

United States District Court,
W.D. Texas, San Antonio Division.

KINETIC CONCEPTS, INC., KCI Licensing, Inc. KCI USA, Inc. and Wake Forest University Health Sciences,
Plaintiffs.

v.

BLUESKY MEDICAL CORPORATION, Medela AG, Medela, Inc., and Patient Care Systems, Inc,
Defendants.

June 28, 2005.

Alan Michael Ferrill, Cox Smith Matthews Incorporated, Kirt S. O'Neill, R. Laurence Macon, Akin Gump Strauss Hauer & Feld LLP, San Antonio, TX, for Plaintiffs.

Randy McClanahan, McClanahan Myers Espey, LLP, Trang Quoc Tran, Tran Law Firm, LLP, David M. Rodi, Elizabeth L. Durham, Lisa Kelly, Mitchell D. Lukin, R. William Beard, Jr., Scott F. Partridge, Baker Botts LLP, James R. Robinson, King & Spalding, LLP, Houston, TX, Kevin M. Sadler, Scott D. Powers, Baker Botts, LLP, Austin, TX, Thad Harkins, Harkins, Latimer & Dahl PC, San Antonio, TX, for Defendants.

ORDER CONSTRUING PATENT '643 CLAIM TERMS

ROYAL FURGESON, District Judge.

BEFORE THE COURT are a number of filings with regard to the claim construction for the disputed claim terms in patent '643. FN1 A *Markman* hearing was held on May 12, 2005, and the parties subsequently submitted additional briefing to the court regarding the proper construction of the disputed claim terms. After due consideration of the arguments presented and the relevant case law, the Court ORDERS the following ' 643 patent term constructions:

- (1) The term "treating a wound" in Claim 13 shall be construed as "giving medical care to an injury."
- (2) The word "appliance" in the term "securing an appliance for applying pressure" in Claim 13(a) shall be construed as a "wound cover that is generally fluid-tight or gas-tight."
- (3) The term "progressed toward a selected stage of healing" in Claim 29(b) is not indefinite and shall not be construed.
- (4) The term "reduction in bacterial density in the wound by at least 50%" in Claim 32(b) is not indefinite and shall not be construed.

BACKGROUND

This case arises under federal patent, trademark, and unfair competition laws, 35 U.S.C. s. 1 et seq. and 15 U.S.C. s. 1050 et seq. Plaintiff Kinetic Concepts, Inc. ("KCI") develops, manufactures, and distributes specialty therapeutic medical devices, including products that provide wound care benefits for patients. At issue in this case is the company's Vacuum Assisted Closure System ("V.A.C. System"). According to Plaintiffs, the V.A.C. System is comprised of a negative pressure wound therapy pump unit, a porous dressing for application over a wound, an occlusive adhesive drape placed over the dressing and sealed to the skin around the wound, and a disposable canister.

Plaintiffs allege that Medela AG and its subsidiaries and distributors have improperly attempted to commercialize their suction pumps for use with specialized dressings to promote wound healing. Plaintiffs further allege that former Medela employee Richard S. Weston founded Bluesky Medical Corporation for the express purpose of trading on the goodwill of KCI and causing injury to KCI by distributing malicious and misleading marketing material about KCI and its products in an effort to promote the "Versatile 1 pump," which is manufactured by Medela and infringes upon V.A.C. System patents. As a result of Defendants' conduct, Plaintiffs assert the following fifteen causes of action: (1) Breach of Contract; (2) Federal Patent Infringement; (3) Federal Trademark Dilution; (4) Violation of Texas Anti-Dilution Statute; (5) Federal False Advertising; (6) Federal Unfair Competition; (7) Federal Trademark Infringement; (8) Common Law Trademark Infringement; (9) Common Law Negligent Interference with Prospective Economic Relations; (10) Common Law Tortious Interference with Prospective Economic Relations; (11) Common Law Tortious Interference with Contractual Relations; (12) Common Law Business Disparagement; (13) Common Law Trade Libel; (14) Common Law Unfair Competition; and (15) Conspiracy. In response, Defendants assert a number of affirmative defenses, counterclaims, and cross-claims. FN2

I. The Patented Inventions

On June 10, 1997, the U.S. Patent and Trademark Office issued to Wake Forest University U.S. Patent No. 5,636,643 ("'643 patent") entitled "Wound Treatment Employing Reduced Pressure" for the V.A.C. System. The record reflects that KCI is the exclusive licensee of the '643 patent by virtue of a written license agreement with Wake Forest effective October 6, 1993. According to Plaintiffs, KCI has the exclusive worldwide right to make, have made, use, lease and sell products incorporating the inventions covered by the '643 patent.

