

United States District Court,
E.D. Pennsylvania.

MEDICAL COMPONENTS, INC,
Plaintiff.

v.

ARROW INTERNATIONAL, INC,
Defendant.

May 20, 2008.

Alfred W. Zaher, Joel L. Dion, Blank Rome LLP, Philadelphia, PA, Katherine P. Bavecchia, Blank Rome, LLP, Washington, DC, for Plaintiff.

Ira Silfin, Kenneth P. George, Rebecca Eisenberg, Amster Rothstein & Ebenstein, LLP, New York, NY, Lisa A. Lori, Michael K. Coran, Klehr Harrison Harvey Branzburg & Ellers, LLP, Philadelphia, PA, for Defendant.

ORDER

PAUL S. DIAMOND, District Judge.

And Now, this 19th day of May, 2008, upon consideration of Plaintiffs Opening Claim Construction Brief (Doc. No. 39), Defendant's Claim Construction Brief (Doc. No. 46), Plaintiff's Reply Brief (Doc. No. 47), and the claim construction hearing I held on Monday, April 28, 2008, it is ORDERED as follows:

1. Plaintiff, Medical Components, Inc., alleges that Defendant, Arrow International, Inc. infringes on Claim 19 of Medcomp's Multilumen Catheter Assembly patent, U.S. Patent No. 6,881,211. Claim 19 of the '211 Patent describes a process for making multilumen catheters. Plaintiff alleges that Defendant manufactures four types of catheters using the process described in Claim 19. On November 21, 2007, Defendant moved for Summary Judgment, arguing that the '211 Patent was anticipated by a separate patent (Patent '117), and is thus invalid. Before I can determine the validity of the '211 Patent, I must construe the terms and limitations of Claim 19. *Dana Corp. v. Am. Axle & Mfg., Inc.*, 279 F.3d 1372, 1376 (Fed.Cir.2002) ("a court may not invalidate the claims of a patent without construing the disputed limitations of the claims and applying them to the allegedly invalidating acts"); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 973 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384 (1996); *Illinois Tool Works, Inc. ex rel. Simco Div. v. Ion Sys., Inc.*, 250 F.Supp.2d 477 (E.D.Pa.2003).

I. Legal Standard

2. Courts begin the claim construction analysis by examining "intrinsic evidence": the patent's claims, specification, and, if in evidence, the prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312, 1316 (Fed Cir.2005). The construction that "stays true to the claim language and most naturally aligns with the

patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed.Cir.1998). If the disputed terms remain unclear after reviewing the intrinsic evidence, courts then consider extrinsic evidence such as expert and inventor testimony, dictionaries, and learned treatises. *Markman*, 52 F.3d at 980.

3. Words within a patent claim are generally given their ordinary and customary meaning—the meaning the words would have for a person of ordinary skill in the art. *Phillips*, 415 F.3d at 1313, *Johnson Worldwide Assocs, Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed.Cir.1999) (claim terms are presumed to "mean what they say"). Two situations exist, however, where courts give terms something other than their ordinary and accustomed meaning: 1) when the patentee has explicitly defined a term in the patent language; or 2) when the term so lacks clarity that the claim scope cannot be ascertained by the language used. *Johnson*, 175 F.3d at 990; *Honeywell Int'l, Inc. v. Univ. Avionics Sys. Corp.*, 493 F.3d 1358, 1361 (Fed.Cir.2007).

II. Discussion

4. Claim 19 of the '211 Patent provides:

A method of making a multilumen catheter assembly, comprising:

forming a unitary catheter tube to have a distal portion and a proximal portion terminating in a proximal end, and a first lumen and a second lumen, each of the first lumen and the second lumen extending longitudinally through the unitary catheter tube;

forming a first distal end tube having a first passageway extending longitudinally therethrough and a second distal end tube having a second passageway extending longitudinally therethrough; and

attaching the first and second distal end tubes to the distal end of the unitary catheter tube such that the first passageway in the first distal end tube is in communication with the first lumen of the unitary catheter tube and the second passageway in the second distal end tube is in communication with the second lumen in the unitary catheter tube.

