United States Court of Appeals for the Federal Circuit

2008-1602

PRESSURE PRODUCTS MEDICAL SUPPLIES, INC.,

Plaintiff-Appellee,

v.

GREATBATCH LTD. (doing business as Enpath Medical, Inc.)

Defendant-Appellant.

Richard H. Zaitlen, Pillsbury Winthrop Shaw Pittman, LLP, of Los Angeles, California, argued for plaintiff-appellee. With him on the brief were Caroline S. Lu; and Andrew B. Grossman, Wilmer Cutler Pickering Hale & Dorr LLP, of Los Angeles, California.

David G. Henry, Patton Boggs LLP, of Dallas, Texas, argued for defendant-appellant. With him on the brief were Chris L. Gilbert, and Carolina Cook. Of counsel was Michael J. Schaengold, of Washington, DC.

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

Judge Ron Clark

United States Court of Appeals for the Federal Circuit

2008-1602

PRESSURE PRODUCTS MEDICAL SUPPLIES, INC.,

Plaintiff-Appellee,

v.

GREATBATCH LTD.
(doing business as Enpath Medical, Inc.)

Defendant-Appellant.

DECIDED: March 24, 2010

Appeal from the United States District Court for the Eastern District of Texas in case no. 9:06-CV-121, Judge Ron Clark.

Before NEWMAN, LOURIE, RADER, GAJARSA, and MOORE, Circuit Judges.

Opinion for the court filed by Circuit Judge RADER, in which Judge Lourie, Judge Gajarsa and Judge Moore join. Opinion concurring in part and dissenting in part filed by Circuit Judge Newman.

RADER, Circuit Judge.

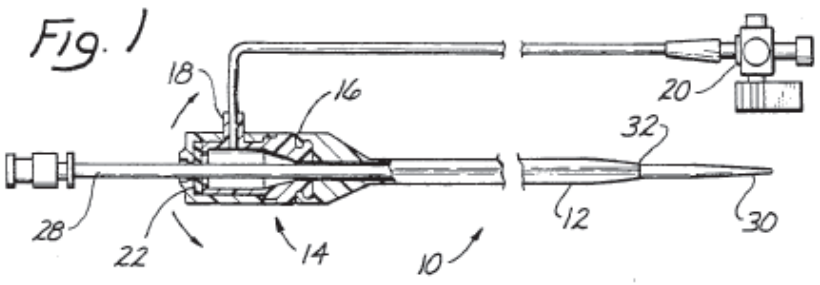
The United States District Court for the Eastern District of Texas construed the claim term "score line" during trial, denied Enpath Medical Inc.'s ("Enpath") motion for Judgment as a Matter of Law ("JMOL") that U.S. Patent Nos. 5,125,904 (the "'904 patent") and 5,312,355 (the "'355 patent") (collectively, the "Lee patents") are invalid, and denied Enpath's motion for leave to amend its answer to assert inequitable conduct. Because the record does not support the district court's claim construction, this court vacates the district court's finding of infringement and remands for further

proceedings in light of the correct claim construction. As the record supports the district court's denial of Enpath's motions for JMOL and leave to amend its answer, this court affirms those denials.

I.

Pressure Products Medical Supplies, Inc. ("Pressure Products") is the exclusive licensee of the Lee patents for a medical device known as an introducer. An introducer is a device that permits a surgeon to place and remove catheters or pacemaker leads into blood vessels during surgical procedures. The introducer has a sheath that often includes a hemostatic valve that remains in the vein and facilitates regulation of blood flow during an operation. After insertion of the lead, the surgeon must remove the sheath and leave, for example, a pacemaker lead in place. Because the sheath cannot be slipped over the pacemaker end, the prior art included "splittable" or "peel-away" sheaths. These sheaths also included a hemostatic valve.

The prior art, however, had no convenient way to remove the valve along with the sheath. Thus, almost any procedure to remove the valve would cause considerable blood loss during a surgical procedure. This invention devised a way to remove both the valve and the sheath by a splitting process. Figure 1 shows the configuration of the invention. Figure 3 shows a splittable hemostatic valve [14] including a means [34, 36] for splitting or separating the valve and sheath [12].



