United States Court of Appeals for the Federal Circuit

03-1081

UTAH MEDICAL PRODUCTS, INC.,

Plaintiff-Appellee,

v.

GRAPHIC CONTROLS CORPORATION,

Defendant-Appellant.

Richard D. Burbidge, Burbidge & Mitchell, of Salt Lake City, Utah, argued for plaintiff-appellee. With him on the brief were Stephen B. Mitchell and Jefferson W. Gross.

Russell E. Levine, Kirkland & Ellis, of Chicago, Illinois, argued for defendant-appellant. With him on the brief were Mary E. Zaug and Christopher R. Liro.

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

Judge Tena Campbell

United States Court of Appeals for the Federal Circuit

03-1081

UTAH MEDICAL PRODUCTS, INC.,

Plaintiff-Appellee,

v.

GRAPHIC CONTROLS CORPORATION,

Defendant-Appellant.

DECIDED: December 4, 2003

Before MAYER, Chief Judge, MICHEL, and RADER, Circuit Judges.

RADER, Circuit Judge.

After a jury verdict, the United States District Court for the District of Utah entered judgment in favor of Utah Medical Products, Inc. The jury found that Graphic Controls Corporation's Softrans® device infringes Utah Medical's U.S. Patent No. 4,785,822 (the '822 patent). The district court denied Graphic Controls' motion for judgment as a matter of law (JMOL) following the jury verdict. In a later bench trial, the district court determined that the '822 patent was not invalid for indefiniteness. Because the district court did not err in its determinations and substantial evidence supports the jury's verdicts, this court affirms the judgment.

I.

The ‘822 patent claims a medical device for measuring the pressure within a body cavity. Medical personnel most commonly use this type of device to measure the pressure inside the uterus of a woman during childbirth. Before the invention of the ‘822 patent, intrauterine pressure was typically measured using fluid-filled intrauterine pressure catheters, or IUPCs. A rigid guide tube was necessary to insert flimsy fluid-filled IUPCs into the uterus. After insertion, the medical personnel would remove the guide tube. A pressure transducer outside the body would then measure the displacement of the fluid within the catheter to indicate the pressure level inside the uterus.

The ‘822 patent discloses and claims a device that utilizes a pressure transducer on the tip of an electronic cable. In contrast to the fluid-filled IUPCs, the pressure transducer directly measures the pressure within the uterus and electronically relays that measurement to an external monitor. The ‘822 patent “provide[s] an apparatus for monitoring intracompartmental pressure which can be inserted, for example, inside a uterus, without the attendant problems associated with the use of a separate, rigid guide tube.” ‘822 patent, col. 4, ll. 16-20. In other words, the ‘822 patent claimed a device with sufficient rigidity that it can be inserted into the uterus without a removable guide tube.

To achieve the required rigidity, claim 1 of the ‘822 patent claims a “stiffener means.” Claim 1 recites:

> 1. An intracompartmental pressure transducer apparatus, comprising:
> a pressure transducer having a diaphragm with first and second sides;
> a protective cushion means for enclosing said pressure transducer therein;
> means for communicating pressure pulses to the first side of said diaphragm through said protective cushion means;
> means for venting the second side of said diaphragm to atmospheric pressure; and
> electrical cable means for electrically connecting the pressure transducer to a monitor device for displaying data corresponding to intracompartmental pressure sensed by said pressure transducer, said electrical cable means having a leading end adapted for insertion into a body compartment, said pressure transducer and said protective cushion means being mounted at said leading end, <u>said electrical cable means further comprising stiffener means permanently encased in said electrical cable means for imparting a desired degree of rigidity to said electrical cable means to facilitate intracompartmental insertion of said transducer using said electrical cable means</u>.

‘822 patent, col. 10, ll. 18-42 (emphasis added). The structure in the ‘822 specification corresponding to

the function of the stiffener means is a steel stylet within the electrical cable means.

