United States District Court,
N.D. Illinois, Eastern Division.

Dr. Sakharam D. MAHURKAR,
Plaintiff.
v.
C.R. BARD, INC. and Bard Access Systems, Inc., and Bard Healthcare, Inc,
Defendants.

May 13, 2003.

In construing claims for patents describing two different catheters, the District Court, Pallmeyer, J., held that: (1) phrase "proximal cylindrical portion," as used in patent claim for a double lumen catheter having an elongated tube with a proximal cylindrical portion enclosing first and second lumens separated by an internal divider, meant that the proximal end of the catheter had a cross-section defined by a fixed curved surface, which could be either a circle or an oval shape; (2) for the second opening of claimed double lumen catheter to be deemed "beveled" within meaning of patent claim, the slant had to be visible to the human eye; and (3) means-plus-function clause "connecting means," as used in patent claim describing components of dual-lumen catheter assembly, meant that the catheter itself had to be visibly attached to a distinct portion, the connecting means, and the catheter tube had to be straight, not curved.

Claims construed.

4,808,155, 4,895,561. Construed.

MEMORANDUM OPINION AND ORDER

PALLMEYER**, J.**

Plaintiff Dr. Sakharam D. Mahurkar is a nephrologist and inventor of catheters, for which he owns several patents. In his Second Amended Complaint, filed August 26, 2002, Plaintiff charges Defendants C.R. Bard, Inc., Bard Access Systems, Inc., and Bard Healthcare, Inc. with infringing two of his patents under 35 U.S.C. s.s. 271(a), (b), and (c): United States No. 4,808,155 (the " '155 patent") and No. 4,895,561 (the " '561 patent"). These patents describe two different catheters. FN1 In December 2002, the court conducted a *Markman* hearing at which the parties presented their respective interpretations of a number of claims in each patent. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995) (*en banc*), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Following is the court's construction of those claims.

FN1. Both patents may be found on the United States Patent and Trademark Office website, *www.uspto.gov*.

BACKGROUND

The role of kidneys in the body is to remove toxins from blood; when kidneys fail to function properly due to disease or injury, blood must be cleansed externally in a process called hemodialysis. Mahurkar v. Arrow Int'l, Inc., 160 F.Supp.2d 927, 930 (N.D.Ill.2001). The patents-insuit and the accused Bard products concern double lumen catheters for use in hemodialysis. In hemodialysis, blood is removed from a patient, diverted

to a blood treatment unit where it is cleansed, and then returned to the patient. (Pl.'s Brief at 1.) Hemodialysis catheters are devices that are inserted into a patient's vein for removal and return of blood. Arrow Int'l, 160 F.Supp.2d at 930. A "double lumen" hemodialysis catheter has two separate lumens, or channels, one for removing uncleansed blood and one for returning cleansed blood. (Pl.'s Brief at 1.)

Plaintiff is a certified nephrologist-a doctor specializing in the treatment of kidneys-who has lived in Chicago for approximately 30 years. (Plaintiff's Opening Brief on Claim Construction, hereinafter "Pl.'s Brief" at 2.) Until his retirement in 1993, Plaintiff conducted research and taught nephrology and internal medicine at Cook County Hospital in Chicago. (*Id.*) Plaintiff first developed a dual lumen catheter in 1980. (*Id.*) He has since become a prolific inventor and has, to date, been awarded 29 United States patents. (*Id.*)

Defendant C.R. Bard is a New Jersey corporation in the business of manufacturing, distributing, and selling catheters in the United States under a variety of brands. (C.R. Bard's Answer to Second Amended Complaint para. 2.) Defendant Bard Access Systems is a Utah corporation that, like C.R. Bard, distributes and sells a variety of catheters. (Bard Access Systems Answer to Second Amended Complaint para. 3.) Defendant Bard Healthcare is a Texas corporation and imports into the United States certain of the accused catheters which it sells to Bard Access Systems. FN2 (Bard Healthcare's Answer to Second Amended Complaint para. 4.)

FN2. Defendants have submitted a joint claims construction brief; therefore, the court shall refer to them collectively as "Defendants" and will not further distinguish the three corporations in this opinion.

