United States District Court,
S.D. New York.

Thierry POURCHEZ and Bard Access Systems, Inc,
Plaintiffs.
v.
DIATEK, INC. and Arrow International, Inc,
Defendants.

No. 03 CIV.0972 WHP

May 8, 2003.

Owner of patent for split-tip catheter, and its licensee, sued competitor for infringement. Construing claims, the District Court, Pauley, J., held that: (1) requirement that catheter's distal ends had to extend "substantially parallel" to its longitudinal axis meant that ends had to be same as or very close to parallel; (2) "rest position" was position in which catheter was motionless prior to being removed from patient; and (3) "flexible" meant that ends had to be capable of being bent or flexed.

Claims construed.

6,001,079. Construed.

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Kenneth M. Bernstein, Kenneth P. George, Amster, Rothstein & Ebenstein, New York City, for Defendants.

MEMORANDUM AND ORDER

PAULEY**, District Judge.**

On December 14, 1999, the United States Patent and Trademark Office issued United States Patent No. 6,001,079 (the " '079 Patent"), titled "Multilumen Catheter, Particularly For Hemodialysis," to Dr. Thierry Pourchez ("Pourchez"). FN1 Bard Access Systems, Inc. ("Bard") is the exclusive licensee of the '079 Patent. Bard and Pourchez filed this patent infringement action on February 11, 2003, claiming that Diatek, Inc. ("Diatek") and Arrow International, Inc. ("Arrow") are selling infringing catheters under the trade names "Cannon Catheter" or "Cannon-Cath." On April 16, 2003, this Court conducted a *Markman* hearing to construe three disputed claim terms from the '079 Patent: (1) "substantially parallel;" (2) "rest position;" and (3) "flexible." After considering the parties' claim construction briefs and their *Markman* presentations, the Court construes the three claims as set forth below.

FN1. A copy of the '079 Patent is attached in the Appendix to this Memorandum and Order.

BACKGROUND

Pourchez, a French citizen, is the inventor and owner of the '079 Patent. (Compl.para.para. 1, 8.) Bard, a Utah corporation with its principal place of business in Salt Lake City, Utah, is engaged in the manufacture and sale of medical products. (Compl.para. 2.) Bard is an exclusive licensee of the '079 Patent, and has the exclusive right to bring actions for its infringement. (Compl.para. 9.) Diatek, a North Carolina corporation with its principal place of business in Winston-Salem, North Carolina, is also engaged in the manufacture and sale of medical products. (Compl.para. 3.) Arrow, a Pennsylvania corporation with its principal place of business in Reading, Pennsylvania, acquired substantially all of the assets of Diatek on November 25, 2002. (Compl.para. 4.)

As the exclusive licensee of Pourchez's invention, Bard developed a "split-tip" catheter according to the '079 Patent. (Compl. para. 9.) Dubbed the "Hemo-Split" catheter, Bard's product is currently before the FDA for approval. (Compl.para. 9.) Defendants manufacture and sell a "split-tip" catheter of their own, the "Cannon Catheter" or "Cannon Cath." (Compl.para. 10.) Plaintiffs allege that defendants' "Cannon Catheter" or "Cannon-Cath" infringes on their rights under the '079 Patent. (Compl.para. 11.) Plaintiffs seek both injunctive and monetary relief for the alleged infringement.

DISCUSSION

I. *General Principles Of Claim Construction*

[1] "[A] patent must describe the exact scope of an invention and its manufacture," as defined by the claims. Markman v. Westview Instruments, Inc., 517 U.S. 370, 373, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). A basic patent action has two phases, "construing the patent and determining whether infringement occurred." Markman, 517 U.S. at 385, 116 S.Ct. 1384. The first phase, claim construction, "is a question of law, to be determined by the court, construing the letters-patent, and the description of the invention and specification of claim annexed to them." Markman, 517 U.S. at 385, 116 S.Ct. 1384. A district court's purpose is to determine "what the words in the claim mean." Markman, 517 U.S. at 374, 116 S.Ct. 1384.

[2] In undertaking claim construction, "[i]t is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., 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). Courts look first to the intrinsic evidence because it comprises the public record, and public policy mandates that competitors be able to ascertain the metes and bounds of patent claims by reviewing the public record. *See* Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed.Cir.2002); Vitronics, 90 F.3d at 1583; Caterpillar Tractor Co. v. Berco, S.P.A., 714 F.2d 1110, 1115 n. 2 (Fed.Cir.1983).