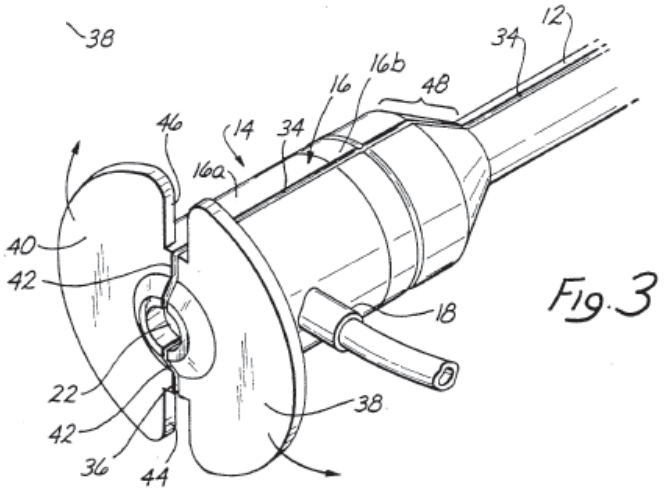


Fig. 3

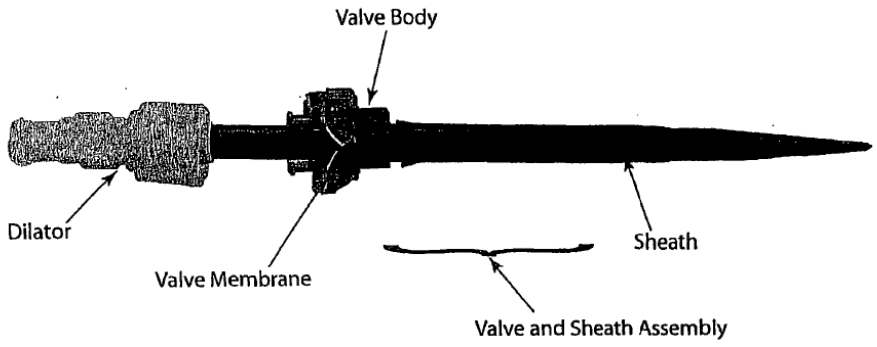
Pressure Products licensed the Lee patents from H. L. Medical Inventions, Inc., owned by the inventor of the '904 and '355 patents, Dr. Hongpyo Henry Lee, M.D., a California cardiologist. Then, Pressure Products sued Enpath in the Eastern District of Texas, alleging that Enpath's FlowGuard™ introducer product ("FlowGuard™") and its ViaSeal™ prototype introducer product ("ViaSeal™") infringe the Lee patents. Enpath and Pressure Products completed claim construction discovery and briefing by July 27, 2007. The magistrate judge held a Markman hearing on August 15, 2007, and entered a Markman order on March 19, 2008, about three months before trial.

Claim 1 of each of the '904 and '355 patents recites the disputed limitation: "means for permitting removal of said hemostatic valve and introducer sheath from said lead or catheter disposed therethrough without requiring said introducer sheath and hemostatic valve to be removed from an end of said lead or catheter." '904 patent col.6 l.66–col.7 l.2; '355 patent col.10 ll.11–15. The magistrate judge ruled that "means for permitting removal" called for a claim construction under 35 U.S.C. § 112, paragraph 6. Under that statutory process for construing functional claim terms, the magistrate judge determined that the structure in the specification that corresponds to the claimed

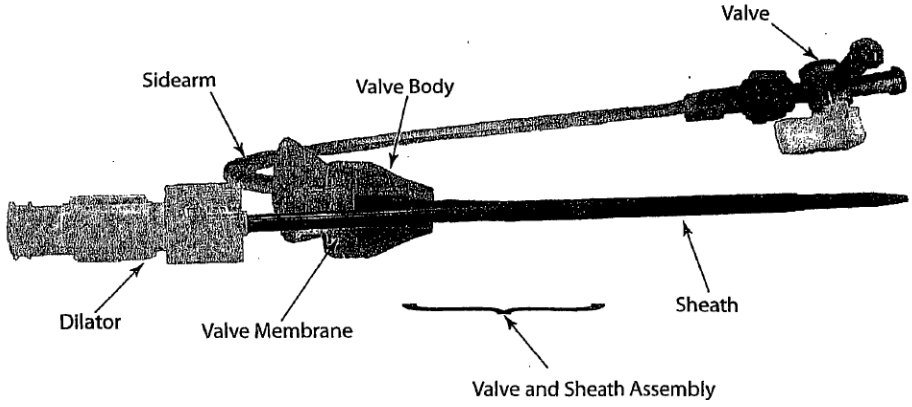
function is "score lines defined in the hemostatic valve and introducer sheath, and equivalents thereof."[1] The term "score line" is recited in dependent claims 4 through 8 of the '904 patent but not in any independent claims. After considering the parties' arguments and relying on a dictionary definition, the magistrate judge defined "score line" as "one or more line(s) defined in the hemostatic valve and introducer sheath." The magistrate judge did not further define the term "score line."

Depictions of Enpath's FlowGuard™ and ViaSeal™ introducers, made of polytetrafluoroethylene ("PTFE"), are shown below.

FlowGuard*



ViaSeal*



[1] Although independent claim 1 of the '355 patent appears to recite specific structure, i.e., "wherein said means for permitting removal of said hemostatic valve comprises a two-part body . . . ," the parties did not raise any argument that the recited structure affects the claim construction.