In Count I of his Second Amended Complaint, Plaintiff claims that Defendants infringed the '561 patent by making, using, importing, distributing, selling and/or offering for sale Flexxicon II Precurve catheters, Niagara curved catheters, Softcell curved catheters, Optiflow, Hemoglide, Niagara Slim-Cath and other catheter assemblies with a preformed bend in the catheter or catheter connecting system. (Second Amended Complaint para.para. 19, 20, 21.) Count II alleges that the Defendants infringed the '155 patent by making, using, importing, distributing, selling and/or offering for sale the same products. FN3 (Id. para.para. 26, 27.)

FN3. In February 2003, the court denied Defendant C.R. Bard's motion for partial summary judgment, in which C.R. Bard argued that it could not be directly liable for patent infringement under Section 271(a) of the patent law because it does not directly sell or offer the accused catheters for sale. Mahurkar v. C.R. Bard, 2003 WL 355636 (N.D.Ill. Feb.13, 2003). The court concluded that Mahurkar had demonstrated that a dispute of fact existed as to whether C.R. Bard used the accused catheters such that it could be directly liable for infringement under Section 271(a).

A. Background on the '155 Patent

The '155 patent is entitled "Simple Double Lumen Catheter." Plaintiff intended the catheter described by the '155 patent to improve patient comfort and reduce trauma on a patient's vein. (Pl.'s Brief at 3.) Plaintiff explains that a patient suffering from chronic kidney failure requires long-term hemodialysis including blood cleansing several times a week for the remainder of her life or until she receives a compatible kidney transplant. (Id.) To limit the puncture damage that would be inflicted on a patient's veins from implanting a new catheter each time, chronic patients usually retain the same catheter in their body continuously over a period of several weeks. (Id.) Unless properly configured, the catheter, especially its tip, can cause extensive pain and trauma to the patient's vein during its extended residence. (Id.) Plaintiff explains that prior to his invention of the '155 patent, catheters typically featured a sharp tip (or distal end) which facilitated puncturing the patient's skin and vessel wall during implantation, (Id. at 4), but could become caught in the walls of the patient's blood vessel and cause trauma. Plaintiff's patented invention is a catheter

that does "not traumatize or become caught in the walls of a blood vessel into which the catheter is inserted ...." ('155 patent, Ex. A to Second Amended Complaint, col. 3, lines 48-51.) The patent specification notes that trauma to the patient is avoided because the catheter "does not have the conical tip or taper that is characteristic of other catheters." (Id., col. 3, lines 60-61.) Without a sharp tip, the catheter of the '155 patent is implanted "in the direction of blood flow in a large vein, surgically under direct vision or over a Seldinger's guide wire through a sheath...." (Id., col. 4, lines 16-17.) In order to prevent cleansed blood from mixing with uncleansed blood, the lumens described by the '155 patent are spatially separated longitudinally along the catheter axis by a divider. (Id., col. 3, lines 31-33, 55-57.) FN4

FN4. The parties have not explained whether this particular feature represents an advance over previous catheters.

B. Background on the '561 Patent

The '561 patent, entitled "Dual-Lumen Catheter-Connecting System," was issued to Dr. Mahurkar on January 23, 1990. The '561 patent concerns the portion of the catheter assembly that connects the catheter tube to the blood treatment unit. Prior to the invention of the '561 patent, extension tubes on catheters were generally straight. When straight catheters were placed in certain veins, such as the subclavian vein (under the clavicle), or the jugular vein (in the neck), the extension tubes protruded awkwardly above the patient's shoulder, or towards the patient's ear. (Id.) In addition to being uncomfortable for patients, these straight catheters had a tendency to become dislodged, sometimes resulting in bleeding that can be profuse and can even be fatal. (Id. at 6.) The patented invention improves patient comfort for certain types of catheter placements, and reduces the likelihood that catheters will pull out of the vein during or between hemodialysis treatments. (Pl.'s Brief at 5.)

