2001)). Here, not only did S&N offer no evidence establishing a reason to combine, but Wake Forest offered substantial evidence that a person having ordinary skill in the art had no reason to combine the prior art references to arrive at the claimed invention. *E.g.*, J.A. 22669:18–25; J.A. 22691:18–22; J.A. 22715:25–16:4; J.A. 22737:7–11; J.A. 22753:24–54:3. In light of the jury's verdict, we must assume that it determined there was no reason to combine the prior art references, and we must defer to this factual finding because it is supported by substantial evidence.

D. Objective Indicia of Nonobviousness

With respect to the '081 asserted claims, the jury found the following indicia of nonobviousness: (1) commercial success; (2) long felt need; (3) copying; (4) unexpected results; (5) acceptance by others; and (6) initial skepticism. With respect to the '651 asserted claims, the jury found that for claims 109 and 116 on the basis of performing the method of claim 42, and claim 121 on the basis of performing the method of claim 42, the same indicia of nonobvious were present. Regarding claim 116, on the basis of performing the method of claim 20, and claim 121, on the basis of performing the method of claim 20, the jury concluded that only copying existed.

Wake Forest presented testimony regarding each of the objective indicia found by the jury. J.A. 22827:3–32:10; J.A. 217771:11–23; J.A. 21077:19–79:15. Wake Forest offered evidence that leading experts in the field were skeptical that the "counterintuitive" device could work. J.A. 22827:3–12, J.A. 22828:21–29:23, J.A. 21078:4–79:5. One expert testified that he "didn't know how you could put this [negative] pressure on a wound and not cut off the blood supply, not cause infection, etc." J.A. 22827:3–9. Indeed, Dr. Argenta, an inventor of the

patents, testified that the hospital where he worked was concerned about allowing him to try his device on a patient with a serious wound, which could not be healed with conventional methods, but the "decision [was] do you let [the patient] die or do you try something." J.A. 20446:3–23. To everyone's surprise, the device completely healed this patient. J.A. 20446:21–47:6. The medical community was so skeptical of the device, moreover, that the patents' inventors had difficultly publishing their findings in peer-reviewed journals, J.A. 20501:1–19 (Reviewers from the journal *Plastic and Reconstructive Surgery* stated that "there was no way that this was possible, that this device could do this"), and they were turned away by conference organizers when they attempted to present the discovery. J.A. 20502:10–15; J.A. 20501:3.

Despite this initial skepticism, over time the device was widely adopted and praised. J.A. 22830:6–31:8, J.A. 21079:10–12. Wake Forest presented testimony from experts that the patented device "changed the way we do surgery," J.A. 21079:11–12, and "changed the way . . . we've been treating wounds for the last twenty, thirty years." J.A. 22831:1–3. Indeed, S&N's own expert testified that the device was "a paradigm shift in wound healing" and that it "is so effective that it's changed the way that [he] and [his] fellow surgeons treat serious wounds." J.A. 22409:11–10:11. To date, the device has been used on more than three million patients. J.A. 21753:22–25. Indeed, Harvard Medical School called the device an "exciting novel therapeutic approach to wounds," J.A. 20504:22–05:2, and the American Association of Plastic Surgeons recognized the device as the last decade's "biggest advance in the plastic surgery field." J.A. 22762:10–15. The effectiveness of the device and this

praise has made it a commercial success with $1.4 billion in annual sales. J.A. 21771:12–13.

Finally, Wake Forest proffered testimony that the device has been copied. For example, in internal documents and marketing materials, S&N repeatedly compares its products to the V.A.C., the commercial embodiment of the patents. J.A. 22760:11–61:23; J.A. 20537:17–39:18; J.A. 20999:1–21. Indeed, S&N's expert admitted that he authored an article explaining how to create "an off-the-shelf or makeshift V.A.C." J.A. 22410:18–12:6.

In the face of this evidence, S&N offered no rebuttal evidence. S&N's own invalidity expert even admitted that he did not consider the objective indicia of nonobviousness in reaching his conclusions regarding the invalidity of the patents. J.A. 22396:20–97:8; J.A. 22415:24–16:15. Significantly, the district court concluded that Wake Forest "present[ed] ample evidence of success of V.A.C. product and the other secondary considerations tending to show non-obviousness." J.A. 37. On the basis of this record, there is more than substantial evidence supporting the jury's findings of commercial success, long-felt need, copying, unexpected and superior results, wide spread acceptance in the field, and initial skepticism.