[3] [4] [5] In reviewing the intrinsic evidence to construe disputed claim terms, a court's "analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.' " Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed.Cir.2001) (quoting 35 U.S.C. s. 112); *accord* Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 326 F.3d 1215, 1220 (Fed.Cir.2003). Further, "a court must presume that the terms in the claim mean what they

say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms." Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed.Cir.1999); *accord* Brookhill-Wilk, 326 F.3d at 1220; Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed.Cir.2002). Dictionaries hold a "special place" in this type of analysis, and although extrinsic to the patent are considered with intrinsic evidence to determine the ordinary meaning of claim terms. Texas Digital, 308 F.3d at 1202 ("categorizing [dictionaries] as 'extrinsic evidence' or even a 'special form of extrinsic evidence' is misplaced"); *accord* Teleflex, 299 F.3d at 1325; CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002).

[6] An exception to this "plain meaning" approach to claim construction arises where the patentee assigns a novel or special meaning to a term. *See, e.g.,* Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358, 1366 (Fed.Cir.2001). However, while "a patentee is free to be his or her own lexicographer and thus may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings," the patentee must clearly state the special definition of the term in the patent specification or history. Vitronics, 90 F.3d at 1582; *accord* Texas Digital, 308 F.3d at 1204; Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed.Cir.1996). The '079 Patent does not evince any effort by Pourchez to act as his own lexicographer with respect to the three disputed claim terms. Therefore, the disputed terms will be construed according to their "ordinary and accustomed meaning." Johnson Worldwide, 175 F.3d at 989.

[7] [8] The specification is an important part of the intrinsic evidence, and claims are to be construed in light of the specification of which they are a part. *See, e.g.,* ATD Corp. v. Lydall, Inc., 159 F.3d 534, 540 (Fed.Cir.1998). However, while a claim must be read in light of its specification, particular embodiments or examples appearing in the specification may not be read to limit the claim. *See* Johnson Worldwide, 175 F.3d at 992 ("[M]ere inferences drawn from the description of an embodiment of the invention cannot limit claim terms ...."); Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1572 (Fed.Cir.1988) ("[P]articular embodiments and examples appearing in the specification will not generally be read into the claims."); *accord* Texas Digital, 308 F.3d at 1204; Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., 261 F.3d 1329, 1338-39 (Fed.Cir.2001); Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1277 (Fed.Cir.1995); Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed.Cir.1988). Further, functional limitations expressed in the specification but not in the claim may not be read into the claim. *See* Interactive Gift Express, 256 F.3d at 1331 ("[C]are must be taken to avoid reading 'limitations appearing in the specification ... into [the] claims.' ") (quoting Intervet Am., Inc. v. Kee-Vet Lab., Inc., 887 F.2d 1050, 1053 (Fed.Cir.1989)); Transmatic, 53 F.3d at 1278 ("[T]he district court erred by importing unnecessary functional limitations into the claim ...."); Ecolab, 264 F.3d at 1367 ("Where the function is not recited in the claim itself by the patentee, we do not import such a limitation."); Sjolund v. Musland, 847 F.2d 1573, 1581 (Fed.Cir.1988) ("[W]hile it is true that claims are to be interpreted *in light* of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims ....").

Finally, courts may consider a patent's prosecution history when reviewing the intrinsicevidence. *See* Vitronics, 90 F.3d at 1582. This Court reviewed the prosecution history submitted by the parties. (Exhibit B to Defendants' Memorandum On Claim Construction ("Def.Mem.").) There is nothing in that history that elucidates the three disputed terms.

[9] Courts may rely on extrinsic evidence only in "instances in which intrinsic evidence is insufficient to enable the court to determine the meaning of the asserted claims." Vitronics, 90 F.3d at 1584; *see also* Interactive Gift Express, 256 F.3d at 1332 ("Relying on extrinsic evidence to construe a claim is 'proper only

when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence.' ") (quoting Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed.Cir.1997)). In this case, the intrinsic evidence is sufficient to determine the meaning of the disputed terms, and the resulting claim language is not genuinely ambiguous. Therefore, this Court puts extrinsic evidence to the side in reaching its determinations.

II. ***THE*** '079 PATENT

The '079 Patent protects a multilumen catheter used for the circulation of fluid between a patient's body and a means for extracting the fluid. (Col. 1, lines 7-10.) FN2 While the catheter is intended primarily for hemodialysis, it can be used for any type of fluid perfusing or extracting. (Col. 1, lines 11-12.) The catheter consists of a distal end, intended to be placed inside a patient's body cavity, and a proximal end, which is intended to be connected to a means for circulating fluid. (Col. 3, lines 5-11.) The relevant language of the claim reads:

FN2. Citations to "Col. [ ], line [ ]" refer to the column and line markers, respectively, contained in the '079 Patent.