Plaintiff's '561 patent addressed this risk by bending a portion of the catheter assembly that remains outside of the patient's vein so that the extension tubes could "be positioned in convenient anatomical sites during the periods between successive treatments to avoid patient discomfort and accidental displacement of the catheter ." ('561 patent, Ex. B to Second Amended Complaint, col. 1, lines 13-16.) Since the extension tubes are curved back toward the distal end of the catheter (the end that is inserted into the patient's vein), they do not stick out, and tugging on the extension tubes will not cause the catheter to become dislodged. (Pl.'s Brief at 7.)

C. Prior Litigation Between the Parties

The present suit is not the first litigation between Plaintiff and Defendants. In 1992, Plaintiff sued C.R. Bard, Bard Access Systems, and a third corporation not a party to the present lawsuit for infringement of his '155 patent. A jury found the accused catheters (different catheters from those accused in this suit) to infringe the '155 patent and the Federal Circuit affirmed, although it remanded for a new calculation of the plaintiff's damages. Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572 (Fed.Cir.1996). That earlier case produced no published opinions regarding claims construction. As mentioned below, Dr. Mahurkar has brought suit against other alleged infringers as well, including Arrow International, Inc. Mahurkar v. Arrow Int'l, Inc., 160 F.Supp.2d 927 (N.D.Ill.2001).

DISCUSSION OF DISPUTED CLAIMS

The parties in this case dispute a number of claim terms in the '155 and '561 patents. The court will address each of the disputed terms in turn. In each instance, the court will examine the claim language itself, giving the terms "their ordinary and accustomed meanings as understood by one of ordinary skill in the art." Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1267 (Fed.Cir.2001). It is well settled that when "interpreting an asserted claim, the court should first look to the intrinsic evidence of the record," such as "the patent itself, including the claims, the specification and, if in evidence,

the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996), citing Markman, 52 F.3d at 979. "In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term." *Id*. When intrinsic evidence is sufficient, it is inappropriate for the court to rely on extrinsic evidence. *Id*. Where one party did not respond in writing to another party's proposed claim term, the court has assumed that the term is no longer disputed, and will not address it in this opinion.

I. '155 Patent

The parties dispute terms in claims 1 and 3 of the '155 patent, and the court will address them each in turn.

A. Claim 1

Claim 1 of the '155 patent states:

A double lumen catheter having an elongated tube with a proximal cylindrical portion enclosing first and second lumens separated by an internal divider, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens, the first lumen extending from the proximal end of said elongated tube, and the second lumen extending from the proximal end of said elongated tube to a second opening spaced in the longitudinal direction away from said first opening, said tube having a non-conical and non-tapered distal end portion having a cross-sectional area smaller than the cross-sectional area of said proximal cylindrical portion, and said distal end portion extending from said second opening and terminating in a blunt distal end to prevent the distal end of the catheter from traumatizing or becoming caught in the walls of the vessel into which the catheter is inserted.

(Col. 4, lines 23-41) (disputed claim terms in bold.)

1. Language in dispute: "proximal cylindrical portion"

Does "proximal cylindrical portion" mean that (1) the proximal end of the catheter has a cross section defined by a fixed curved surface, or (2) the proximal end of the catheter is an elongated tube that has a proximal portion that is circular in cross section? FN5
FN5. For each issue to be decided by the court, Plaintiff's proposed claim interpretation is listed as (1) and Defendants' proposed claim interpretation is listed as (2).

Answer: "proximal cylindrical portion" refers to a tube that is either circular or oval in cross section.
[1] Plaintiff proposes that the court construe the term to mean that the proximal end of the catheter has a cross-section defined by a fixed curved surface (which would encompass shapes other than circles). (Pl.'s Brief at 18.) Defendants, on the other hand, construe the term to mean an elongated tube that has a proximal portion that is circular in cross-section. (Defs.' Brief at 22.)