E. The Ultimate Conclusion of Obviousness

Having determined that the jury's explicit and several implicit factual findings are supported by substantial evidence, "we examine the [ultimate] legal conclusion [of obviousness] de novo to see whether it is correct in light of" these factual findings. *Jurgens*, 927 F.2d at 1557 (internal citations omitted); *see also Wyers v. Master Lock Co.*, 616 F.3d 1231, 1248 (Fed. Cir. 2010) (Linn, J., concurring). Despite the district court's detailed analysis, we

find that, on the basis of the jury's factual findings, it erred by granting S&N's Motion for JMOL.[10]

While the Supreme Court made clear that a mechanical application of the teaching-suggestion-motivation test, requiring an explicit teaching in the prior art, is inappropriate, "[w]e must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention." *Innogenetics*, 512 F.3d at 1374 n.3.

As noted above, S&N never offered evidence articulating why a person having ordinary skill in the art would combine the primary references to obtain the disclosed inventions. Although expert testimony regarding motivation to combine is not always required, the technology at issue here is not the type of technology where common sense would provide the motivation to combine these references. *See Master Lock Co.*, 616 F.3d at 1240 n.5 ("However, as we [have] noted . . . 'expert testimony regarding matters beyond the comprehension of laypersons is sometimes essential,' particularly in cases involving complex technology. In such cases, expert testimony may be critical, for example, to establish . . . the existence (or lack thereof) of a motivation to combine references." (internal citations omitted)).

At a minimum, creation of the claimed apparatus or method requires combining the Zamierowski references, which disclose treating or healing of wounds, with the

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[10] This conclusion is consistent with the PTO's determination on reexamination that claims of the '651 and '081 patents were patentable in the face of some references at issue here. While this determination is not binding on this court, the jury was informed of the results of the reexamination and S&N does not dispute the admissibility of this evidence.

Chariker-Jeter publications that disclose a seal capable of maintaining negative pressure. The record is devoid of any reason someone would combine these references, however. Indeed, Wake Forest's experts testified that there was no reason to combine them. J.A. 22865:15–66:17; J.A. 22868:13–69:19; J.A. 22870:22–71:12. In addition, both of these references independently accomplish similar functions, namely, draining fluids. Because each device independently operates effectively, a person having ordinary skill in the art, who was merely seeking to create a better device to drain fluids from a wound, would have no reason to combine the features of both devices into a single device. Nor do the Bagautdinov references provide such motivation to combine the Zamierowski references and the Chariker-Jeter publications to arrive at the method and apparatus claimed in the patents in suit. Again, the Bagautdinov references disclose only the draining of purulent wounds; it says nothing about treating wounds within the district court's construction, much less the healing of such wounds with negative pressure.

As Dr. Argenta noted, moreover, if any of the doctors who created the devices disclosed in the prior art thought that negative pressure actually healed wounds, they would have left the devices in place until the wounds were fully healed. J.A. 22870. All of the doctors removed the devices after the wounds were drained, but before healing with negative pressure began. This indicates that the doctors were not using the disclosed devices and methods to heal wounds with negative pressure because they did not believe that these devices were capable of such healing. In fact, several of the primary references disclosed methods that purposefully minimize granulization while the devices were in place because of the perceived dangers associated with negative pressure. This amounts to

significant evidence of teaching away. On the basis of this evidence, hindsight provides the only discernable reason to combine the prior art references. Unless one knew that negative pressure could be used to treat wounds, there would be no reason to combine the prior art to arrive at the claimed device and methods.

It is clear, moreover, that the district court concluded that the invention was obvious because it believed the claims contained elements that were not new. This reasoning is incorrect: "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. Because none of the prior art references disclosed utilizing negative pressure to heal wounds, this is not even a case where the inventions at issue are merely composed of elements that were known in the art. Indeed, nearly seven years after the '081 patent was filed, Dr. Attinger testified that he still did not believe the apparatus and method disclosed in the patents would work. J.A. 22827:3–29:2.