During prosecution of the ‘822 patent, the examiner cited U.S. Patent No. 4,576,181 to Wallace and U.S. Patent No. 3,710,781 to Hutchins. Wallace discloses an external transducer that measures a patient’s internal pressure from the outside of the body. The patentee distinguished Wallace by stating “there is no stiffener means disclosed in the Wallace [ ] patent which forms part of the electrical cable.” Hutchins discloses a transducer-tipped catheter that was inserted with the temporary use of a steel stylet. The patentee explained:

> It is also important to note with respect to Hutchins [ ] that the stylet [ ] is not part of the electrical cable. . . . Applicant’s claimed apparatus is not a catheter but is simply an electrical cable which has a stiffener means permanently encased with the electrical wires that run to the transducer. The stylet [ ] in Hutchins [ ] does not form part of any electrical cable but instead runs through a lumen and is designed for removal so that the lumen can then be used to inflate a balloon, when such is used at the tip of the catheter.

In 1987, Utah Medical introduced its Intran 100 IUPC, an early embodiment of the ‘822 patent. Accordingly, the Intran 100 was a transducer-tipped IUPC with a steel stylet permanently encased within the plastic cable for rigidity. In early 1990, Utah Medical introduced another transducer product, the Intran Plus IUPC (also known as the Intran 400). The Intran Plus was also rigid enough to insert without the use of a guide tube, but it did not use a steel stylet. Instead, the Intran Plus incorporated a harder plastic into the plastic casing of the cable. Further, the hard plastic casing of the cable means featured dual-lumen geometry. The new plastic cable’s geometry and hardness replaced the steel stylet. The trial record shows that, when first introduced, the Intran Plus was the only transducer-tipped IUPC on the market. The record also shows that the product enjoyed considerable commercial success. In its marketing campaign for the Intran Plus, Utah Medical proclaimed that the ‘822 patent protected its product.

Before 1993, Graphic Controls sold only fluid-filled IUPCs. In 1994, Graphic Controls approached Utah Medical about a license to sell the Intran Plus under a private label. Utah Medical refused. In 1995, Graphic Controls introduced its Softrans® device, which Graphic Controls admittedly developed by copying the Intran Plus design. The Softrans® device is also a transducer-tipped IUPC

that achieves its rigidity from the hardness and geometry of the plastic casing of the electrical cable. Subsequently, Utah Medical brought this action against Graphic Controls, alleging the Softrans® device infringes the '822 patent.

At the district court, Utah Medical alleged that Graphic Controls' Softrans® IUPC infringes claim 1 of the '822 patent. In January 2000, the district court issued an order construing various claim limitations of the '822 patent. At that time, the district court defined the "stiffener means" limitation as "[a] stylet, or its equivalent structure, that imparts sufficient rigidity to the cable means so that the transducer can be inserted without the use of an external guide tube." Utah Med. Product, Inc. v. Graphic Controls Corp., No. 2:97CV00427, slip op. 563, 661 (D. Utah Jan. 19, 2000) (claim construction order). The court further noted: "[T]he stylet, or its equivalent structure, is a separate component from the cable means but must be permanently encased within the cable means." Id.

Graphic Controls moved for summary judgment. The district court denied the motion because it perceived a factual issue in the question of whether the Softrans® device utilizes an equivalent structure to a steel stylet as a stiffener means. During oral argument on pre-trial motions in November 2001, the district court slightly, but significantly, amended the original claim construction. The district court indicated that it "unwittingly" may have taken the issue of equivalent structure away from the jury with the phraseology in the original construction of "stiffener means." To remedy the problem, the district court clarified its construction to read, "a stylet that imparts sufficient rigidity to the cable means so that the transducer can be inserted without the use of an external guide tube. The stylet is a separate component of the cable means, but must be permanently encased within the cable means. Therefore, this claim element, and its equivalent structure, do not include a structure that is removable from the cable means." Significantly, the district court amended the phrase "separate component from the cable means" to read "separate component of the cable means."

In January 2002, the district court held a two-week trial on infringement and damages. Specifically, the trial addressed whether the Softrans® device contained the equivalent of the stiffener means disclosed in the '822 patent, and, if so, what damages would remedy infringement. The jury

found that Graphic Controls' Softrans® IUPC infringes claim 1 of the '822 patent, because the hardness and geometry of the plastic casing was an equivalent structure to the steel stylet disclosed in the '822 patent. After finding infringement, the jury awarded Utah Medical lost profits as damages. Utah Medical alleged lost profits of $20,887,965, and the jury awarded $20,000,000.