said distal end of said catheter having a dividing point (12) located at a fixed predetermined distance D1 from said proximal end (6), and having at least two distinct elongated end portions (13, 14) extending from said dividing point, said dividing point being nearer to said distal end than to said proximal end,
wherein said at least two end portions, in at least one rest position of the catheter, extend substantially parallel to a longitudinal axis of said catheter, each over a predetermined length (L1, L2) measurable between a free end of said distal end (13A, 14A) and the dividing point (12),

wherein said at least two end portions are each made of flexible material so as to be flexible at least under the effect of a lateral action due to the displacement of a fluid

(Col. 3, line 12-Col. 4, line 4.)
The innovation of the '079 Patent, as detailed in the specification, is that:

These technical characteristics, when the distal end of the catheter is placed on the axis of a fluid flow such as a bodily fluid flow, allow the end portions, due to their flexibility and independence, to act like a sail set parallel to the wind and thus are not practically subject to obstruction.

In effect, the agitation and flexion of these end portions considerably reduces the risk of clogging substances being deposited on the surfaces of the perfusing and/or extracting channels with which these end portions are equipped.

(Col. 2, lines 46-55.)

III. ***Disputed Terms***

A. " ***Substantially Parallel*** **"**

[10] The first disputed term of the '079 Patent is "substantially parallel." The '079 Patent teaches that the distal ends of the catheter must "extend substantially parallel to a longitudinal axis of said catheter." (Col. 3,

lines 19-20.) Defendants argue that "substantially parallel" means "the same as or very close to parallel." (Def. Mem. at 10.) Plaintiffs argue that defendants' proposed construction is "completely abstract" and "vague," and that "substantially parallel" must be construed in light of functional and exemplary language contained in the specification. (Plaintiffs' Claim Construction Memorandum ("Pl.Mem."), at 10-11.) Plaintiffs argue that the proper construction of "substantially parallel" in the '079 Patent is "that the two end portions, or tips, when disposed within a vascular channel of the body, are sufficiently close to parallel, such that, when the catheter is placed within a body lumen or cavity, the end portions essentially conform to the direction of fluid flow ('like a sail parallel to the wind')." (Pl. Mem. at 18.)

As there is no clearly manifested intent by the patentee to act as his own lexicographer, this Court must look to the plain meaning of the phrase "substantially parallel." Johnson Worldwide, 175 F.3d at 989. In examining that term, plaintiffs' proposed construction violates the plain meaning principle. Further, on a closer review of the intrinsic evidence, it is clear that defendants' proposed construction is appropriate.

"Substantially" is defined as "largely but not wholly that which is specified." *Webster's Ninth New Collegiate Dictionary* 1176 (9th ed.1983); *accord Shorter Oxford English Dictionary* 3091 (5th ed.2002) ("essentially, intrinsically ... actually, really"). It is clear that defendants' proposed construction of "substantially parallel" comports much more closely with the dictionary definition of "substantially" than does plaintiffs' proposal.

[11] Further, the patentee's use of the terms "parallel" and "substantially parallel" interchangeably bolsters the conclusion that the patentee intended the phrase to mean "the same as or very close to parallel." The Abstract, which appears on the first page of the '079 Patent, reads "wherein said end portions, in a rest position of the catheter, extend parallel to the longitudinal axis thereof." When read in conjunction with the corresponding language in the specification and the claim,FN3 the patentee's failure to include the modifier "substantially" in front of "parallel" in the Abstract is probative of an intent to use the terms interchangeably. *See* Amhil Enters. Ltd. v. Wawa, Inc., 81 F.3d 1554, 1559, 1562 (Fed.Cir.1996) (patentee's use of phrases "substantially vertical" and "vertical" interchangeably in the specification and during prosecution of patent left the "reader with the impression that 'substantially vertical' and 'vertical' mean essentially the same thing"). Plaintiffs' suggestion that it would be error to consider language in the Abstract when construing a claim term (Transcript of *Markman* hearing, dated April 16, 2003 ("Tr.") at 52) is incorrect as a matter of law. *See* Hill-Rom Co., Inc. v. Kinetic Concepts, Inc., 209 F.3d 1337, 1341 n. 1 (Fed.Cir.2000) (abstract is part of the intrinsic evidence of a patent, and courts "frequently look[ ] to the abstract to determine the scope of the invention"). Accordingly, the '079 Patent's use of the phrases "parallel" and "substantiallyparallel" interchangeably in materially identical contexts militates in favor of construing the term as defendants have proposed, namely "the same as or very close to parallel."

FN3. "Wherein said at least two end portions, in at least one rest position of the catheter, extend *substantially parallel* to a longitudinal axis of said catheter ...." (Col. 3, lines 18-23 (emphasis added) (claim)); "in at least one rest position of the catheter, extend substantially parallel to the longitudinal axis of this catheter ...." (Col. 2, lines 36-38 (emphasis added) (specification).)