Finally, the significant objective indicia of nonobviousness strongly weigh against a finding of obviousness. *Mintz*, 679 F.3d at 1378 (Evidence of objective indicia of nonobviousness "may often establish that an invention appearing to have been obvious in light of the prior art was not." (citation omitted)); *In re Cyclobenzaprine*, 676 F.3d at 1075–76 (same); *see also Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1310 (Fed. Cir. 2010) ("Secondary considerations 'can be the most probative evidence of nonobviousness in the record, and enables the . . . court to avert the trap of hindsight.' " (quoting *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 960 (Fed. Cir. 1986)); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008) ("Objective indicia may often be the most probative and cogent evi-

dence of nonobviousness in the record." (quoting *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1288 (Fed. Cir. 2002) (citation omitted)). We require analysis of the objective indicia because they "provide objective evidence of how the patented device is viewed in the marketplace, by those directly interested in the product." *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1391 (Fed. Cir. 1988). As discussed above, the medical community scoffed at this device when it was initially introduced. The industry was skeptical that the device worked even after reading studies that established that it did in fact work. J.A. 21078:19–21079:5. After the system was disseminated, moreover, everyone began using it, and the method and apparatus were copied. This evidence provides a key objective insight into how the medical community viewed the patented device.

Significantly, this is not a case where the jury found the presence of only one or two objective indicia of nonobviousness. Nor is it a case where S&N seriously disputes those findings. Rather, the evidence strongly establishes the existence of nearly every objective indicia of nonobviousness, namely commercial success, long-felt need, copying, unexpected and superior results, wide spread acceptance in the field, and initial skepticism. *See Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1092 (Fed. Cir. 1987) ("[P]raise from a competitor tends to indicat[e] that the invention was not obvious." (alteration in original) (internal quotation omitted)); *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997) (acknowledging that the accused infringer's "recognition of the importance of this advance is relevant to a determination of nonobviousness."). We recently warned about the dangers of ignoring objective indicia of nonobviousness in *Mintz*, where we said: "[s]imply because the technology can be easily understood does not

mean that it will satisfy the legal standard of obviousness. In fact, objective consideration of simple technology is often the most difficult because, once the problem and solution appear together in the patent disclosure, the advance seems self-evident." 679 F.3d at 1379. The objective indicia of nonobviousness serve a particularly important role in a case, like this one, where there is a battle of scientific experts regarding the obviousness of the invention. In such a case, the objective indicia provide an unbiased indication regarding the credibility of that evidence.

Here, the objective evidence strongly supports the jury's findings under the first three *Graham* factors and cuts against the view that the claimed inventions were an obvious combination of known elements from the prior art.

On this record, S&N has not proven by clear and convincing evidence that the asserted claims are obvious. The district court committed error by failing to defer to the jury's factual findings and granting JMOL on obviousness. Because the district court concluded that the other issues raised in S&N's motion for JMOL were moot in light of its decision to grant JMOL on obviousness, we reverse and remand, so the district court can consider those arguments in the first instance.

CONCLUSION

REVERSED AND REMANDED

COSTS

Each party shall bear its own costs.

United States Court of Appeals for the Federal Circuit

KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC., KCI MEDICAL RESOURCES, KCI MANUFACTURING, AND MEDICAL HOLDINGS LIMITED,
Plaintiffs,

AND

WAKE FOREST UNIVERSITY HEATLH SCIENCES,
Plaintiff-Appellant,

v.

SMITH & NEPHEW, INC.,
Defendant-Appellee.

2011-1105

Appeal from the United States District Court for the Western District of Texas in case no. 08-CV-0102, Judge W. Royal Furgeson.

DYK, *Circuit Judge*, concurring.

I agree with the majority that deference is owed to the jury's implied findings in support of its nonobviousness verdict for the reasons ably set forth in the majority opinion. However, I write separately because, in my view, the majority errs in its construction of the "healing" limitations of these claims. Because the jury was not

properly instructed on claim construction, it is impossible to determine what findings the jury made. At the same time, because the accused infringer did not seek a construction of the "healing" limitations, we should assume the jury used the correct construction. Under this construction, there was not substantial evidence that the claim limitations were absent from the prior art (though not in a single reference) or that secondary considerations supported a finding of non-obviousness, but there was substantial evidence for the jury to have found insufficient motivation to combine. On this ground, I agree with the majority that the accused infringer has not established invalidity for obviousness as a matter of law.

I Claim Construction

As the majority describes, the asserted claims cover an apparatus and method for treating wounds by applying suction, or "negative pressure," and Bagautdinov, Chariker-Jeter, and Zamierowski are three groups of prior art that disclose similar suction treatment systems. The jury found that none of the asserted claims would have been obvious over this prior art, but the district court granted judgment as a matter of law ("JMOL") that all of the asserted claims were invalid for obviousness.