These introducers include a feature that Enpath calls a "cut" or "slit" (or what Pressure Products refers to as a score line) at the top of the PTFE tube or sheath to allow for removal. The trial record included testimony that Enpath's cut or slit facilitates splitting and removing the PTFE tube; very few, if any, PTFE introducers did not include this feature. Indeed, Enpath's manufacturing procedure describes creating a slit at the proximal end of the sheath. During trial, Pressure Products' expert, Mr. Joseph Thomas, testified that this manufacturing procedure placed the slit or score in the device so that the PTFE tube or sheath could be peeled or torn apart. According to Mr. Thomas, the molecular composition of the PTFE would make the sheath split evenly along its entire length. Also at trial, Pressure Products presented X-rays of Enpath's FlowGuard™ and ViaSeal™ introducers that indicated the sheath ends are cut or scored. In contrast, the record showed that introducers not made of PTFE require scoring along the entire length of the sheath bodies to permit their even splitting and removal. In papers submitted to the Food and Drug Administration, Enpath described its FlowGuard™ device as having "[a] scored/splittable introducer sheath."

The jury trial began on June 6, 2008. At the close of Pressure Products' proof, the district court, sua sponte, defined "score line" as a "linear perforation; slit; slot; tab; line; severing; weakening; or tear that can be partial or complete." The court supplemented its definition of the term in response to Enpath's cross-examination of Pressure Products' witnesses over a two-day period. To avoid any jury confusion about the meaning of "score line," the court decided to supplement the definition of that term. In the words of the trial court, "it seems fairly obvious it's something that, in fact, does need to be defined because defendants are pushing on it." Enpath initially agreed with

the district court's decision to supplement the definition but later objected to the amended construction. On June 12, 2006, the jury returned a verdict for Pressure Products, finding that Enpath's FlowGuard™ and ViaSeal™ introducers literally infringed the Lee patents. The jury found the Lee patents valid and infringed and awarded $1.1 million in damages. The jury also determined that the infringement was not willful.

Before trial, Enpath had moved for leave to amend its answer to assert the defense of inequitable conduct. Enpath premised its motion on allegedly new evidence concerning a declaration submitted during the reexamination of the '904 patent. The district court denied Enpath's motion as untimely. Enpath filed its motion eighteen months after Pressure Products filed its complaint and over one year after Enpath filed its answer and counterclaims. Moreover, Enpath's motion came ten months after the deadline to join additional parties under the original scheduling order, and eight months after the deadline to amend the pleadings under the amended scheduling order.

After trial, the district court denied Enpath's JMOL motion that the Lee patents are invalid and permanently enjoined Enpath's sales of FlowGuard™ and ViaSeal™ products. The court, however, stayed the injunction as to FlowGuard™ sales, conditioned on Enpath's deposit into an escrow account or the court registry of an ongoing royalty.

Enpath timely appeals the district court's final judgment, its construction of "score line," and the denial of Enpath's motions for JMOL and leave to amend its answer. This court has jurisdiction over this case under 28 U.S.C. § 1295(a)(1).

II.

This court reviews claim construction without deference. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). Claim construction, though dependent on the language of the claims themselves, see Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc), requires this court to read that language "in view of the specification, of which they are a part." Id. at 1315 (internal quotation marks omitted). The specification is the "single best guide to the meaning of a disputed term." Id. (citation omitted). A court should also consider the patent's prosecution history, id. at 1317, and may rely on dictionary definitions, "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Id. at 1322–23.

This court reviews the denial of a motion for JMOL under the law of the regional circuit. 800 Adept, Inc. v. Murex Sec., Ltd., 539 F.3d 1354, 1366 (Fed. Cir. 2008). The United States Court of Appeals for the Fifth Circuit reviews a district court's denial of a motion for JMOL without deference. Thomas v. Tex. Dep't of Criminal Justice, 220 F.3d 389, 392 (5th Cir. 2000). Thus, this court must uphold a JMOL in favor of the jury verdict unless "there is no legally sufficient evidentiary basis for a reasonable jury to [reach that result]." Bryant v. Compass Group USA Inc., 413 F.3d 471 (5th Cir. 2005) (citing Fed. R. Civ. P. 50(a)).

The denial of a motion to amend a pleading under Rule 15(a) is a procedural matter also governed by the law of the regional circuit. Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1357 (Fed. Cir. 2007). Rule 16(b) provides that once a scheduling order has been entered, it "may be modified

only for good cause and with the judge's consent." It requires a party "to show that the deadlines cannot reasonably be met despite the diligence of the party needing the extension." S&W Enters., LLC v. Southtrust Bank of Ala., NA, 315 F.3d 533, 535 (5th Cir. 2003). As to post-deadline amendments, a party "must show good cause for not meeting the deadline before the more liberal standard of Rule 15(a) will apply to the district court's denial of leave to amend." Sw. Bell Tel. Co. v. City of El Paso, 346 F.3d 541, 546 (5th Cir. 2003).

III.

During trial, the district court defined "score line"— the corresponding structure of the means-plus-function limitation in claim 1 of the '904 patent. The district court defined the term largely in response to Enpath's cross-examination of Pressure Products' witnesses. Enpath's cross examination strategy revealed a dispute over the trial court's definition of the term "score line" in its Markman order. While recognizing the potential for surprise and prejudice in a late adjustment to the meaning of claim terms, this court also acknowledges that the trial court is in the best position to prevent gamesmanship and unfair advantage during trial. Moreover, this court understands that a trial judge may learn more about the technology during the trial that necessitates some clarification of claim terms before the jury deliberates. Indeed, before the district court defined "score line," it acknowledged that it was in a better position than the magistrate judge at the Markman hearing to understand the operation of sheaths due to extensive expert testimony from both parties.