5. The Parties dispute the construction of the following terms or phrases: (1) proximal and distal; (2) forming; (3) unitary catheter tube; and (4) extending longitudinally through. I will address in turn each term or phrase.

A. Proximal and distal

6. Plaintiff argues that "proximal" means the direction away from the insertion tips of the catheter, and "distal" signifies the direction closer to the insertion tips. Defendant contends that these are interchangeable terms that refer to opposite ends of the catheter, and that Plaintiff's distinction is significant only with respect to the product's medical use, not the manufacturing process described in Claim 19. I agree with Defendant.

7. Plaintiff uses the terms proximal and distal in Claim 19 to clarify that during manufacturing the two tubes that will be inserted into the patient's body must attach to the end of the catheter that will also be inserted in the patient when the catheter is in use. (Hr'ng Tr. 12, 14, April 28, 2008). Plaintiff thus seeks to distinguish Claim 19 from prior art in which attachments are made to the end of the catheter that remains outside the patient's body. (Hr'ng Tr. 13-14, April 28, 2008). Plaintiff conceded during the claim construction hearing,

however, that whether these ends are deemed proximal and distal or vice versa is irrelevant to the method of making the '211 catheter. (Hr'ng Tr. 12-13, April 28, 2008, "the labels that you give to those two ends are not necessarily limiting ... So long as you understand which end is going to go in the body and which end is going to go outside of the body."). Accordingly, it appears that Plaintiff agrees with Defendant that proximal and distal are interchangeable terms that refer to opposite ends of the catheter.

8. Plaintiff nevertheless argues that because the terms proximal and distal are defined in the '211 specification, those definitions are dispositive. Patent '211, Column 5, lines 52-54. To be dispositive, the intrinsic evidence must show that the patentee "clearly set forth" or "clearly redefine [d]" a term. *Bell Atlantic Network Servs., Inc. v. Covad Comm'n Group, Inc.*, 262 F.3d 1258, 1268 (Fed.Cir.2001); *see also Schering v. Amgen*, 222 F.3d 1347, 1353 (Fed.Cir.2000). In the instant case, although Plaintiff defined the terms proximal and distal, immediately before that definition, Plaintiff also explicitly disclaimed any limitation that those definitions might impose on the patent's scope. *Id.*, Column 5, lines 48-49 ("certain terminology is used herein for convenience only and is not to be taken as a limitation on the present invention."). It thus appears that Plaintiff sought to eat its cake and have it too. Plaintiff intended to: (1) obtain patent approval and ensure patent validity against prior art by limiting the patent scope; and (2) protect against future infringement by disclaiming any limitations on the patent scope. Because the intrinsic evidence shows that Plaintiff disclaimed the very definitions it now seeks to impose on Claim 19, I cannot find that Plaintiff's definitions of the terms proximal and distal are dispositive. Rather, I adopt Defendant's construction that in Claim 19, proximal and distal are interchangeable terms that refer to opposite ends of the catheter.

B. Forming

9. Plaintiff argues that "forming" means making a solid object using any suitable molding process. Defendant counters that forming is a commonly understood term that requires no construction because it was not given any special meaning in the '211 Patent. I agree with Defendant.

10. The law requires that all patent applications include a patent specification that offers an example of a best mode for carrying the invention out described in terms that will "enable any person skilled in the art to which it pertains ... to make and use the same." 35 U.S.C. s. 112. The patent specification provides only a preferred embodiment of the invention, however, and is not intended to define the scope of the invention. Rather, the patent claims define the invention's scope. *Schmidinger v. Welsh*, 383 F.2d 455, 460 (3d Cir.1967), *see Nautilus Group, Inc. v. Icon Health and Fitness, Inc.*, 82 Fed. Appx. 691, 694, (Fed.Cir.2003) (claims "recite the outer boundaries of the scope encompassed by the invention"; the specification describes an embodiment of the invention); *see, e.g., Yenser v. Agrotors, Inc.*, 764 F.Supp. 974, 982 (M.D.Pa.1991) (disclosure that separate electrical connectors of wire gauge between work platform and fuselage specified the "best mode" of connection did not constitute a limitation of the patent claim).