In April 2002, the district court held a bench trial on various remaining issues, including Graphic Controls' allegation that the '822 patent is invalid due to indefiniteness. The district court found that the '822 patent was not indefinite, because the '822 patent specification properly apprises one of ordinary skill in the art that any permanently encased stiffening structure was within the scope of the stiffener means element. On September 19, 2002, the district court entered final judgment in the case, which was slightly amended by a November 5, 2002, order.

Graphic Controls timely moved for judgment as a matter of law, or in the alternative a new trial, on the issues of infringement and damages. The district court denied that motion, and Graphic Controls timely filed this appeal. This court has jurisdiction under 28 U.S.C. § 1295 (a)(1) (2000).

II.

On appeal, Graphic Controls challenges the district court's interpretation of "stiffener means," the jury's infringement verdict, the district court's indefiniteness ruling, and the jury's damages award. This court reviews claim construction without deference. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc); Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996).

This court applies the same standard of review applied by the trial court when reviewing a JMOL motion following a jury verdict. See Applied Med. Res. Corp. v. United States Surgical Corp., 147 F.3d 1374, 1376 (Fed. Cir. 1998). Thus, in order to prevail, Graphic Controls "must prove that the jury's factual findings were not supported by substantial evidence or that the facts were not sufficient to support the conclusions necessarily drawn by the jury on the way to its verdict." Id. This court will not substitute its own view of the evidence for that of the jury. See Riles v. Shell Exploration & Prod. Co.,

298 F.3d 1302, 1308 (Fed. Cir. 2002).

This court reviews indefiniteness under 35 U.S.C. § 112, paragraph 2, as a question of law without deference. Personalized Media Communications, LLC v. Int'l Trade Comm'n, 161 F.3d 696, 702 (Fed. Cir. 1998). "If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." Miles Lab., Inc. v. Shandon, Inc., 997 F.2d 870, 875 (Fed. Cir. 1993).

"The assessment of damages is a question of fact, and is decided by the jury when tried to a jury." Festo Corp. v. Shoketsu Kogyo Kabushiki Co., 72 F.3d 857, 866 (Fed. Cir. 1995), vacated on other grounds, 520 U.S. 1111 (1997). This court reviews a jury's damages award for substantial evidence. Crystal Semiconductor Corp. v. Tritech Microelectronics Int'l, Inc., 246 F.3d 1336, 1346 (Fed. Cir. 2001). This court will vacate a jury's award of damages only if the award is "against the clear or great weight of the evidence." Shockley v. Arcan, Inc., 248 F.3d 1349, 1362 (Fed. Cir. 2001).

The Federal Circuit applies its own law with respect to issues of substantive patent law and certain procedural issues pertaining to patent law, but applies the law of the regional circuits on non-patent issues. Institut Pasteur v. Cambridge Biotech Corp., 186 F.3d 1356, 1368 (Fed. Cir. 1999). Therefore, this court will follow the law of the United States Court of Appeals for the Tenth Circuit and review the district court's evidentiary rulings in this case under an abuse of discretion standard. See United States v. Fingado, 934 F.3d 1163, 1164 (10th Cir. 1991).

Claim Construction

Graphic Controls seeks a judgment of noninfringement because the district court erred in claim construction, or because no reasonable jury could find that the differences between the Softrans® stiffening structure and the structure disclosed in the '822 patent are insubstantial. Turning first to claim construction, the parties do not dispute that the claim element "stiffener means" is a means-plus-function element and governed by 35 U.S.C. § 112, ¶ 6. Therefore, the "stiffener means" element "shall be construed to cover the corresponding structure . . . described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6 (2000). The only structure identified in the '822 patent specification as

performing the stiffening function is a steel stylet. See '822 patent, col. 4, ll. 62-63; col. 7, l. 63 – col. 8, l. 10.