Enpath posits that the trial judge's late adjustment prejudiced its defense and compromised its ability to respond. While somewhat sympathetic to those concerns in

general, this court is not prepared to substitute its judgment for that of the district judge, who understood the entire context far beyond the limitations of the written record on review in this proceeding. Moreover, the district court made the adjustment early enough in the trial to give Enpath an opportunity to consider the new construction and adjust its arguments to account for the change. Thus, this court does not consider the trial court's supplemental definition of a claim term during trial to present a fundamental procedural flaw that jeopardizes the jury's verdict. As this court has recognized, "district courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves." Pfizer, Inc. v. Teva Pharm., USA, Inc., 429 F.3d 1364, 1377 (Fed. Cir. 2005); see also Utah Med. Prods., Inc. v. Graphic Controls Corp., 350 F.3d 1376, 1381–82 (Fed. Cir. 2003) (holding that the district court did not err in amending its claim construction during oral arguments for pretrial motions nearly two years after the original construction). Moreover, "[w]hen the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute." O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1360 (Fed. Cir. 2008).

Although originally agreeing with the district court's decision to supplement its definition of "score line," Enpath now contends that the district court erred by relying on O2 Micro for its decision. According to Enpath, "the district court was in no way faced with the jury interpreting the 'means for permitting removal' or 'score line' limitations because the magistrate judge had already construed those terms." Enpath cites to a non-binding district court decision distinguishing O2 Micro, as well as Broadcom Corp. v. Qualcomm Inc., 543 F.3d 683, 694 (Fed. Cir. 2008). In both cases, the district court

declined to supplement the definition of claim terms that had already been construed in earlier claim construction orders.

In this case, the magistrate judge defined "score line" as "one or more line(s) defined in the hemostatic valve and introducer sheath" in the context of dependent claims 4 through 8 of the '904 patent. The words "score line" do not appear in independent claim 1 of the Lee patents. Instead, that independent claim includes a mean-plus-function limitation "means for permitting removal" (i.e., "score lines defined in the hemostatic valve and introducer sheath, and equivalents thereof"). The magistrate judge then determined that the structure in the specification that corresponded to this functional limitation was a score line. The magistrate judge did not define "score line" in the context of the structure corresponding to independent claim 1 of the Lee patents. Without a definition of "score line" in the Markman order for that corresponding structure, the trial judge observed that the trial proceedings invited the jury to define this term on its own in a manner this court has questioned in O2 Micro, 521 F.3d at 1360, and Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996) (holding that claim construction is a matter of law for the court). Therefore, the trial court undertook to supplement the Markman order by clarifying the meaning of "score line" as the structure corresponding to independent claim 1.

Although this court concludes that it was proper for the trial court to supplement the definition of "score line," this court must now evaluate the merits of the trial court's definition of "score line." In the context of the corresponding structure to independent claim 1 of the Lee patents, the trial court erred in expanding the definition of "score line"

to include structures not disclosed in the specifications of the Lee patents. Section 112 requires that the corresponding structure must be "described in the specification."

The Lee patents give a laundry list of prior art references. See '904 patent col.1 ll.41–61; '355 patent col.1 ll.45–63. The trial court included the structures disclosed within that list of prior art references as corresponding structures for claim 1 by including them in its definition of "score line." In doing so, the trial court impermissibly expanded the corresponding structure of claim 1 to include structures not described in the specification.

Trial courts cannot look to the prior art, identified by nothing more than its title and citation in a patent, to provide corresponding structure for a means-plus-function limitation. In this case, these references provide alternatives to scoring. Although many of the disclosed alternatives may well be determined to be structural equivalents permitted by section 112, paragraph 6—a question of fact for the jury—these alternative methods of splitting or peeling cannot be treated as the disclosed structures for the removal means. Simply mentioning prior art references in a patent does not suffice as a specification description to give the patentee outright claim to all of the structures disclosed in those references.

In Atmel Corp. v. Info. Storage Devices, Inc., 198 F.3d 1374, 1381 (Fed. Cir. 1999), this court refused to utilize the concept of incorporation by reference to include a structure in the prior art as a corresponding structure for a means-plus-function claim element. In Atmel, this court held that the title of a prior art reference could provide the structure for a mean-plus-function element because "Atmel's expert, Callahan, testified that this title alone was sufficient to indicate to one skilled in the art the precise structure

of the means recited in the specification." Id. at 1382. His testimony was essentially unrebutted. Id. If, on the other hand, the title did not disclose the prior art structure, the structures in the prior art reference could not be a corresponding structure to the means-plus-function claim element. Id. (holding that "the district court properly held that the Dickson article [prior art cited in the patent] may not take the place of structure that does not appear in the specification").