In contrast, plaintiffs' proposed construction of "substantially parallel" impermissibly attempts to import limitations from the specification into the claim, and is undermined by the language of the claim itself. The description in the specification of the distal ends behaving "like a sail set parallel to the wind" is merely a trope, and such examples or representations may not be read to limit a claim. *See* Transmatic, 53 F.3d at

1277; Constant, 848 F.2d at 1572; Specialty Composites, 845 F.2d at 987. In addition, plaintiffs' proposed construction of "substantially parallel" seeks to import functional limitations from the specification that do not appear in the claim, such as "when the catheter is placed within a body lumen or cavity, the end portions essentially conform to the direction of fluid flow." FN4 (Pl. Mem. at 18.) This is not permissible. *See* Ecolab, 264 F.3d at 1367; Advanced Cardiovascular Sys., 261 F.3d at 1338-39; Transmatic, 53 F.3d at 1278.

FN4. In fact, one of the functional limitations that plaintiffs seek to impose on the "substantially parallel" claim-the requirement that the catheter be "disposed within a vascular channel of the body"-not only does not appear in the claim, but is nowhere in the '079 Patent.

Finally, plaintiffs' proposed construction is undermined by the language of the claim itself with respect to the proper reference point by which to determine whether the distal ends are parallel. Plaintiffs' proposed construction advocates determining the parallelism of the distal ends in relation to the "direction of fluid flow." FN5 The claim itself, however, teaches that a determination of whether the distal ends are parallel must be made in relation to the longitudinal axis of the catheter, and makes no mention of fluid flow.FN6 Thus, plaintiffs' proposed construction of "substantially parallel" is improper, and cannot be accepted by this Court.

FN5. In addition, the Court notes that the "direction of fluid flow" language in the specification does not relate to a determination of whether the distal ends are "substantially parallel" in at least one rest position, but instead refers to the catheter's anti-clogging characteristics. (*Compare* Col. 2, lines 48-49 *with, e.g.,* Col. 2, lines 36-37.)

FN6. In addressing this issue during the *Markman* hearing, plaintiffs again resorted to importing functional limitations into the claim in order to rescue their construction of "substantially parallel." To define the term, plaintiffs suggested that "when the catheter is then implanted in the body cavity that's referred to in the patent, it will be implanted in the direction of that cavity along that axis. So the axis of the catheter is going to match up with the axis of the fluid flow." (Tr. at 32.)

Contrary to plaintiffs' contentions, nothing in Fig. 1 of the '079 Patent, depicting the invention, or in the prosecution history is inconsistent with defendants' proposed construction. (Pl. Mem. at 12-14.) The construction of "substantially parallel" as "the same as or very close to parallel" clearly contemplates the slight deviation from strict parallelism necessitated by the "physical separat[ion]" of the distal ends at the "fixed dividing po[i]nt." (Def. Mem. Ex. B at Arrow 80.) The same analysis applies to the embodiment of the invention depicted in Fig. 1, which shows a slight deviation from parallel at the dividing point, represented at 12 in Fig. 1, with a return to almost strict parallelism as the figure approaches the tips of the distal ends of the catheter, represented at 13A and 14A in Fig. 1. (Col. 3, lines 23-25; Fig. 1). The construction "the same as or very close to parallel," therefore, is not inconsistentwith either the prosecution history or the sole embodiment of the invention contained in the '079 Patent. *Cf.* Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1355 (Fed.Cir.1998) ("A patent claim should be construed to encompass at least one disclosed embodiment in the written description portion of the patent specification."); ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed.Cir.1984). ("[C]laims should be so construed, if possible, as to sustain their validity.").

[12] Finally, this Court rejects plaintiffs' contention that defendants' proposed construction of "substantially parallel" is too vague and abstract to provide meaningful guidance. (Pl. Mem. at 10-11; Tr. at 60-61 (describing defendants' proposed construction as an "Olympian abstraction").) Courts need not construe claims to be objectively verifiable in order for a construction to be valid, especially when the claim incorporates the term "substantially." *See* Ecolab, 264 F.3d at 1367 ("[T]he term 'substantially' is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter.' ") (quoting Pall Corp. v. Micron Seps., 66 F.3d 1211, 1217 (Fed.Cir.1995)); Mickowski v. Visi-Trak Corp., 36 F.Supp.2d 171, 178 (S.D.N.Y.1999) ("[T]he term 'substantially' has been included merely to bridge the gap between the abstract description of a method and its practical application in the real world.") (*vacated, appeal reinstated by* 247 B.R. 236 (Bankr.N.D.Ohio 2000)). Contrary to plaintiffs' contention during the *Markman* hearing that defendants' citations are "all over the map and quite inconsistent in terms of how close to parallel something is supposed to be" (Tr. at 40), this Court notes that other courts construing "substantially" in similar contexts have reached nearly identical results. *See, e.g.,* Ecolab, 264 F.3d at 1367-69 (holding that "substantially uniform" should be construed as "largely but not wholly in the same form"); LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1354 (Fed.Cir.2001) (en banc) ("[T]he claim language supports the correctness of the district court's interpretation of 'substantially completely wetted' as '[l]argely, but not necessarily wholly, surrounded by resin.' "); Amhil Enters., 81 F.3d at 1562 (construing "substantially vertical face" as "the same as or very close to 'vertical face' "). Accordingly, this Court construes "substantially parallel" as "the same as or very close to parallel."