Graphic Controls assigns legal error to the district court's change in its initial claim construction. In Graphic Controls' view, the district court erred by amending its claim construction in light of the accused device. See Neomagic Corp. v. Trident Microsystems, Inc., 287 F.3d 1062, 1074 (Fed. Cir. 2002) ("It is well settled that claims may not be construed by reference to the accused device").

Contrary to Graphic Controls' allegation, the record does not show that the district court construed the "stiffener means" limitation based on the accused device. Rather the transcript of the pre-trial hearing shows that the district court amended the claim construction to clarify its original intent. At that hearing, the trial court noted that Graphic Controls interpreted its original claim construction to exclude equivalent structures as a matter of law. The trial court had not intended to foreclose factual issues about equivalent structures. Accordingly, the district court clarified its construction to more closely align its interpretation with the claim language and the specification's description of the stiffening function. This court discerns no error in the trial court's clarification of its original construction.

In the trial court's original claim construction, it focused on the structural relationship between the stylet and the plastic cable as defined in the '822 patent. In its initial effort to define that relationship, the trial court defined the stylet as encased within, and separate from, the plastic cable. This preliminary construction ruled out the use of the plastic cable itself as a stiffening means as a matter of law. This construction seemed correct at first because a thing cannot be encased within itself.

The trial court recognized, however, that this construction did not correctly define the claimed invention. Claim 1 states that the "electrical cable means further compris[es] stiffener means permanently encased in said electrical cable means for imparting a desired degree of rigidity to said electrical cable means." '822 patent, col. 10, ll. 18-42. The electrical cable means, as defined in the '822 patent, includes a stiffener means as a permanent component. Therefore, based on the structure of

the claim, the stiffener means is a separate component of the cable means, rather than a component separate from the cable means. Recognizing this proper reading of the claim language, the trial court amended its original claim construction.

As the claim language shows, the plastic cable cover is not synonymous with the term "electrical cable means" in claim 1. The electrical cable means is a combination of various elements, including the stiffener and the plastic sheath. The cable means is not the plastic sheath alone. The "permanently encase in" language does not refer to the plastic sheath, but to the entire electrical cable means. Therefore, nothing in the claim language supports the contention that the stiffener means and the electrical cable are two separate structures, one encased within the other. Rather, the stiffener means is a permanent component of the electrical cable means and, thus, must be encased within the overall electrical cable means, which includes several components.

The specification supports the trial court's amended claim construction. The specification of the '822 patent states: "[T]he overall cable means of the apparatus is comprised of [a] stylet [], insulating layer or sheath [], conductors [] and outer insulation layer or sheath []." '822 patent, col. 8, ll. 20-23. This description of the invention includes the stylet as one component of the overall cable means. The specification did not separate the stylet from the cable as suggested by the trial court's original claim interpretation. Recognizing the shortcomings of its original attempt to define the scope of the claims, the district court admirably amended its construction to supply a better definition before trial.

The prosecution history of the '822 patent also supports the district court's conclusion. The '822 patentee distinguished Wallace and Hutchins by clarifying that the stiffener means forms a permanent part of the electrical cable as a whole. The district court correctly interpreted this limitation to require a stylet, or equivalent structure, that forms a permanent part of the electrical cable means. The district court's claim construction gives proper meaning to the "permanently encase in" language by explaining that the stiffening function must be performed by a structure that is a permanent, unremovable component of the overall electrical cable means. After reaching this correct interpretation of the relationship between the cable means and the stiffener means, the trial court properly reserved the

factual issue regarding which structures qualify as equivalents for the jury. Accordingly, this court affirms the district court's construction of the stiffener means.

Infringement Verdict

An infringement analysis under section 112, paragraph 6, "begins with determining whether the accused device or method performs an identical function to the one recited in the claim." IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1430 (Fed. Cir. 2000) (citing Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1211-12 (Fed. Cir. 1998)). "If the identical function is performed, the next step is to determine whether the accused device uses the same structure . . . found in the specification, or [its] equivalents." Id. This issue is a question of fact. See id. (citing Odetics, Inc. v. Storage Tech. Corp., 185 F.3d 1259, 1268-69 (Fed. Cir. 1999)).