The magistrate judge construed "score line" consistent with the specification as "one or more lines defined in the hemostatic valve and introducer sheath." The magistrate judge, citing a dictionary, explained that "'score' has been defined to mean 'any scratch, line or groove' that is formed by the scoring process." The trial court went on to supplement the magistrate's construction and defined "score lines," the structure for permitting removal, as "linear perforation; slit; slot; tab; line; severing; weakening; or tear that can be partial or complete."

Pressure Products argues that the trial court correctly construed the term "score lines" according to the doctrine of claim differentiation. Claim 1 claims "means for permitting removal of said hemostatic valve and introducer sheath." Claims 4 through 8 of the '904 patent claim "a score line defined in said hemostatic valve and introduce sheath" as the means for permitting removal. As such, Pressure Products argues that the means-plus-function element of claim 1 must encompass structures other than score lines, namely, those structures disclosed in the prior art references mentioned in the patent. This argument fails, however, because a means-plus-function claim element already includes structures other than the corresponding structure explicitly described in the specification, namely, equivalents of the corresponding structure. See 35 U.S.C.

§ 112, ¶ 6. Therefore, as the means-plus-function claim element of claim 1 includes the equivalents of score lines, the magistrate judge's claim construction does not violate the doctrine of claim differentiation.

The specification does not expressly describe use of a cut or a slit or a tear for removal. The specification explains, "[t]he score line comprises a pair of lines defined in the hemostatic valve and introducer sheath. The pair of score lines are diametrically opposed from each other on the hemostatic valve and introducer sheath." '904 patent col.3 ll.14–18. The patent further explains, "score lines 34 and 36 are shown as having a V-shaped cross section but have such a shape and depth as to permit the entire length of introducer sheath 10 to be manually separated." Id. col.6 ll.7–10. The specification recognizes a difference between score lines and slots. Id. col.6 ll.28–32 ("However, it is entirely possible that score lines 34 and 36 will be continued through flanges 38 and 40 to provide deep scores instead of open slots 44 and 46." (emphasis added)).

The trial court erroneously used structures from the prior art references listed in the patent to provide a definition for score lines encompassing structures not disclosed expressly in the patent specification. As such, this court detects error in the trial court's definition. Score lines are "one or more lines defined in the hemostatic valve and introducer sheath" as supported by the specification. This court remands for further proceedings in light of the proper construction of the term "score lines." Those further proceedings will allow appropriate measures to also ascertain the structural equivalents of the express structure in the specification corresponding to the claimed function.

IV.

The district court denied Enpath's JMOL motion for invalidity of the Lee patents. Enpath asserts it presented clear and convincing evidence that Haindl's German Patent Number 3834600 ("the Haindl '600 patent") anticipates and renders obvious the Lee patents. It further asserts that Pressure Products did not overcome its prima facie case of invalidity.

To demonstrate anticipation, Enpath's expert witness, Dr. Ethan Podet, provided for the jury claim construction charts comparing every element of the claims at issue to the Haindl '600 patent. Pressure Products' expert witness, Dr. Eli Gang, rebutted Dr. Podet's testimony by testifying that the Haindl '600 patent does not teach or suggest a critical component of the Lee patents, i.e., the combination of both a splittable hemostatic valve and a splittable introducer sheath. Dr. Gang also examined each of the other prior art references cited in Dr. Podet's expert report and gave reasons why they did not show anticipation or obviousness. Anticipation requires "a single prior art reference [that] discloses each and every limitation of the claimed invention." Schering Corp. v. Geneva Pharm., 339 F.3d 1373, 1377 (Fed. Cir. 2003). Moreover, the Patent and Trademark Office ("PTO") examined the Haindl '600 patent twice during the examination and re-examination of the '904 patent. The PTO, nevertheless, allowed the '904 patent, instilling the statutory presumption of validity into the Lee patents.

To rebut Dr. Podet's obviousness testimony, Pressure Products used Dr. Hans-Guenter Haindl's declaration filed during the reexamination of the '904 patent. In the declaration, Dr. Haindl states that his invention, the Haindl '600 patent, lacks a hemostatic, splittable valve as claimed by the '904 and '355 patents. Dr. Haindl's

declaration also states that the Haindl '600 patent does not include an "enabling disclosure" of a splittable assembly.

Furthermore, Pressure Products offered secondary evidence of non-obviousness including evidence of commercial success, long felt need, skepticism of experts, and unexpected results of the commercial embodiment of the Lee patents. This court "has repeatedly explained, [that secondary consideration evidence] is not just a cumulative or confirmatory part of the obviousness calculus but constitutes independent evidence of nonobviousness." Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1365 (Fed. Cir. 2008). In terms of the skepticism of experts and unexpected results, the record confirms that other medical device companies initially turned down the opportunity to license the Lee patents because they did not believe that the invention would work. Enpath did not offer any evidence that rebutted or challenged Pressure Products' secondary evidence of non-obviousness.

In sum, the trial record shows ample support for the jury's judgment that the claimed invention would not have been anticipated or rendered obvious by prior art at the time of invention. Enpath has not shown that the jury's verdict on these points was unreasonable or based on insubstantial evidence. Because substantial evidence supports the jury's verdict, the district court did not err in denying Enpath's motion for JMOL on invalidity.