Both parties focus on the language "semicircular or 'D' shaped," but form opposite conclusions regarding the meaning of these terms. Plaintiff contends that the specification provides support for embodiments comprised of lumens either of a semicircular cross section or of an alternative D shaped cross section. (Plaintiff's Reply to Defendants' Response Brief Re. Claim Construction, hereinafter "Pl.'s Reply" at 10.) Plaintiff recognizes that if the lumens were semicircular, the cylindrical portion would be circular, but argues that if the D shaped lumens are used, the cylindrical portion would therefore be oval in shape. (*Markman* Hearing Transcript, hereinafter "Tr." 100.) FN6 Defendants counter that "D shaped" and "semicircular" are to be read as synonyms, and therefore only support a circular proximal cylindrical portion. (Tr. 111.) Alternatively, Defendants claim that the inside shape of the lumens does not necessarily define the outside shape of the cylindrical portion. (*Id*.) Therefore, in theory, the lumens could be something other than semicircles, but the outside cylinder would still be a circular tube.

FN6. The court interprets this to mean that the shape of the lumens dictates the shape of the cylindrical portion, which makes logical sense. However, Plaintiff conceded that this need not always be the case. (Tr. 117.) For example, the cylindrical portion could be larger in diameter than the two lumens inside it, and thus a different shape than the one formed by the two lumens.

Even though the parties agree that the shape of the lumens does not necessarily define the shape of the outside cylindrical portion, the court notes that the specification, which describes the preferred embodiment of the patent, does suggest that the shape of the lumens determines the shape of the cylinder. The specification describes the "internal planar axial divider or septum" as "defining the return lumen and inlet lumen *within the interior of the hollow tube*." ('155 patent, Ex. A to Second Amended Complaint, Col. 3, lines 21-25) (emphasis added.) The specification also states that the divider "bisect[s] the tube into the two lumens." (Id., Col. 3, lines 25-27.) While "tube" may not refer to the "cylindrical portion" (the tube could be inside of the cylindrical portion), the description of the patent's preferred embodiment, from which the language is quoted, does not refer to the cylindrical portion at all. This indicates that the term "tube" is used as a synonym for the cylindrical portion in the description, and suggests that although the lumens need not always define the shape of the cylinder, in the case of the preferred embodiment, they do. Therefore, assuming that D shaped means something other than semicircular, Defendants' interpretation is overly narrow.

Further evidence in favor of Plaintiff's interpretation comes from claim 7, which describes an alternate embodiment of the invention. Claim 7 depicts the septum inside the proximal cylindrical portion as "planar ... and dividing the interior of said proximal cylindrical portion into first and second lumens." (Id., Col. 4, lines 67-68, Col. 5, lines 1-2.) Claim 8, which modifies claim 7, claims "[t]he double lumen catheter as claimed in claim 7, wherein the first and second lumens and said distal end portion are each 'D' shaped in cross section." (Id., Col. 5, lines 23-25.) It is not disputed that the term "cylindrical" encompasses a circular tube. But if it truly encompassed *only* a circular tube, as Defendants contend, and if "D shaped" were equivalent to semicircular, then it would have been superfluous for claim 8 to specify D shaped lumens. The court concludes that claim 8 describes an alternative embodiment of the patent, one in which the lumens are D shaped but not necessarily semicircular. And this makes sense from a practical point of view: the letter "D" can be represented in various ways and does not obviously equate with a semicircle. For these reasons the court adopts Plaintiff's proposed claim interpretation; "proximal cylindrical portion" means that the proximal end of the catheter has a cross-section defined by a fixed curved surface, which can be either a circle or an oval shape.

2. Language in dispute: "non-tapered distal end portion" FN7

FN7. Defendants define the term "non-conical" as well as "non-tapered," however, Plaintiff does not address the meaning of "non-conical." The court therefore assumes that term is not disputed and adopts Defendants' proposed construction, interpreting "non-conical" to mean that the distal end portion does not have a conical shape anywhere along its length.

Does "non-tapered distal end portion" mean (1) a distal end portion that has a perimeter wall that does not become progressively smaller toward the distal end reducing the cross section area of the distal end portion, or does it more generally mean (2) a distal end portion that is not tapered anywhere along its length? Answer: the court interprets the language to mean that the distal end of the catheter does not taper anywhere along its length.