The parties do not dispute that the hardness and geometry of the Softrans® device perform the stiffening function in the '822 patent. The jury had to decide whether that structure (i.e., hard plastic formed in a dual-lumen geometry) is an equivalent structure to the steel stylet disclosed in the specification. To qualify as an equivalent of the structure disclosed in the specification under section 112, paragraph 6, the structure of the accused device could have no more than insubstantial differences from the steel stylet. See Valmont Indus., Inc. v. Reinke Mfg., 983 F.2d 1039, 1043 (Fed. Cir. 1993). Because the jury resolved this issue of fact, Graphic Controls can prevail only if this court concludes that no jury could reasonably find the differences between the two structures insubstantial. See IMS Tech., 206 F.3d at 1430.

At trial, the jury considered a variety of evidence on each side of this factual question. Graphic Controls argued that the use of stiff plastic in dual-lumen geometry is dramatically different than a steel stylet. In addition, Graphic Controls suggested that Utah Medical attempted, but failed initially, to use plastic to perform the stiffening function, instead electing to use a steel stylet as described in the '822 patent.

The record also shows that Utah Medical used a steel stylet in its early transducers due to cost constraints, not an inability to effectively use plastic. The record also includes expert testimony that

persons of skill in this field would recognize that the dual-lumen hard plastic cable was interchangeable as a stiffening member with a steel stylet. Indeed the record illustrates the evolution of the stiffener means from a steel stylet to a hardened plastic in dual-lumen geometry. The record also shows that the hard plastic stiffener means serves as a separate, permanent component of the electrical cable means, much like the sap of a tree is a separate, permanent component of a tree.

Based on this evidence and the trial court's correct claim construction, the jury found the stiffening structure of the Softrans® device to be equivalent to the steel stylet of the '822 patent. As discussed briefly above, substantial evidence supports this conclusion. Section 112, paragraph 6, "requires two structures to be equivalent, but it does not require them to be 'structurally equivalent,' i.e., it does not mandate an equivalency comparison that necessarily focuses heavily or exclusively on physical construction." IMS Tech., 206 F.3d at 1436. Rather the equivalents analysis under section 112, paragraph 6, proceeds with reference to the context of the invention and the relevant field of art. Id. The jury properly relied on the record evidence in this field of medical technology to reach its factual finding. Because a reasonable jury could, and in fact did in this case, find that the accused device was an equivalent of the steel stylet, this court affirms the verdict of infringement.

Indefiniteness

Even though paragraph six of section 112 allows the use of means-plus-function language in a claim, "one is still subject to the requirement that a claim 'particularly point out and distinctly claim' the invention found in the second paragraph of section 112." See In re Donaldson Co., 16 F.3d 1189, 1195 (Fed. Cir. 1994); 35 U.S.C. § 112 (2000). The statute permits claims in the abbreviated language of means-plus-function terminology. With regard to that claim format, this court has stated: "Structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim. This duty to link or associate structure to function is the quid pro quo for the convenience of employing § 112, ¶ 6." B. Braun Med., Inc. v. Abbott Labs., 124 F.3d 1419, 1424 (Fed. Cir. 1997).

Graphic Controls asserts, both in the context of claim construction and in the context of

invalidity, that because the ‘822 patent specification does not expressly link the function of stiffening to the plastic cable cover, any claim allowing the plastic cable cover to perform that function is indefinite. Graphic Controls argues that the ‘822 patent clearly discloses a plastic cable cover, but does not link that cover to the stiffening function. Therefore, in Graphic Controls’ view, allowing the claims to cover the Softrans® device, which uses the plastic cover to stiffen the device, renders the claim invalid as indefinite, because the patent fails to apprise one of ordinary skill that the plastic cover could serve that function.