B. " *Rest Position* "

[13] The second term in dispute is "rest position." The '079 Patent teaches that the proper configuration in which to determine whether the distal ends are substantially parallel to the longitudinal axis of the catheter is "in at least one rest position of the catheter." (Col. 3, lines 19-20.) Defendants argue that the term "rest position" should be construed as "a position where the catheter is motionless." (Def. Mem. at 18) Defendants go on, however, to argue that this elusive "rest position" can "only occur when the catheter is outside of the patient's body," and is limited to the time period prior to insertion because after it is removed, "the catheter has no medical significance and it is discarded." (Def. Mem. at 18, 21.) Plaintiffs argue that the proper construction of "rest position" is "a position assumed by the catheter when it is not being used to circulate fluids." (Pl. Mem. at 18.) Both proposed constructions are flawed.

The plain meaning of "rest," as defined in the dictionary, is the "freedom from, cessation of, or absence of labour, exertion, or activity ... Absence, loss, or cessation of motion." *Shorter Oxford English Dictionary* 2552 (5th ed.2002); *accord The American Heritage Dictionary* 1486 (4th ed.2000) (defining "rest" as the "cessation of work, exertion, or activity .... Termination or absence of motion"). Again, upon a cursory review defendants' proposed construction-absent the proposed requirement that the catheter be outside a patient's body prior to insertion-more closely tracks the plain meaning of the term "rest."

Once again, plaintiffs' proposed construction improperly attempts to import limitations from the specification into the claim. *See* Ecolab, 264 F.3d at 1367; Transmatic, 53 F.3d at 1277-78. Plaintiffs' argument that the catheter is in a rest position at all times other than when it is "being used to circulate fluids" attempts to import from the specification the explanation that the "invention ... [is] used for the circulation of at least one fluid between a cavity of a patient's body and a means for circulating this fluid such as a fluid perfusing and/or extracting means." (Col. 1, lines 7-10.) This and similar language found elsewhere in the specification is not found in the claim with respect to the "rest position" of the catheter. In fact, the claim speaks about the catheter's proximal end being "adapted *to be connected* to a means (9) for

circulating fluid" (Col. 3, lines 11-12 (emphasis added)), suggesting that any active circulation of fluid is at a point in time after the "rest position" of the catheter is determined. (Col. 2, lines 26-29 ("As neither the circulating means 9 nor the elements 10, 11 for connecting to this means 9 *are subjects of the invention,* these elements 10, 11 and the means 9 are not represented in detail.") (emphasis added).)

Further, even when read in light of the specification, plaintiffs' proposed construction is improper. The specification of the '079 Patent teaches that the distal ends of the catheter move "like a sail parallel to the wind" when "placed on the axis of fluid flow" (Col. 2, line 48), and that the "agitation and flexion of these end portions considerably reduces the risk of clogging substances being deposited on the surfaces of the perfusing and/or extracting channels with which these end portions are equipped." (Col. 2, lines 52-55.) Plaintiffs admit that this "agitation and flexion" is the "essential function that makes [the catheter] inventive, that's important about it and solves the problems of the prior art ... [i]t is the essence of the invention" (Tr. at 34), and it is this constant "agitation and flexion" when placed on the axis of fluid flow that is antithetical to the plain meaning of the word "rest" as the absence of motion or labor.

Plaintiffs argue that the "agitation and flexion" of the distal ends caused by fluid flow is simply "passive" movement, and therefore not labor or work. (Pl. Mem. at 3-4.) Since the plain meaning of "rest" encompasses *both* the absence of motion and the absence of work, plaintiffs argue, their proposed construction is not contrary to the plain meaning of "rest." *See* Texas Digital, 308 F.3d at 1203 ("If more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings."); *see also* Brookhill-Wilk, 326 F.3d at 1221-22 (same). Plaintiffs' argument, however, is premised on too narrow a view of "work."