"It is elementary in patent law that, in determining whether a patent is valid . . . the first step is to determine the meaning and scope of each claim in suit." *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1334 (Fed. Cir. 2004) (quoting *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001)); *see also TI Grp. Auto. Sys. (N. Am.), Inc. v. VDO N. Am., L.L.C.*, 375 F.3d 1126, 1139 (Fed. Cir. 2004) ("Our validity analysis is a two-step procedure: 'The first step involves the proper interpretation of the claims.'" (quoting *Beachcombers, Int'l, Inc. v. WildeWood Creative Prods., Inc.*, 31

F.3d 1154, 1160 (Fed.Cir.1994)). The meaning of a claim is a purely legal issue, which we determine de novo. *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1451 (Fed. Cir. 1998). The majority disregards this well established procedure by failing to directly address the proper construction of the central claim limitations related to "healing."

The majority excuses its failure to do so on the ground that these claim construction issues "were neither raised nor discussed before the district court, and were not argued in this appeal." Maj. Op. at 2 n.1. I agree with the majority that the parties have failed to address the claim construction issues directly, and have chosen instead to address the issues without the benefit of a proper claim construction. Nonetheless, defendant-appellee Smith & Nephew does contest the extent to which "healing" is required by the claims, arguing that "Wake Forest attempted to redefine its claimed invention throughout this litigation and continues to do so on appeal" by "mischaracterize[ing] the claims as requiring 'active' treatment of 'clean' wounds for 'extended' periods of time in order to heal the wounds," even though "none of those limitations is in the claims." Def.-Appellee's Br. 41.[1] And despite the parties' failure to seek a proper construction of the "healing" limitations, it is simply not possible to meaningfully address the question of obviousness without construing these limitations either by making implicit assumptions about claim scope (as the majority does) or by explicitly construing the claims (as I propose).

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[1] Smith & Nephew also raises the argument that "there is a lack of substantial evidence to support the jury's finding of nexus between the '081 claims and the secondary considerations." *Id.* at 66.

The asserted claims are claims 2 and 5 of U.S. Patent No. 5,645,081 ("the '081 patent") and claims 42, 109, 116, and 121 of U.S. Patent No. 7,216,651 ("the '651 patent"). The '081 claims both require the apparatus to create negative pressure "for facilitating the *healing* of wounds"[2] and to have a "sealing means . . . for *maintaining* said negative pressure." '081 Patent col. 9 ll. 52-58 (emphases added). The asserted '651 method claims all require "*maintaining*" negative pressure until the wound has "*progressed toward a selected stage of healing*." '651 Patent col. 23 l. 50, col. 25 ll. 47-48 (emphases added). The district court was not asked to construe "maintaining," "healing," or "a selected stage of healing" (collectively, "the 'healing' limitations"), but it did rule that the claims do not have a minimum-time limitation, a construction not challenged on appeal. J.A. 13390. We are unable to determine whether the asserted claims are obvious as a matter of law without understanding the meaning of these "healing" limitations. Because these claim terms are central to these appeal, our obligation to construe these limitations cannot be avoided simply because the district court failed to do so.

In my view, the "healing" limitations are properly construed as requiring only some progress toward healing—for example, the formation of some new tissue or skin—and not complete healing or wound closure. The language of the "selected stage of healing" limitation itself clearly indicates that only some progress toward healing is required. Additionally, claim 20 of the '651 patent (upon which claims 109, 116, and 121 depend) refers to "maintaining reduced pressure to promote the formation

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[2] The accused infringer appears to agree that this preamble language is a claim limitation. *See* Def.-Appellee's Br. 62 ("The '081 claims merely require an apparatus that *facilitates* the healing of wounds.").

of granulation tissue," and claim 121 specifies that "the selected stage of healing comprises re-epithelialization of at least a portion of the wound." '651 Patent col. 23 ll. 48-49, col. 30 ll. 30-31. The district court construed "granulation tissue" as "tissue formed during wound healing" and "re-epithelialization" as "re-growth of skin." J.A. 10373, 10377 (emphases omitted). Neither party objected to these constructions on appeal. These additional limitations in claims 20 and 121 demonstrate that "a selected stage of healing" cannot refer to complete healing. Furthermore, the unasserted dependent claims 118-120 and 122-124 of the '651 patent provide other more restrictive examples of "selected stage[s] of healing": "substantial closure of the wound," "substantially filling the wound with granulation tissue," "migration of epithelial and subcutaneous tissue toward the wound," and "a reduction in the volume [diameter or depth] of the wound by a predetermined amount." Under the "presumption that an independent claim should not be construed as requiring a limitation added by a dependent claim," *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006), "a selected stage of healing" is presumed to not include these limitations.