The district court properly rejected Graphic Controls’ argument on this issue. The ‘822 patent discloses a plastic cable cover. The ‘822 patent does not disclose the structure utilized by the Softrans® device to provide rigidity -- a hard plastic, dual-lumen cable cover. The district court did not construe claim 1 of the ‘822 patent to allow a structure disclosed in the specification, but not linked to the function at issue, to perform the stiffening function. The simple plastic cover disclosed in the patent was not the equivalent to the steel stylet. Rather, the equivalent found by the jury featured a hardened plastic extruded in a specific geometry. The jury determined that this specific structure, not merely a simple plastic cable cover, performed the stiffening function. In other words, the cable cover of Graphic Controls’ accused device contains additional structure beyond the cable cover disclosed in the ‘822 patent. Therefore, the district court correctly discerned that the patent adequately informs one of skill in this art that a separate, permanent component of the electrical cable means, namely a hardened plastic in a specific rigid geometry, could perform the stiffening function. This court affirms the district court’s holding that claim 1 of the ‘822 patent is not invalid for indefiniteness.

Damages Verdict

Graphic Controls argues that the jury’s damages verdict was unsupported by the evidence because the evidence showed multiple competitors in the IUPC industry and the verdict was based on a two-competitor market theory. Graphic Controls cites the evidence showing that companies other than Utah Medical and Graphic Controls sold IUPCs during the relevant time period. In Graphic Controls’ view, this evidence prohibited the jury from concluding that all of Graphic Controls’ sales of the Softrans® device would have been made by Utah Medical.

Although Utah Medical does not dispute that multiple companies competed in the IUPC industry, the record gives a more complete portrayal of the market factors supporting the jury verdict. Although Graphic Controls and Utah Medical are not the sole IUPC suppliers, the evidence clearly established they were the only companies that sold transducer-tipped IUPCs rather than fluid-filled IUPCs. Expert testimony explained that the two types of IUPCs do not directly compete in price or performance. According to the record, a customer seeking the higher-priced transducer-tipped IUPCs would have only two choices. Therefore, the jury reasonably treated the transducer-tipped IUPC market as a separate and distinct market. In this market, the record shows only two competitors, Graphic Controls and Utah Medical.

Because the record supports the jury's identification of the relevant market, the jury reasonably concluded that nearly every customer that purchased the Softrans® device from Graphic Controls would have purchased the Intran Plus from Utah Medical without Graphic Controls in the market. The evidence, therefore, supports the jury's verdict of $20 million, which is approximately 96% of Graphic Controls' sales of the Softrans® device. This court finds that the jury's damages verdict is not "against the clear or great weight of the evidence" and therefore affirms that verdict. Shockley, 248 F.3d at 1362.

Finally, Graphic Controls argues the district court abused its discretion in excluding the expert testimony and evidence of license agreements Graphic Controls asserted to support a reasonable royalty model of damages. The district court held a Daubert hearing, see Daubert v. Merrill Dow Pharm., Inc., 509 U.S. 579 (1993), to determine whether Graphic Controls' evidence was reliable and concluded that the license agreements used by Graphic Controls to support its expert's testimony were not relevant to the facts of this case.

The exclusion of expert testimony is reviewed under an abuse of discretion standard in this case. See United States v. Brown, 326 F.3d 1143, 1146 (10th Cir. 2003). Nothing in the evidence of record supports Graphic Controls' claim that the district court abused its discretion in excluding the proposed evidence as unreliable. Graphic Controls attempted to offer expert testimony based on industry license agreements and some Utah Medical license agreements to establish that a reasonable royalty rate for the

‘822 patented technology was about 6%. The district court concluded, after fully considering the evidence, that Graphic Controls had not shown that the license agreements used in its expert’s analysis were in any way comparable to the ‘822 patent. This ruling is supported, in part, by evidence tending to show that Utah Medical led the market in developing transducer-tipped IUPCs. Ultimately, the district court determined that presenting Graphic Controls’ expert testimony evidence to the jury would mislead and confuse the jury, as it was not a reliable means of calculating a reasonable royalty for the technology of the ‘822 patent. The district court did not abuse its discretion.

III.

In summary, the district court properly construed the “stiffener means” element of claim 1 of the ‘822 patent and correctly held that claim not invalid for indefiniteness. In addition, the jury reasonably found infringement of claim 1. The record also supports the jury’s damages award. Finally, the district court properly excluded Graphic Controls’ reasonable royalty evidence. The judgment of the district court is, therefore, affirmed.

COSTS

Each party shall bear its own costs.

AFFIRMED