Reading the claim in light of the specification, it is clear that the catheter protected by the '079 Patent is not only working when it is actively exchanging fluid, but is also working to prevent obstruction when it undergoes the "agitation and flexion" that is the self-proclaimed "essence of the invention." (Tr. at 34-37.) *See Webster's Third New International Dictionary Of The English Language* 2634 (Unabr.1993) (defining "work" as "sustained physical or mental effort valued as it overcomes obstacles and achieves an objective or result"). In this case, the sustained effort is the "agitation and flexion" of the distal ends, the obstacle is the "risk of clogging substances being deposited on the surfaces of the perfusing and/or extracting channels," and the objective or result is that the catheter is "practically not subject to obstruction." (Col. 2, lines 47-55; *see also* Col. 1, lines 29-31 ("One object of the invention is to obtain a catheter having a risk of obstruction by clogging that is substantially reduced relative to the known catheters."); Tr. at 31 ("[T]he object of the invention ... is to make sure that this catheter doesn't clog up.").) Plaintiffs' artificial distinction between self-locomotion and "passive" movement is not supported in the claim or the specification. Moreover, it is inconsistent with plaintiffs' own proposed construction, as any "work" done by the catheter when it is "circulating fluid" is caused by an external force, i.e. "a means for circulating this fluid such as a fluid perfusing and/or extracting means." (Col. 1, lines 8-9.) Therefore, in this case, "work" and "motion" are synonymous, and plaintiffs' proposed construction of "rest position" as limited to those times when the catheter is "being used to circulate fluids" is improper.

Defendants' proposed construction is also mistaken when it seeks to limit the catheter's rest position to one where the catheter is "outside of the patient's body" and prior to insertion. While there appears to be some evidence in the specification that "rest position" should be construed as a position outside of the body,FN7 there are no temporal or functional limitations expressed in the claim itself. *See* Ecolab, 264 F.3d at 1367; Transmatic, 53 F.3d at 1277-78. At the *Markman* hearing, plaintiffs claimed that "there is no factual basis to assume that the [catheter] is never motionless for a particular moment in the body." (Tr. at 47.) The Court

has no evidence to dispute this contention, and therefore there is no reason to impose an "outside the body, prior to insertion" limitation on "rest position" at this time.

FN7. For example, at Col. 1, lines 19-20, it states that the catheter is " *intended* to be placed in a cavity of a patient's body" (emphasis added), and at Col. 1, lines 66-67 it states that the catheter is " *intended* to be placed inside a cavity of a patient's body (*not represented*)" (emphasis added).

However, it is proper to impose the limitation that rest position must be determined prior to the time the device is removed from a patient. The claim itself states that the invention is a "multilumen catheter." (Col. 2, line 65.) Once the catheter is removed from a patient's body, it is no longer a "multilumen catheter," or any other viable medical device. Rather, it is medical waste, as the following colloquy at the *Markman* hearing demonstrates:

Court: Isn't it essentially medical waste and useless after it's taken out of the body?

Plaintiffs: Well, no, I don't think so.

Court: Could you reuse it?

Plaintiffs: Well, you can reuse almost any medical device, your Honor. I don't think that any of the companies would sell them for that purpose ....

(Tr. at 48-49.) Therefore, this Court construes "rest position" as "a position in which the catheter is motionless prior to being removed from a patient."

C. " *Flexible* "

[14] Finally, the parties ask this Court to construe the term "flexible," although oral argument revealed no real dispute between the parties. (Tr. at 64-65.) However, the parties proposed slightly different constructions, and to the extent there are differences, this Court will construe the term.

The '079 Patent teaches that "wherein said at least two end portions are each made of flexible material so as to be flexible at least under the effect of a lateral action due to the displacement of a fluid." (Col. 4, lines 1-4.) Defendants argue that "flexible" in this instance should be construed as "capable of being bent or flexed at least under the effect of a lateral action due to the displacement of a fluid." (Def. Mem. at 23.) Plaintiffs argue for an almost identical construction, "capable of being flexed or bent due to the action of bodily fluid flow." (Pl. Mem. at 18.)

There is no material difference between the proposed constructions. Defendants, however, properly limit their proposal to the functional limitation stated in the claim itself, that it be "capable of being bent or flexed at least under the effect of a lateral action due to the displacement of a fluid." (Col. 4, lines 2-4.) In contrast, plaintiffs attempt to engraft a functional requirement that the fluid flow in question be "bodily fluid flow," a limitation found nowhere in the claim and presumably gleaned from the specification. Therefore, this Court construes "flexible" in the '079 Patent as "capable of being bent or flexed at least under the effect of a lateral action due to the displacement of a fluid."