[2] The parties agree that the distal end portion of the catheter refers to the section of the first lumen (the return lumen) that extends from the second opening described in the claim language to the end of the

catheter and is the end that is inserted into a patient. (Defs.' Brief at 25, Pl.'s Reply at 11.) The parties also agree that "tapering" refers to a shrinking of the cross section area of the distal end. Plaintiff disputes that the claim language requires that the distal end portion must remain uniform in cross section throughout its length, however, contending instead that the claim only dictates that the perimeter wall does not become progressively smaller as it nears the distal end. Defendants argue on the other hand that "non-tapered" means that the distal end portion is not tapered anywhere along its length.

On this issue, the court agrees with Defendants that the term "non-tapered" means that the distal end's cross section area does not change throughout its length. Claim 1 describes the distal end portion as "having a cross-sectional area smaller than the cross-sectional area of said proximal cylindrical portion." The use of the singular word "a" indicates only one cross-sectional area. The language from the specification indicating that "[b]oth lumens ... are straight along their entire lengths" lends more support to the conclusion that the width of the distal end does not change anywhere along its length.

Plaintiff argues that the prosecution history supports his interpretation, and explains that "non-tapered" was added to distinguish his invention from that of a double lumen catheter designed by Dr. Geoffrey S. Martin, in which the cross section of the lumens "smoothly tapers to provide a circular cross-section at the tip." (Tr. 127, U.S. Patent No. 4,451,252, col. 4, lines 37-39, Ex. H to Pl.'s Brief.) Plaintiff contends that because he specifically represented to the Patent Office that he included the word "non-tapered" to distinguish his invention from Martin's, the court should only exclude Martin's description of a tapered end to the '155 patent. (Tr. 128.) The court, however, finds the Defendants' argument more convincing. As Defendants point out, there is nothing in the claim language that indicates Plaintiff was limiting his affirmative disclaimer to only the taper shown in Martin's patent, (Tr. 133), nor do the words chosen lend themselves to the very restrictive construction Plaintiff wants to give them. Plaintiff suggests that the patent language would have the meaning Defendant ascribes to it only if it stated that the distal end was to be "nonconical and nontapered *anywhere along its length*." (Tr. 143) (emphasis added.) The court believes the additional language Plaintiff urges as necessary would instead be superfluous. The logical conclusion one makes upon reading the negative claim language is that it means the distal end shall not be tapered anywhere along its length.

Plaintiff also argues that because the words "substantially uniform" are used in claim 7 to describe the cross section of the tube containing the distal end portion, then by implication "non-tapered" must mean something different from "uniform." The court is not persuaded by this argument. As Defendants point out, the terms are used to describe two different things. "Substantially uniform" modifies the internal cross section of the tube. "Non-tapered," on the other hand, describes the outside appearance or shape of the distal end. If anything, the terms complement each other: if the distal end did taper, then the cross section of the tube would probably not be substantially uniform. For these reasons the court construes the term to mean that the distal end of the catheter does not taper anywhere along its length.

3. Language in dispute: "blunt distal end"

Does "blunt distal end" mean (1) an end that is not sharp so that it does not cause trauma or get caught in the walls of a vessel into which the catheter is inserted, or (2) that the distal end of the tube is cut or formed in a direction generally perpendicular to the longitudinal axis of the catheter?
Answer: the court interprets "blunt distal end" to mean that the distal end of the catheter is not sharp, but it need not be perpendicular to the longitudinal axis of the catheter.

[3] The final disputed term in claim 1 is over the description of the tip of the distal end, which the claim language describes as "blunt ." Plaintiff contends that blunt means an end that is not sharp so that it does not cause trauma or get caught in the walls of a vessel into which the catheter is inserted. Defendants argue that the term blunt means that "the distal end of the tube is cut or formed in a direction generally perpendicular to the longitudinal axis of the catheter." Defendants point to the specification language which states that "the

[catheter] tube terminates with a blunt distal end which is normal to the axis of the catheter." (Col. 3, lines 58-60.) Plaintiff argues that the claim is not limited to the specific embodiment described in the specification or in a drawing. Rather, Plaintiff's focus is on the explanation for which the term blunt was used in the claim, which Plaintiff explains was to ensure that the distal end would not be so sharp as to cause harm to the patient upon insertion.