V.

The district court denied Enpath's motion for leave to amend its answer to assert the defense of inequitable conduct. Enpath based its defense on a November 5, 2007 declaration of Mr. Steven Kontos, a biomedical engineer and designer of catheters and

devices used with catheters. Mr. Kontos stated in his declaration that although he recognized his signature, he did not remember signing two 1995 declarations supporting the patentee during re-examination of the '904 patent. Enpath contends the district court's denial was an abuse of discretion.

Two different standards exist for the denial of a motion for leave to amend the pleadings. The more rigid standard of Rule 16(b) is applicable to motions filed after a scheduling order deadline has expired and requires a showing of good cause to file outside the deadline. See S&W Enters., L.L.C. v. Southtrust Bank of Ala., NA, 315 F.3d 533, 536 (5th Cir. 2003). Under the more liberal standard of Rule 15(a), the trial court should grant leave to file absent a substantial reason for denial, such as undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies with other amendments, futility of the amendment, or undue prejudice to the opposing party. See Foman v. Davis, 371 U.S. 178, 182 (1962); see also Stripling v. Jordan Prod. Co., LLC, 234 F.3d 863, 872–73 (5th Cir. 2000) ("[Rule 15(a)] evinces a bias in favor of granting leave to amend.").

Enpath contends that Rule 15(a) applies in this case because the district court set a "Final Amended Pleadings" deadline of April 5, 2007 for the plaintiff but not for Enpath. The district court's scheduling order further set a deadline of April 26, 2007 to "Respond to Amended Pleadings" but did not set an explicit deadline to file motions for leave to amend the pleadings. Thus, when Enpath filed its motion on December 7, 2007, no scheduling order deadline had passed as applied to Enpath. However, even under the more liberal standard of Rule 15(a), leave to amend is not automatic. See

Parish v. Frazier, 195 F.3d 761, 763 (5th Cir. 1999); Avatar Exploration, Inc. v. Chevron, U.S.A., Inc., 933 F.2d 314, 320 (5th Cir. 1991).

Prejudice is the "touchstone of the inquiry under rule 15(a)." Lone Star Ladies Invest. Club v. Schlotzsky's Inc., 238 F.3d 363, 368 (5th Cir. 2001). Thus, prejudice to the nonmoving party may be sufficient to deny leave to amend. See Mayeaux v. La. Health Servs. & Indem. Co., 376 F.3d 420, 427 (5th Cir. 2004) (denying a motion to amend a pleading that would have fundamentally altered the nature of the case and imposed additional discovery requirements and undue prejudice on the nonmoving party).

Enpath raised its inequitable conduct defense in two motions on November 16, 2007 and December 7, 2007. To plead inequitable conduct with particularity as required under Rule 9(b), Enpath contends that it could not file these motions until it received the November 5, 2007 Kontos declaration. The district court reasoned that allowing Enpath to amend its pleadings "almost certainly" would have resulted in undue delay and would have "very likely" resulted in undue prejudice to Pressure Products.

The district court also considered the length of time that the Kontos declarations were available to Enpath before bringing its motions to amend. The 1995 declarations were publicly available at least since November 19, 1996, the date the PTO reissued the '904 patent. Moreover, Enpath received a copy of the '904 patent's file wrapper as early as January 16, 2007. Nothing prevented Enpath from conducting discovery on the two 1995 Kontos declarations shortly following this date. Accordingly, because Enpath has not met its high burden of showing that the district court abused its discretion in

denying Enpath's motions for leave to amend its answer, this court affirms the district court's denial.

Since the trial court's ruling on this motion to amend, this court has issued significant opinions requiring specific and demanding showings of evidence before a party may assert the defense of inequitable conduct. See, e.g., Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008) ("We review the district court's inequitable conduct determination under a two-tier standard; we review the underlying factual determinations for clear error, but we review the ultimate decision as to inequitable conduct for an abuse of discretion."). Moreover,

> The burden of proving inequitable conduct lies with the accused infringer . . . . To successfully prove inequitable conduct, the accused infringer must present "evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO]." . . . Further, at least a threshold level of each element–i.e., both materiality and intent to deceive-must be proven by clear and convincing evidence. . . . And even if this elevated evidentiary burden is met as to both elements, the district court must still balance the equities to determine whether the applicant's conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable. . . . Thus, even if a threshold level of both materiality and intent to deceive are proven by clear and convincing evidence, the court may still decline to render the patent unenforceable.

Id. (internal citations omitted); see also Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1329 n.5 (Fed. Cir. 2009) ("Whereas an inference of deceptive intent must be reasonable and drawn from a pleading's allegations of underlying fact to satisfy Rule 9(b), this inference must be "the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard." (emphasis added, internal citations omitted)).

Based on these cases, this court doubts that the motion to amend would even satisfy these higher standards of proof to invoke the doctrine in the first place. These subsequent cases further support the trial court's action to deny the motion to amend.

VI.