11. Plaintiff argues that I should import terminology from the '211 Patent specification to define the term forming as it appears in Claim 19. A construing court may not import terminology from the preferred embodiment as a claim limitation unless the intrinsic evidence shows that the patentee clearly intended such a restriction. *Teleflex, Inc. v. Ficoso N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed.Cir.2002), *Nautilus*, 82 Fed. Appx. at 694; *see, e.g., Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1341 (Fed.Cir.1999) (court could not read into the claim that the invention must be made of sheet aluminum simply because the preferred embodiment provided that the invention is made of sheet aluminum). The intrinsic evidence respecting the '211 Patent does not show that Plaintiff clearly intended the preferred embodiment to restrict

the scope of Claim 19. The '211 specification provides that "[t]he unitary catheter tube ... may be formed using any suitable heat molding process including injection molding, expansion/compression molding and extrusion." Column 11, lines 4-6. The expression "may be" clearly indicates that Plaintiff did not intend to limit the term forming in Claim 19 based on the specification language.

12. During the claim construction hearing, Plaintiff argued that I should nevertheless construe the term forming because it would be improper to leave a term unconstrued when the parties dispute that term's meaning. (Hr'ng Tr. 17:19-24, April 28, 2008, citing *O2 Micro Int'l v. Beyond Innovation Tech., Co. et al.*, 521 F.3d 1351 (Fed.Cir.2008) for the proposition that all disputed terms require court construction)). In *O2 Micro* the district court erred in relying on the plain and ordinary meaning of the words "only if" because the parties disputed the scope of those words, not their meaning. *Id.* at 1361-1362 (plaintiffs argued that disputed terms "only if" applied strictly during "steady state operation" of the invention; defendants countered that the terms applied at all times without exception). The Federal Circuit thus held that "[w]hen the parties present a fundamental dispute regarding the scope of a claim term it is the court's duty to resolve it." *Id.*

13. In the instant case, the Parties dispute the meaning, not the scope, of "forming"-a term that has a plain and ordinary meaning. As the Federal Circuit confirmed in *O2 Micro*, district courts are not obligated to construe terms with plain and ordinary meanings. *Id.* at 1360-1361; *see, e.g.*, *Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc.*, 249 F.3d 1341, 1349 (Fed.Cir.2001) (district court was not required to construe the term "melting" where that term did not depart from its ordinary meaning). Accordingly, I agree with Defendant: the term "forming" requires no construction.

C. Unitary catheter tube

14. Plaintiff argues that a "unitary catheter tube" is a single, flexible multilumen tube. Defendant concedes this point. (Hr'ng Tr. 21:19-22, April 28, 2008). Accordingly, I adopt Plaintiff's proposed construction of the phrase unitary catheter tube.

D. Extending longitudinally through

15. Plaintiff argues that the phrase "extending longitudinally through" means "extending all the way through." (Hr'ng Tr. 28:4, April 28, 2008). Although Defendant suggests that the phrase is not in dispute, it nonetheless contends that Plaintiff's proposed definition is unnecessary because the ordinary meaning of the phrase is sufficiently clear. (Hr'ng Tr. 28:19-21, April 28, 2008). I disagree. I am obligated to construe the phrase because it is not sufficiently clear. *Johnson*, 175 F.3d at 990.

16. The '211 catheter cannot function unless the lumens extend the full length of the unitary catheter. Plaintiff's proposed construction thus "stays true to the claim language and most naturally aligns with the patent's description of the invention." *Renishaw PLC*, 158 F.3d at 1250. Accordingly, I adopt Plaintiff's proposed construction that extending longitudinally through means extending all the way through.

III. Conclusion

17. In sum, I construe the disputed terms of Claim 19 as follows: (1) proximal and distal are interchangeable terms that refer to opposite ends of the '211 catheter; (2) forming requires no construction; (3) a unitary catheter tube is a single, flexible multilumen tube; and (4) extending longitudinally through means extending all the way through.

AND IT IS SO ORDERED.

E.D.Pa.,2008.

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