On November 13, 1990, the U.S. Patent and Trademark office also issued U.S. Patent No. 4,969,880 ("'880 patent") with regard to the V.A.C. System, entitled "Wound Dressing and Treatment Method." The record further reflects that all right, title and interest in and to the '880 patent was assigned to KCI by written assignment dated August 16, 1994 and that KCI subsequently assigned those interests to KCI Licensing by written assignment dated September 19, 2001.

The Abstract for the '643 Patent provides the following summary of the invention at issue:

A method of treating tissue damage comprises applying a negative pressure to a wound sufficient in time and magnitude to promote tissue migration and thus facilitate closure of the wound. The method is applicable to wounds, burns, infected wounds, and live tissue attachments. A wound treatment apparatus is provided in which a fluid impermeable wound cover is sealed over a wound site. A screen in the form of an open-cell foam screen or rigid porous screen is placed beneath the wound cover over the wound. A vacuum pump supplies suction within the wound cover over the treatment site.

II. '643 Patent *Claims*

At issue in this Order is Plaintiffs' charge that Defendants infringed on claims in the '643 patent. The parties have stipulated to agreed constructions for most of the '643 patent claims, but the terms underlined below in claims 13, 29, and 32 of the '643 patent remain in dispute:

-> Claim 13: "A method of *treating a wound* comprising the steps of (a) *securing an appliance for applying reduced pressure* to the wound; and (b) providing reduced pressure to said appliance in alternating intervals of application and non application."

-> Claim 29: "A method of treating a wound comprising the steps of: (a) applying reduced pressure to the wound; and (b) maintaining said reduced pressure until the wound has *progressed toward a selected stage of healing*, wherein said maintaining of said reduced pressure is conducted in alternating periods of application and nonapplication of the reduced pressure."

-> Claim 32: "A method of treating a wound comprising the steps of: (a) applying a reduced pressure to the wound; and (b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing, wherein said selected stage of healing is a *reduction in bacterial density in the wound by at least 50%*."

First, with regard to the term "treating a wound" in Claim 13, Defendants contend that the term should be construed consistently with its plain and ordinary meaning of "giving medical care to an injury." Alternatively, Defendants endorse defining the term in accordance with the following definition Plaintiffs allegedly asserted to the FDA, "(1) trauma to any of the tissues in the body, especially that caused by physical means and with interruption of continuity [or] (2) a surgical incision." In contrast, Plaintiffs contend that the term should not be construed because the jury would have no difficulty understanding the ordinary meaning of these words.

Second, concerning the term "securing an appliance for applying reduced pressure" in Claim 13, Defendants argue that the term is a means-plus-function limitation under 35 U.S.C. s. 112 para. 6 and accordingly "appliance" should be construed to include the following three structural elements: (1) a fluid impermeable cover, (2) a sealing means, and (3) a suction port. Plaintiffs respond that s. 112 does not apply to the term and that "appliance" should be afforded its ordinary meaning.

Third, Defendants maintain that the terms "progressed toward a selected stage of healing" in claim 29 and "reduction in bacterial density in the wound by at least 50%" in claim 32 invalidate the patent claims because they are indefinite. Plaintiffs refute this challenge by arguing that the record reflects that a person of ordinary skill understands the meaning of these terms and that, as a practical matter, Plaintiffs have no track record of singling out doctors for infringement suits based on their particular methods of treatment.