The court agrees with Plaintiff that blunt is a general term and in this context indicates simply that the distal end is not sharp. Without the need to resort to a dictionary, the meaning seems plain: most knives, for example, do not have flat or straight edges, yet the adjective "blunt" is commonly used to describe knives. There is nothing in the claim language itself that indicates the distal end must be perpendicular to the axis of the lumens, and the specification clearly describes the preferred, but not the only, embodiment of the patent.

B. Claim 3

Claim 3 states as follows, with the element to be construed in bold:

The double lumen catheter as claimed in claim 2, wherein said second opening is defined by a bevel arising at its proximal end on the outer periphery of said cylindrical portion opposite the second lumen and terminating at its distal end on the planar divider.

1. Language in dispute: "bevel"

Does "bevel" mean (1) an angle that one surface or line makes with another when they are not at right angles (i.e. not 90 degrees), or (2) a visibly sloping, slanted angle?
Answer: a bevel means a visibly sloping, slanted angle.

[4] The court agrees with Defendants that in order for the second opening to be deemed "beveled," the slant must be visible to the human eye. Plaintiff notes that the specification does not refer to a visible slant, but provides that "the bevel is formed by simply cutting the desired angle of bevel through the wall of that half of the tube that forms the lumen ..." (Col. 4, lines 5-9.) Thus, Plaintiff urges, any non-90 degree angle might qualify. If taken literally, the court notes the language appears to contemplate selection of an angle so closely resembling 90 degrees, for example 89 degrees, that it would be indistinguishable from 90 degrees to the naked eye. Plaintiff argued during the *Markman* hearing that if the court adopts Defendants' proposed construction, this will make the term more vague, rather than clarify the issue. The court concludes to the contrary, that if a jury is instructed that the bevel as contemplated by the patent means visibly beveled, jurors should be capable of determining whether, to the naked eye, the accused patents infringe this particular claim.

II. The '561 Patent

The elements of the '561 patent requiring construction by the court are found in Claims 34, 38 and 42.FN8 As the court noted earlier, this case does not represent the first time Dr. Mahurkar has sued for patent infringement. In the late 1990's, Mahurkar sued Arrow International, Inc. for, among other things, infringing the '561 patent. Mahurkar v. Arrow Int'l, Inc., 160 F.Supp.2d 927 (N.D.Ill.2001). Judge Denlow construed the disputed '561 patent claims, some of which overlap with disputed claims in this suit. Id. The court notes that while it is not bound by Judge Denlow's construction of certain '561 patent claims, the court welcomes the guidance provided by his well-reasoned and thoughtful opinion.

FN8. While there are only three elements to construe with regard to the '561 patent, the terms appear in more than one claim. The court will focus on claim 34.

A. Claim 34

Claim 34 states as follows, with language to be construed in bold:

A dual-lumen catheter assembly comprising:

a dual lumen catheter, and connecting means attached to the proximal end of said catheter and forming a pair of internal passageways which communicate at one end thereof with the dual lumens in said catheter, said passageways curving back toward the distal end of said catheter so that forces exerted on said connecting means at the other ends of said passageways will tend to move said catheter in the same direction as FN9 said exerted forces.

FN9. The printed patent reads "in a direction opposite that of" said exerted forces, which was apparently an error. On the day the patent was issued, Plaintiff corrected this error by submitting a Certificate of Correction that changed "a direction opposite that of" to "the same direction as" in each place the phrase appears. (Ex. C to Pl.'s Brief.)

('561 Patent, Ex. B to Pl.'s Brief, Col. 11, lines 14-23.)

1. Language in dispute: "catheter"

Does "catheter" mean (1) only that portion of the catheter assembly intended to be inserted into the patient's vein, or (2) a tubular device for withdrawing fluids from, or introducing fluids into, a cavity of the body, such as a blood vessel?
Answer: "catheter" means a tubular device for withdrawing fluids from, or introducing fluids into, a cavity of the body, such as a blood vessel.