CONCLUSION

For the reasons set forth above, this Court construes the disputed terms as follows: (1) "Substantially parallel" means "the same as or very close to parallel;" (2) "rest position" means "a position in which the catheter is motionless prior to being removed from a patient;" and (3) "flexible" means "capable of being bent or flexed at least under the effect of a lateral action due to the displacement of a fluid."

SO ORDERED.

APPENDIX

APPENDIX

US006001079A

United States Patent [19]

Pourchez

[11] **Patent Number: 6,001,079**

[45] **Date of Patent: Dec. 14, 1999**

[54] **MULTILUMEN CATHETER, PARTICULARLY FOR HEMODIALYSIS**

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PCT Pub. Date: Mar. 13, 1997

[30] **Foreign Application Priority Data**

Sep. 5, 1995 [FR] France 95 10515

[51] **Int. Cl.**[6] **A61M 3/00; A61M 5/00**

[52] **U.S. Cl.** **604/43; 604/271**

[58] **Field of Search** 604/27, 29, 28, 604/284, 19, 49, 54, 93, 258, 266, 254, 271, 239, 43, 1021/108, 112; 600/381

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[57] **ABSTRACT**

A multilumen catheter (1) of a type comprising two inner lumens (2, 3) defined by a wall (2A, 3A) for guiding a fluid (4), and two opposite ends (5, 6), namely a distal end (5) and a proximal end (6), characterized in that the distal end is formed of two elongated and discrete end portions (13, 14) located beyond a so-called dividing point (12) at a predetermined distance D1 from the proximal end (6), wherein said end portions, in a rest position of the catheter, extend parallel to the longitudinal axis thereof, each over a predetermined length (L1, L2) measurable between a free end (13A, 14A) and the dividing point (12), are each made of a flexible material, contain a segment of at least one lumen (2, 3) and have at least one channel (7, 8) for delivering and/or sampling the fluid.

3 Claims, 1 Drawing Sheet

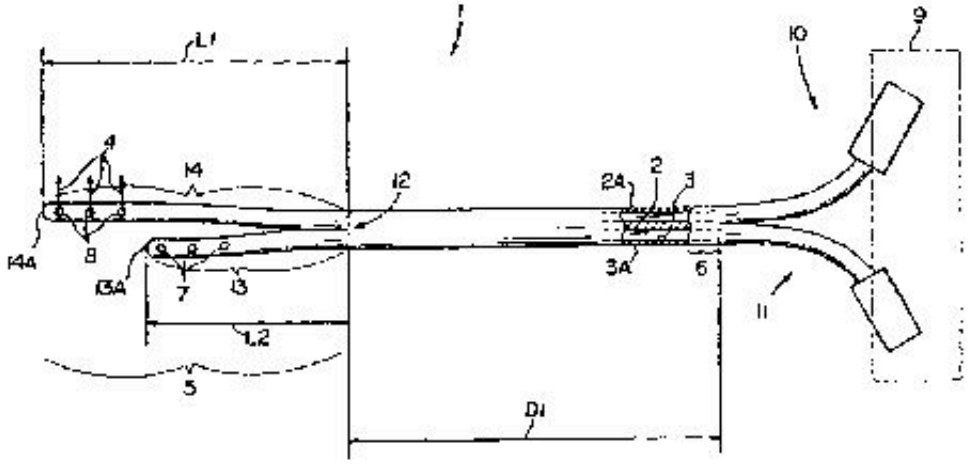
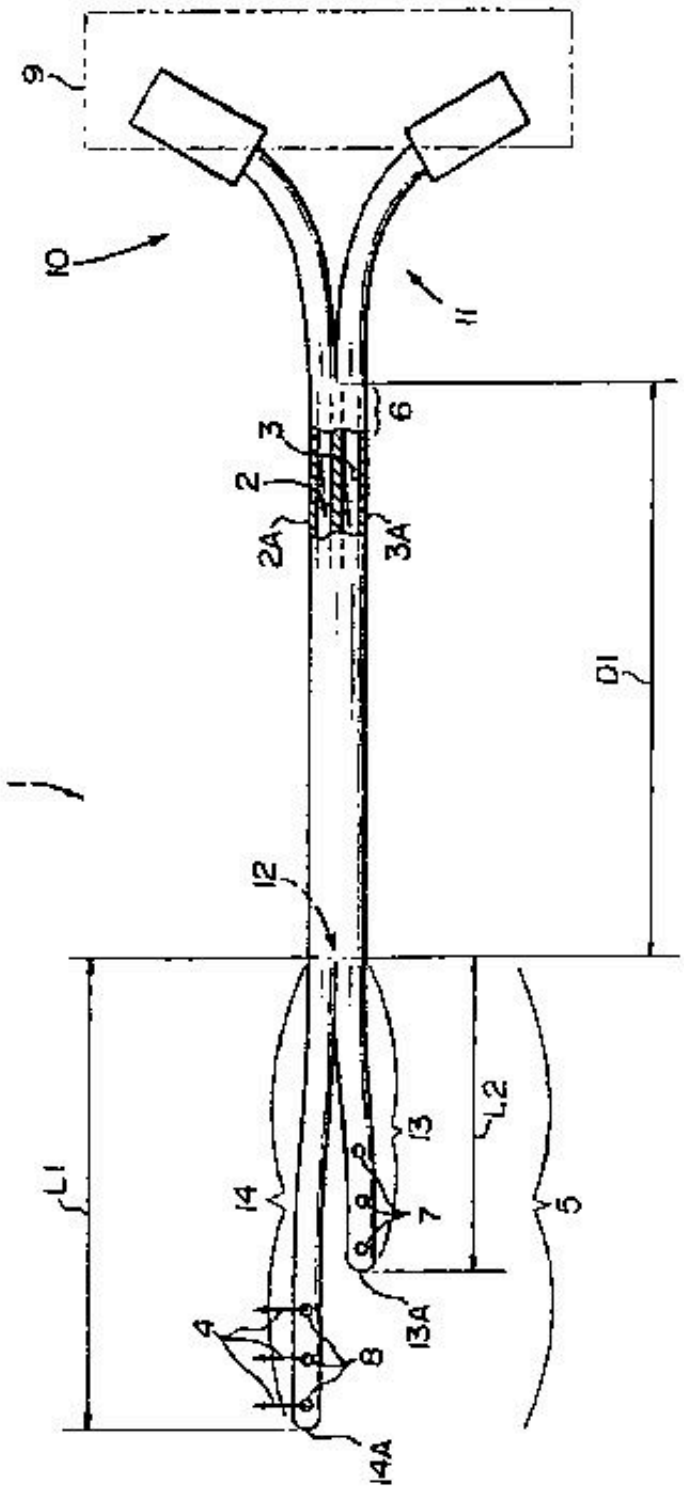