Claim language defines claim scope, and "the first step in an infringement analysis is to construe the claims, i.e., to determine the scope and meaning of that which is allegedly infringed." FN3 Disputes as to the meaning and scope of terms used in the claims are determined as a matter of law, based on the claims, the rest of the patent specification, and the prosecution history. FN4

DISCUSSION

I. Claim 13- "treating a wound"

Because the meaning of the phrase "treating a wound" remains in dispute and the patent's specification and prosecution history do not indicate that the patentee has given the term an unconventional meaning, the Court finds that the phrase should be interpreted according to its plain and ordinary meaning as "giving medical care to an injury." FN5

II. Claim 13(a)- "securing an appliance for applying pressure"

Defendants argue that the phrase "securing an appliance for applying pressure" is a means-plus function limitation that should be construed pursuant to 35 U.S.C. s. 112 para. 6. For a method claim such as the one at issue here, " s. 112 is implicated only when steps plus function without acts are present." FN6

"To invoke a presumption of s. 112 para. 6 application, a claim drafter must use language that expressly signals the recitation of a function as distinguished from an act." FN7 The disputed phrase in this claim is introduced by the phrase, "A method of treating a wound comprising the steps of." Use of the word "step," by itself, does not invoke a presumption that 112, para. 6 applies. FN8 Rather, the Federal Circuit has held that the phrase "steps of" colloquially signals the introduction of specific acts and should not presumptively invoke application of s. 112, para. 6.FN9 The contested element in this case is not in classical step-plus-function form.

Claim elements without express step-plus-function language may nevertheless fall within the parameters of s. 112, para. 6 if they merely claim the underlying function without recitation of acts for performing that function.FN10 In this matter, use of the phrase "steps" of recites the step of "securing an appliance for applying reduced pressure to the wound." Because the phrase "step for" is lacking in the disputed claim element, this language tends to show that the verb "securing" recites an act rather than a function.FN11

The function of the element at issue in this matter, namely, "applying reduced pressure," appears explicitly in the claim language. The preposition "for" introduces this underlying function and links the "applying" function to the act of "securing." In other words, the function of "applying" is the result achieved by performing the claimed act of "securing." The claim recites more than a function and discloses "securing" as an act by using the introductory terms "steps of." Accordingly, because this limitation is not constructed in explicit step-plus-function form and specifies an act associated with the underlying function, the claim drafter did not invoke s. 112 para. 6.FN12

Although the Court rules that s. 112 para. 6 has not been invoked in this claim, the Court finds that the term "appliance" warrants a more precise construction because it is clear from the patent specification and prosecution history that the inventors did not intend to use the term in its broad, ordinary meaning. Plaintiffs request that the Court define appliance as "a device or instrument," but the Court "can neither broaden nor narrow the claim to give the patentee something different than what he has set forth." FN13 The patent specification routinely refers to "appliance" as a wound cover that is "generally fluid-tight or gas-tight." FN14 "A patentee is his own lexicographer." FN15 The Court consequently interprets the term "appliance" to refer to a "wound cover that is generally fluid-tight or gas-tight."

III. Claim 29(b)- "progressed toward a selected stage of healing"; and Claim 32(b)- "reduction in bacterial density in the wound by at least 50%"

Defendants allege that disputed claims 29 and 30 are indefinite and should be held invalid because they

have an unjust chilling effect on competitors and interfere with physicians' choices concerning methods of wound treatment. An issued patent is presumed valid, and in order for Defendants to sustain their indefiniteness argument, they must overcome the strong presumption that the Patent Office properly carried out its administrative functions.FN16 Defendants bear the burden of proof by clear and convincing evidence to sustain the claim of invalidity.FN17 The U.S. Supreme Court has defined this as evidence that "could place in the ultimate factfinder an abiding conviction that the truth of [the] factual contentions are 'highly probable.'" FN18

The Federal Circuit instructs that interpretations of claims that render the claimed invention inoperable should be viewed with skepticism.FN19 "When claims are amenable to more than one construction, they should when reasonably possible be interpreted so as to preserve their validity." FN20

"A decision on whether a claim is invalid under s. 112, 2d para. , requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." FN21 Some courts have held that in order for indefiniteness to be established, one or more witnesses must testify that the claim cannot be understood by one of skill in the art.FN22