There is also no indication in the specifications that "healing" or "selected stage of healing" refers to any particular stage of healing; the '651 patent simply notes that "[a]n initial stage of wound healing is characterized by the formation of granulation tissue" and that "[a] selected state of improved condition may include" a number of conditions, including any "stages of improvement or healing appropriate to a given type of wound or wound complex." '651 Patent col. 1 ll. 40-41, col. 12 ll. 59-66. The '081 patent does not define "facilitating . . . healing" (as used in the claim preambles), but it notes that the invention may be used to "promote the migration of . . .

tissue," "reduce bacterial density in a wound," or "prevent[] the infection [in a burn wound] from becoming [too] severe," all of which seem to be examples of "facilitating . . . healing." '081 Patent col. 1 ll. 57-58, col. 2 ll. 1-2, col. 3 l. 67-col. 4 l. 1.[3]

Although the majority opinion does not explicitly construe the "healing" limitations, it seems to make three assumptions as to the meaning of these limitations. First, the majority suggests that the claims require application of negative pressure for a particular extended length of time. For example, the majority explains that Bagautdinov did not sustain pressure "for a long enough period of time" and taught away from applying negative pressure "for extended periods"; and that Chariker-Jeter taught "away from continued long-term use of the device, as directed by the '081 and '651 patents." Maj. Op. at 32, 39. But as discussed above, the district court correctly determined that the claims do not have a minimum time limitation, and that construction is not challenged on appeal.

Second, to some extent, the majority suggests that the claims require more than some progress toward healing, such as complete healing or closure. For example, the majority states that "the invention applies 'negative pressure . . . for a time sufficient to facilitate *closure* of the wound,'" that Bagautdinov was different from the claimed invention because it was not used "to treat wounds *until*

[3] While the patent does mention that the invention includes application of negative pressure "for a time sufficient to facilitate closure of the wound," *id.* col. 2 ll. 48-49, it nowhere suggests that "healing" is synonymous with "closure," or that "facilitat[ing] closure" requires the application of negative pressure until closure. As noted the patentee did not challenge the court's construction that there is no time limit in the claims.

closure," and that the asserted claims "require wounds to be *healed* by negative pressure." Maj. Op. at 4, 33-34 (emphases added). To the extent the majority reads a requirement of complete closure into the claims, this seems to me to be incorrect—as discussed above, the "healing" limitations merely require some progress toward healing, such as the formation of granulation tissue or regrowth of skin.

Third, the majority seems to suggest that the prior art was different from the claimed invention because the *purpose* of the prior art was drainage and cleaning, rather than healing. The majority explains that Bagautdinov was "for draining fluid" and was "discontinued when the purulent wound has been cleaned"; that Zamierowski is "used to either drain from or inject fluid into the wound" and was not used "for wound therapy"; and that Chariker-Jeter was a "drainage system" that was "discontinued when the fistula closed or substantial drainage from the fistula stopped." Maj. Op. 31-33, 36, 38-39. However, the claims do not contain a purpose requirement—it is enough that healing is disclosed by the prior art, even if this was not the intention of the prior art inventors. As the Supreme Court explained, "[i]n determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007); *see also Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1339 (Fed. Cir. 2004) ("A finding that two inventions were designed to resolve different problems . . . is insufficient to demonstrate that one invention teaches away from another."); *In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992) ("[T]he law does not require that the references be combined for

the reasons contemplated by the inventor."). It is irrelevant that the prior art had the purpose of drainage as long as it used negative pressure to heal wounds within the meaning of the claims.

As discussed below, the majority's erroneous claim construction leads it to incorrectly conclude that the claim limitations are not found in the prior art and that secondary considerations supported a finding of nonobviousness.

II Limitations Present in the Prior Art

Under the correct claim construction, contrary to the majority, the claim limitations are disclosed in the prior art. Because the jury received no instruction on the meaning of the "healing" limitations, it is impossible to determine whether the jury's findings in support of its nonobviousness verdict were based on the correct construction.[4] However, the party challenging validity, Smith & Nephew, did not seek a jury instruction on the "healing" limitations. "[L]itigants waive their right to present new claim construction disputes if they are raised for the first time after trial." *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1331 (Fed. Cir. 2009) (quoting *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1359 (Fed. Cir. 2006)). We therefore should assume that the jury used the correct claim construction.