Because the district court erred by including structures not described in the specification in the definition of the corresponding structure to the means-plus-function claim element, this court vacates and remands for a determination of infringement using the correct claim construction. Because the record supports the district court's denial of Enpath's motions for JMOL and leave to amend its answer, this court affirms those denials.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED

COSTS

Each party shall bear its own costs.

United States Court of Appeals for the Federal Circuit

2008-1602

PRESSURE PRODUCTS MEDICAL SUPPLIES, INC.,

Plaintiff-Appellee,

v.

GREATBATCH LTD. (doing business as Enpath Medical, Inc.)

Defendant-Appellant.

Appeal from the United States District Court for the Eastern District of Texas in Case No. 9:06-CV-121, Judge Ron Clark.

NEWMAN, Circuit Judge, concurring in part, dissenting in part.

I join the court's affirmance of the district court's judgment on the issues of validity and inequitable conduct. However, I would also affirm the court's judgment on the issue of infringement, for reversible error has not been shown in the district court's claim construction, and the jury's verdict is supported by substantial evidence.

The claim clause at issue is a means-plus-function clause, presented in both U.S. Patent Nos. 5,125,904 and 5,312,355, claim 1 of both patents starting with the same clauses, as follows:

> 1. A sheath assembly for use with a lead or catheter comprising:
> an introducer sheath;

> a hemostatic valve coupled to said introducer sheath, said hemostatic valve and introducer sheath being arranged and configured to permit introduction of at least one lead or catheter therethrough;
>
> means for permitting removal of said hemostatic valve and introducer sheath from said lead or catheter disposed therethrough without requiring said introducer sheath and hemostatic valve to be removed from an end of said lead or catheter, . . .

The magistrate judge construed the "means for permitting removal" as a "score line," which is the primary structure shown in the specification, and adopted the dictionary definition of "score" as "'any scratch, line, or groove' that is formed in the scoring process," from the Academic Press: Dictionary of Science and Technology (1992).

After presentation of the plaintiff's case in chief, the district court further construed the means-plus-function clause in view of the debate that became manifest in the examination and cross-examination of the witnesses, for, as the district court observed, it was "fairly obvious it's something that, in fact, does need to be defined because defendants are pushing on it. And I would gather defendants agree with that analysis. Is that correct?" Counsel for the defendant, Enpath, responded: "Yes, your Honor." A3769. My colleagues on this panel confirm that this additional claim construction by the judge was appropriate. Claim construction is a matter of law, and it is essential that the jury be correctly instructed on the law, lest the entire trial be tainted. See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1360, 1362 (Fed. Cir. 2008) ("When the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve the dispute. . . . [I]t is the court's duty to resolve it."). This procedure is not unusual. As this court explained in Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc., 429 F.3d 1364, 1377 (Fed. Cir. 2005), "district courts may engage in a rolling claim construction, in which the

court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves."

As provided by statute, means-plus-function claim terms are construed in light of the structures described in the specification and equivalents thereof:

> §112 ¶6. An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The district court construed the "means for permitting removal" clause with reference to the patents' specifications and the prior art cited in the specifications. The patents state that "the prior art has devised a number of splittable or peel away sheaths. The sheath is scored so that it is withdrawn by splitting or peeling it off from the pacemaker catheter." '904 patent col.1 ll.41-44; '335 patent col.1 ll.45-48. The patents also state that the way the splittable structure is implemented or the peel-away feature is realized is not critical to the invention:

> [T]he detailed nature by which such splittable structure is implemented or how [the] peel-away feature is realized is not critical to the invention. Any method now known or later devised by which such sheaths 12 and valve assemblies 14 may be split or separated may be employed and are contemplated as being within the scope of the invention.

'904 patent col.5 ll.59–66; '355 patent col.7 ll.37–44. Both the '904 and the '355 patents cite prior publications showing various separation methods, as included in the court's claim construction. Referring to this information and the testimony at trial, the district court construed the "means for permitting removal [of the valve and sheath]" as a "linear perforation, slit, slot, tab, line, severing, weakening, or tear that can be partial or complete." This elaborated claim construction was presented, quoting the majority opinion, "to avoid

any jury confusion about the meaning of 'score line.'" Maj. Op. at 5. My colleagues assign no error to this procedure.

The references were incorporated to show the prior art, not to define what was new. The splitting and separation of the sheath was not what was new; what was new was the combination with removal of the hemostatic valve. Thus for the splitting of the plastic, the cited references showed various ways in which that had been done in the past, and the patents stated that "any method now known or later devised by which such sheaths 12 and valve assemblies 14 may be split or separated may be employed and are contemplated as being within the scope of the invention." '904 patent col.5 ll.62–66; '355 patent col.7 ll.41–44.