[5] Claim 34 begins with the components of a dual-lumen catheter assembly: a catheter, connecting means, and a pair of internal curving passageways. As Judge Denlow noted, the claim language appears to support the construction proposed by Plaintiff because it says that a catheter assembly requires a catheter and other items. Judge Denlow concluded therefore that the term catheter logically means only that portion of the assembly intended to be placed into the body and not the entire apparatus which contains other parts as described by the claim. Arrow Int'l, 160 F.Supp.2d at 946.

This court respectfully disagrees with Judge Denlow's conclusion on this issue. Defendants' proposed construction does not contradict the claim language and, in this court's view, makes more logical sense. If Plaintiff were correct that the term catheter only refers to the portion of the tube intended to be inserted into the patient, then the meaning of that term would differ from patient to patient, even if the same catheter assembly is used. As Defendants point out, some patients are smaller than others, and the length of the tube that is inserted into the body will by necessity differ from one patient to another. Plaintiff does not dispute this; he argues that it is nevertheless acceptable to define a term in reference to its particular usage in different contexts. While this may be true, the court does not find anything in the claim language or the specification indicating that the term should be construed so fluidly.

Defendants point out that the description of the invention contemplates a catheter extending from the distal to the proximal end. (Defs.' Brief at 14.) Specifically, Defendants point out that claims 34, 38 and 42 recite, respectively, a catheter assembly and blood treatment system, each comprising a "dual-lumen catheter," and "connecting means attached to the proximal end of said catheter [with passageways curving back toward] the distal end of said catheter." Claims 35 and 39 recite a "connecting means [that] comprises a connector fastened to the proximal end of the catheter." ('561 Patent, Ex. B to Second Amended Complaint, Col. 11, lines 24-32 and 61-65 and Col. 12, lines 1-4; Defs.' Brief at 13-14.) They argue that if the location of the proximal end of the catheter changes based on each individual patient, then the location of the connecting

means would change as well, since it is described in claim 34 as attached to the proximal end. (Id., Col. 11, line 15.) The court agrees that such a fluid definition is hard to reconcile with the specific language in the claim that the proximal end is attached to a connecting means. If Plaintiff's proposed construction were adopted, then the term "connecting means" would likely have to include a portion of the catheter tube, perhaps a significant portion, depending on the size of the patient.

Plaintiff points out that the background of the invention section describes that catheters are "typically allowed to remain in patients for several weeks, and sometimes for several months." (Id., Col. 1, lines 32-34.) Additionally, the background section explains the potential problems with catheters including the potential for them to become dislodged or cause pain or discomfort in patients because of continual movement within the vein. (Id., Col. 2, lines 1-5.) Plaintiff argues that these statements indicate that the catheter is something which is wholly inside of the patient. The court notes, however, several devices which are commonly described as being inserted inside a person, but a portion of which almost always remain outside of the person's body. Thermometers, otoscopes, and intravenous devices are inserted into persons, often with portions remaining external to the body.

Plaintiff points out that the summary of the invention states that the primary object of the invention is "to provide an improved dual-lumen catheter-connecting system which permits the catheter to remain relatively stable during the entire time the catheter remains inserted in the patient." (Col. 2, lines 34-38.) Once again, the court is not convinced this supports his proposed definition of the claim term. The fact that a portion of the catheter protrudes from the patient's body would not defeat Plaintiff's goal of ensuring stability when a portion of a catheter has been inserted into the patient.

Finally, the court believes Defendants' proposed definition makes the most logical sense. Imagine an embodiment of the '561 patent on display for examination by health care providers. How would a manufacturer's representative describe the product to a potential user? Where would she say the proximal end of the catheter is? How would she describe the tube that is inserted into the patient? It simply makes more sense to describe the catheter as extending from the distal end, the end that is first inserted into the patient's body, to the proximal end, where the connecting means attaches the catheter to the remainder of the apparatus. For these reasons the court adopts Defendants' proposed claim term.