Under the proper construction, the Bagautdinov, Chariker-Jeter, and Zamierowski groups of prior art all meet the limitations of "maintaining" negative pressure "for . . . healing" or until a "selected stage of healing"

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[4] The jury did answer some specific questions in addition to giving a general verdict of nonobviousness, *see* J.A. 65-70, but none of those specific questions is relevant to this issue.

because they explicitly disclose the re-growth of tissue and skin (i.e., the formation of granulation tissue and re-epithelialization). The Bagautdinov method "accelerates . . . sealing of purulent wounds," and "the appearance of granulated tissue" was seen around the fourth or fifth day of vacuum treatment. J.A. 10003, 10027. One of the Chariker-Jeter publications states that "an increased rate of granulation and re-epithelialization is seen with the closed suction wound drainage system." J.A. 10051. And Zamierowski states that it "promotes healing" and that "the present invention is particularly well adapted for the . . . regeneration of skin graft donor sites." J.A. 10063, 10067.[5] Because each of these references applied negative pressure for "healing" within the meaning of the claims, it is irrelevant whether these references teach away from more prolonged application of negative pressure. There is no substantial evidence to the contrary. The majority errs in concluding that these claim limitations were not present in the prior art.

III Secondary Considerations

The majority also errs, in my view, in finding that the jury could properly rely on secondary considerations to

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[5] The majority's suggestion that Zamierowski "failed to disclose maintaining negative pressure until the wound has progressed to a selected stage of healing," Maj. Op. at 36, is thus incorrect; the majority cites testimony that merely states that Zamierowski does not discuss granulation tissue formation. *See* J.A. 22457:15-19 (Q. "It follows, from the fact that he doesn't mention granulation, that he's not stating that he promotes granulation tissue growth?" A. "Well . . . he doesn't state: My device promotes granulation tissue."); J.A. 22669:5-8 ("[H]e really does not talk about the healing, maintaining the pressure until the wound has progressed to the selected stage of healing. He doesn't talk about granulation tissue formation, promotion of that.").

find the claims non-obvious. The failure to construe the "healing" limitations affects not only the prima facie case of obviousness, but also the analysis of secondary considerations, as we cannot determine whether the jury's findings of secondary considerations were based on a proper understanding of claim scope. "Evidence of secondary considerations must be reasonably commensurate with the scope of the claims." *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011). Secondary considerations related to a patentee's commercial product is not probative of nonobviousness if the asserted claims are far broader than that commercial embodiment. Here, as the majority notes, there was substantial evidence that the patentee's product (1) was a commercial success; (2) was responsive to a long-felt need; (3) was copied by others; (4) had unexpected results; (5) was accepted by others; and (6) faced initial skepticism. Maj. Op. at 42. These secondary considerations, however, were related to the use of the commercial device utilizing the patent for extended periods to close and completely heal wounds.[6] This evidence would clearly be relevant if the patent claims were limited to complete healing or wound closure, but as discussed above, the claims require only some progress toward healing. There was no substantial evidence that there were secondary considerations relevant to the

[6] For example, Dr. Argenta, an inventor on the patents, testified that he was surprised when a patient with a serious wound "*heal[ed] completely*" after several months of treatment. J.A. 20446:22 (emphasis added). Another expert testified that when a patient with an ulcer that would not heal was healed after eight weeks of treatment, he was "stunned" "[b]ecause we had used the best techniques we knew to date *to close this wound* and none had worked and this technique, which was counter-intuitive, worked." J.A. 22828:23-22829:2 (emphasis added).

invention as set forth in the claims as opposed to the far narrower commercial embodiment.

IV Motivation to Combine

As the majority describes, there is, however, substantial evidence that Bagautdinov and Chariker-Jeter treat pus pockets and fistulae, respectively, rather than "wounds," and that Bagautdinov, Zamierowski, and the Chariker-Jeter public use do not disclose an adequate seal. Thus, at the very least, to find obviousness, a person of ordinary skill would have needed a motivation to combine the treatment of "wounds" by Zamierowski with the seal from the Chariker-Jeter publications. While motivation to combine may be addressed on summary judgment or JMOL in appropriate circumstances, *see Wyers v. Master Lock Co.*, 616 F.3d 1231, 1240 (Fed. Cir. 2010), it is still a question of fact, and the accused infringers have failed to show that there was not substantial evidence to support a finding of insufficient motivation to combine. In other words, under the assumption that the jury used the correct construction of the "healing" limitations, there is substantial evidence for the jury to have at least found the asserted claims nonobvious due to insufficient motivation to combine. Thus, I agree with the majority's ultimate conclusion that the district court erred in granting JMOL of obviousness.