My colleagues rule that the district court should have ignored these cited references, and should not have recognized their content, or even their titles, in construing the "means" portion of the claim. Although this objection was not raised to the district court, my colleagues now deem it to be reversible error to have considered the references, which include Littleford, "Split Sleeve Introducers for Pacemaker Electrodes and the Like," U.S. Pat. No. 4,243,050 (1981); Osborne, "Tear Apart Cannula," U.S. Pat. No. RE 31,955 (1985); Boarini et al., "Peelable Catheter with Securing Ring and Suture Sleeve," U.S. Pat. No. 4,411,654 (1983); and Moorehead, "Medical Layered Peel Away Sheath and Methods," U.S. Pat. No. 4,983,168 (1991).

It cannot be error for the district court to have recognized that splittable sheaths were well known, and to have construed the "means for permitting removal" clause in light of this knowledge. The only error that my colleagues ascribe to the district court's claim construction is that the court included equivalent structure from the prior art set forth in the

specifications and brought out in the testimony of witnesses, instead of relying solely on a dictionary definition. No flaw has been ascribed to the district court's action to explain to the jury what is included in the "means for permitting removal" clause, for this construction of law was the responsibility of the judge, not the jury.

The majority opinion states that Atmel Corp. v. Information Storage Devices, Inc., 198 F.3d 1374, 1381 (Fed. Cir. 1999) prohibits a patentee from relying on an "incorporated" reference to describe a corresponding structure under §112, ¶6. That is an incorrect generalization. In Atmel, the flaw was that no structure at all was described to perform the claimed function apart from the incorporated reference, and that this description could not come solely from the incorporated reference. See id. at 1382 ("Fulfillment of the §112, ¶6 tradeoff cannot be satisfied when there is a total omission of structure. There must be structure in the specification."). However, that is far removed from the situation here. The '904 and '355 patents fully describe structures that perform the claimed function of removal of the valve and sheath, describing splittable sheaths of various forms, and explaining that there are many known ways of splitting or peeling plastic.

No blanket rule prohibits reliance on prior art for known information. Precedent is contrary. See Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1329 (Fed. Cir. 2001) ("When a document is 'incorporated by reference' into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein."). This expedient is not without logical limitations, but incorporated material is viewed as it would be treated by a person experienced in the field of the invention. See Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998) ("It is the person of ordinary skill in the field of the invention through whose

eyes the claims are construed."). Information is incorporated by reference into patent specifications for various purposes, and known information may usefully be incorporated by reference, to illustrate known structures that are known alternatives or equivalents to those in the specification. This enables patents to remain concise statements of what is new, not cumbersome repetitions of what is already known and readily provided by reference. In re Howarth, 654 F.2d 103, 106 (CCPA 1981) ("[A]n applicant may, in the interests of economy of time and space, incorporate certain types of documents by specific reference in his application to such source materials."); see Loom Co. v. Higgins, 105 U.S. (Otto.) 580, 586 (1881) ("[A patentee] may begin at the point where his invention begins, and describe what he has made that is new and what it replaces of the old. That which is common and well known is as if it were written out in the patent and delineated in the drawings.").

My colleagues assign no error to the technologic content of the district court's claim construction, no unfairness to the procedure, and no absence of support for the jury verdict. Enpath does not argue that its devices' means for removing the sheath and valve are non-infringing, and does not argue that the jury verdict is not supported by substantial evidence. The record states that Enpath told the Food and Drug Administration that its device has "a scored/splittable introducer sheath." The record also contains evidence that the Enpath manufacturing process creates a slit at the proximal end of the sheath. There is no basis for suspecting that substantial evidence does not support the jury verdict, whether on the magistrate judge's initial claim construction, or on the district court's elaborated claim construction.

Enpath has not argued that there was not substantial evidence of infringement on the magistrate judge's definition of "score" as a "'scratch, line or groove' that is formed by

the scoring process." Indeed, one wonders why a general definition in a dictionary is preferable to the definitions in specific technological references in the specification. While this court in Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc), recognized that dictionaries can be useful in explaining terms to judges who are unfamiliar with technical terminology, dictionaries are not superior to clear definitions in technological references on the same subject matter.[1]

Enpath now challenges the propriety of the district court's reworking the claim construction during the trial, although at the time Enpath encouraged the court to do so. Enpath states that it was prejudiced because it prepared for trial based on the magistrate judge's claim construction, but Enpath does not state that it requested and was denied additional time to adjust its defense. See Newell Companies, Inc. v. Kenney Mfg. Co., 864 F.2d 757, 765 (Fed. Cir. 1988) ("Trials must be fair, not perfect."); Devices for Medicine, Inc. v. Boehl, 822 F.2d 1062, 1066 (Fed. Cir. 1987) (same). This attack on the district court's procedure is as unwarranted as it is tardy.

I would affirm the district court's claim construction, for it conforms to the specification, the prosecution history, and the evidence at trial. The district court construed the claims to include the structure set forth in the specification and equivalents thereof, drawing on the subject matter incorporated by reference in the specification, and on the evidence at trial. Neither procedural flaw, nor harmful error, has been shown. Respectfully, I dissent.

[1] This ruling negating reliance on information incorporated by reference can have far-reaching consequences, in prohibiting reliance on incorporated published material, thereby requiring the applicant to reproduce possibly large amounts of published text, even if only to show variants known in the prior art, as here.