2. Language in dispute: "connecting means"

Does "connecting means" refer to (1) either a, a Y-shaped connector connected to the catheter at one end and fastened to bent extension tubes that curve back toward the distal end of the catheter, and equivalents thereof; or b, a unitary connecting member connected to the catheter at one end and forming two internal U-shaped passageways, each of which is in communication with one of the lumens of the catheter, and equivalents thereof, or (2) a connector attached to the tubular, flexible instrument at its proximal end, the connector having attached thereto a pair of passageways, each passageway being in fluid communication with one of the two lumens of the catheter tube and curving back toward the distal end of the catheter. Answer: the disclosed structures corresponding to the "connecting means" include a Y-connector fastened to bent extension tubes and a unitary connecting member.

[6] "Connecting means" is a means-plus-function clause. Pursuant to 35 U.S.C. s. 112, para. 6, a claim element "may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof." The claim elements written in this format are construed to cover the corresponding structures described in the specification, and equivalents thereof. *Id*. A court's task in construing a means-plus-function element is twofold. First, the court identifies the function portion of the element and construes any disputed terms in the function language. Second, the court identifies the corresponding structures disclosed in the specification linked or associated with that function. Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1308 (Fed.Cir.1998). To determine the claimed function, the court must construe the specific terms in the claim. Chiuminatta Concrete Concepts,

145 F.3d at 1308. A means-plus-function claim is indefinite, and thus invalid, if the specification fails to disclose an adequate structure corresponding to the means limitation. Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352, 1360-61 (Fed.Cir.2000). Not all of the aspects of the structure disclosed in the specification should be included in the court's claim construction. Details of the disclosed structure that are "unrelated to the recited function" are not "corresponding structure," and do not limit the scope of the means clause. Chiuminatta Concrete Concepts, 145 F.3d at 1308.

Here, the function set forth in the claim is attaching the proximal end of the catheter to the portion of the assembly which forms a pair of internal passageways which communicate at one end thereof with the dual lumens in the catheter. The specification discloses two different corresponding structures which are linked to the function and which tend to support Plaintiff's proposed interpretation. First, the specification discloses a Y-shaped connector or hub connected to two extension tubes that curve back toward the distal end of the catheter. ('561 Patent, Ex. B to Second Amended Complaint, Col. 5, lines 10-14.) Second, the specification discloses using a "unitary connecting member" instead of the hub and two extension tubes:

... the curved passageways provided by [the] extension tubes may instead be formed by a unitary connecting member fastened to the proximal end of the dual-lumen catheter. More specifically, the unitary connecting member may form two internal U-shaped passageways, each of which is in communication with one of the lumens of the catheter.

(Id., Col. 8, lines 14-22.)

Thus, the "connecting means" may be: (1) a Y-shaped connector connected to extension tubes that curve back toward the distal end of the catheter, and equivalents thereof; and (2) a unitary connecting member forming two internal U-shaped passageways, each of which is in communication with one of the lumens of the catheter, and equivalents thereof. Other details of the specific structures mentioned in the specification such as the size of the hub and the materials used to make the extension tubes, are details "unrelated to the recited function" and therefore do not limit the claim. Chiuminatta Concrete, 145 F.3d at 1308.

Based on its prior interpretation of "catheter," the court notes that the proximal end of the catheter tube is straight and is attached either to the Y-shaped connector or the unitary connecting member, which can be curved. While Plaintiff argues it would be superfluous to have a "connector" between the unitary connecting member and the catheter, the court concludes that the connecting means must be something physically separate from the catheter. The proximal end of the catheter is therefore the location where the two pieces of the catheter assembly meet. Plaintiff argues that this requirement would render claim 35 superfluous, which calls for a "connector" between the connecting means and the catheter, but the court is not persuaded. (*Id.,* Col. 11, lines 24-26.) Neither party has defined "connector;" therefore the court assumes there are other ways of attaching the connecting means to the end of the catheter, and claim 35 is not superfluous. Rather, it describes one method of attaching the catheter to the rest of the assembly. Plaintiff's proposed claim interpretation of connecting means is therefore adopted, and the court notes once more that it interprets the claim language to mean that the catheter itself must be visibly attached to a distinct portion, the connecting means, and the catheter tube must be straight, not curved.

CONCLUSION

The parties are directed to proceed in conformity with this court's claim interpretations.

N.D.Ill.,2003.
Mahurkar v. C.R. Bard, Inc.

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