In the matter at hand, no witness has testified that the claim cannot be understood by one of skill in the art of wound care. In contrast, Dr. Michael Morykwas and Dr. Wilson C. Hayes have submitted affidavits that the disputed claims can be understood. Defendant Medela maintains that Dr. Morykwas's statements are "irrelevant" because "Mr. Morykwas is a Ph.D., not a physician or nurse with wound treatment experience." FN23 The Court finds Defendant's challenge of Dr. Morykwas expertise in wound care to be unfounded. Dr. Morykwas has served as a consultant on the General and Plastic Surgery Devices Advisory Panel for the United States Food and Drug Administration, has lectured and written extensively on subjects related to wound care, and is a named inventor of the '643 patent. Dr. Morykwas possesses personal experience with the devices at issue in this lawsuit and has spent more than 15 years conducting experiments with and observing the use of similar wound care devices.

Claim language, "progressed toward a selected stage of healing," may be unclear, but the '643 patent's written description clarifies the meaning of the phrase by providing a list of more than five examples of states of improved condition.FN24 Similarly, the phrase "reduction in bacterial density in the wound by at least 50%" is clarified by intrinsic evidence such as Example 2, which details procedures and calculations that have reduced bacterial density in the manner specified in Claim 32. The patent sets forth methods to reduce the bacterial density in the wound by at least 50%, and Defendants have failed to show there is "no practicable means of detecting infringement." FN25 Based on this analysis, the Court concludes that Defendants have not met their burden of showing that they likely will succeed on the merits of this claim at trial, and as such, the Court declines at this time to invalidate these claims on the grounds of indefiniteness.

CONCLUSION

For the foregoing reasons, the Court ORDERS that the four remaining disputed terms be construed in accordance with the discussion above.

The Court ORDERS that:

(1) The term "treating a wound" in Claim 13 be construed as "giving medical care to an injury."

(2) The word "appliance" in the term "securing an appliance for applying pressure" in Claim 13(a) be construed as a "wound cover that is generally fluid-tight or gas-tight."

(3) The term "progressed toward a selected stage of healing" in Claim 29(b) is not indefinite and shall not be construed.

(4) The term "reduction in bacterial density in the wound by at least 50%" in Claim 32(b) is not indefinite and shall not be construed.

It is SO ORDERED.

FN1. *See, for instance*, List of Claim Terms to be Construed (Docket No. 134); Medela's AG and Medela, Inc.'s Opening Memorandum Regarding Construction of the Patent Claim (Docket No. 140); Plaintiff's Brief on Claim Construction (Docket No. 141); Emergency Motion for Brief Continuance of Claim Construction Hearing (Docket No. 159); Joint Motion for Continuance of Claim Construction Hearing and Scheduling of Status Conference (Docket No. 160); Plaintiffs' letter brief responding to Court's Order of May 17, 2005 regarding Markman issues dated May 31, 2005 (Docket No. 207); Defendant Blue Sky Medical Group's Letter Brief concerning claim construction dated May 31, 2005, placed under seal (Docket No. 208); Defendant Medela's Letter Brief regarding construction of four remaining disputed claim terms from the '643 patent dated May 31, 2005, placed under seal (Docket No. 210).

FN2. *See, for instance*, Defendant Blue Sky Medical Group Incorporated's Cross Claim and Answer to Plaintiffs Third Amended Complaint (Docket No. 137); Medela, Inc. and Medela AG's Motion for Leave to File Amended Answers to Third Amended Complaint, Additional Defenses, Second Amended Counterclaims and Jury Demands (Docket No. 175); Defendant Richard Weston's Answer to Plaintiff's Third Amended Complaint, Counterclaims, and Joinder of Wake Forest University (Docket No. 194); Medela, INC. and Medela AG's Reply in Support of Motion for Leave to file Amended Answers to Third Amended Complaint, Additional Defenses, Second Amended Counterclaims and Jury Demands (Docket No. 218).

FN3. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1324 (Fed.Cir.2003) (citing *Markman v. Westview Instr., Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996)).

FN4. *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996); *Markman*, 52 F.3d at 979-80.

FN5. *See Hockerson-Halbertstadt, Inc. v. Avia Group International, Ltd.*, 222 F.3d 951, 955 (Fed.Cir.2000); *see also Johnson Worldwide Associates, Inc. v. Zebco Corp.*, 175 F.3d 985, 989-90 (Fed.Cir.1999) ("The general rule is, of course, that terms in the claim are to be given their ordinary and accustomed meaning.").

FN6. *Epcon Gas Systems, Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1028 (Fed.Cir.2002) *citing* O.I.

Corp. v. Tekmar Co. Inc. , 115 F.3d 1576, 1583 (Fed.Cir.1997).

FN7. Seal-Flex, Inc. v. Athletic Track and Court Construction, 172 F.3d 836, 849 (Fed.Cir.1999) (Rader concurrence).

FN8. *See* O.I. Corp., 115 F.3d at 1583 (*holding* "Claiming a step by itself, or even a series of steps, does not implicate section 112, para. 6.").

FN9. Seal-Flex, 172 F.3d at 849.

FN10. *Id.* at 850.

FN11. *See id.*

FN12. *See id.* at 850-51.

FN13. Autogiro Co. of America v. United States, 181 Ct.Cl. 55, 384 F.2d 391, 395-96 (1967); *see* E.I. DuPont De Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed.Cir.1988).

FN14. *See* '643 Patent, col. 3, ll. 6-7; '643 Patent, col. 5, ll. 41-42; '643 Patent, col. 6, ll. 28; '643 Patent, col. 6, ll. 39-40.

FN15. Canaan Prod., Inc. v. Edward Don & Co., 388 F.2d 540, 544 (7th Cir.1968); *see* Liebel-Flarshem Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed.Cir.2004).

FN16. *See* 35 U.S.C. s. 282(2002).

FN17. Hewlett-Packard Co. v. Bausch & Lomb, 909 F.2d 1464, 1467 (Fed.Cir.1990); Minnesota Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1301 (Fed.Cir.2002).

FN18. Colorado v. New Mexico, 467 U.S. 310, 316, 104 S.Ct. 2433, 81 L.Ed.2d 247 (1984).

FN19. *See* Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1557 (Fed.Cir.1996) *overruled on other grounds*, 535 U.S. 722, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002); ACS Hosp. Sys., Inc. v.

Montefiore Hosp., 732 F.2d 1572, 1577 (Fed.Cir.1984).

FN20. Modine Mfg. Co., 75 F.3d at 1556; *accord* Rhine v. Casio Inc., 183 F.3d 1342, 1345 (Fed.Cir.1999); Whittaker Corp. v. UNR Indus., Inc., 911 F.2d 709, 712 (Fed.Cir.1990).

FN21. Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576 (Fed.Cir.1986); Morton Int'l, Inc. v. Cardinal Chemical Co., 5 F.3d 1464, 1470 (Fed.Cir.1993).

FN22. *See ie.* BOC Health Care, Inc. v. Nellcor Inc., 892 F.Supp. 598, 603 (D.Del.1995), *aff'd*, 98 F.3d 1357 (Fed.Cir.1996)(unpublished).

FN23. Defendant Medela's May 31, 2005 Letter to the Court, Docket No. 210, p. 8.

FN24. '643 Patent, col. 12, ll. 47 -54; *see* Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313, 1325 (Fed.Cir.2002) ("The intrinsic evidence may provide context and clarification about the meaning of claim terms.").

FN25. Gould, Inc. v. Graphic Controls Corp., 196 USPQ 13 (N.D.Ill.1977); *see also In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1171-72 (U.S. Int'l Trade Comm.1983), *aff'd sub nom.* Massachusetts Institute of Technology v. AB Fortia, 774 F.2d 1104, 227 USPQ 428 (Fed.Cir.1985) ("The dispute is whether, as a practical matter, members of the public may have difficulty determining whether or not they infringe these claims because they might have difficulty ascertaining the appropriate molecular weight to be used in the conversion formula. We do not feel that this is a question of definiteness at all. However, assuming it to be a question of definiteness, respondents have failed to carry their burden.").

W.D.Tex.,2005.

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