FIG. 1



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MULTILUMEN CATHETER, PARTICULARLY FOR HEMODIALYSIS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to a device called a multilumen catheter, used for the circulation of at least one fluid between a cavity of a patient's body and a means for circulating this fluid such as a fluid perfusing and/or extracting means.

The invention relates more particularly, though not exclusively, to a catheter for hemodialysis.

2. Description of Related Art

The term multilumen catheter designates a catheter comprising at least two inner lumens defined by a wall, each of which is intended for guiding at least one fluid.

A catheter of this type also comprises two opposite ends, one of which is called a distal end since it is specifically intended to be placed in a cavity of a patient's body in order to deliver and/or sample the fluid to or from it through at least one channel, the other being called a proximal end, since it is specifically intended to be connected to a fluid circulating means such as a fluid perfusing and/or extracting means.

With the known catheters, the risk of clogging substances being deposited on the surfaces of the perfusing and/or extracting channels is substantial.

One object of the invention is to obtain a catheter having a risk of obstruction by clogging that is substantially reduced relative to the known catheters.

SUMMARY OF THE INVENTION

To this end, the subject of the invention is a catheter of the above-mentioned type, this catheter being characterized in that in order to constitute its distal end, it comprises, beyond a so-called dividing point located at a predetermined distance from its proximal end, at least two distinct elongated end portions which:

in at least one rest position of the catheter, extend substantially parallel to the longitudinal axis of this catheter, each over a predetermined length measurable between a free end and the dividing point,

are each made of flexible material so as to be flexible at least under the effect of a lateral action due to the displacement of a fluid,

contain at least one segment of at least one of the lumens and have at least one channel for delivering and/or sampling the fluid.

BRIEF DESCRIPTION OF THE DRAWING

The invention will be clearly understood by reading the following description given as a non-limiting example in reference to the appended drawing. FIG. 1 is a side view of one embodiment of a catheter according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The drawing shows an elongated device called a catheter 1 comprising:

at least two inner lumens 2, 3, defined by a wall 2A, 3A, each of which is intended for guiding at least one fluid 3,

two opposite ends 5, 6, one of which 5 is called a distal end, since it is specifically intended to be placed inside a cavity of a patient's body (not represented) in order to deliver and/or sample the fluid 4 to or from it through at least one channel 7, 8, the other end 6 being called the proximal end, since it is specifically intended to be connected to a means 9 for circulating a fluid 4, such as a fluid perfusing and/or extracting means.

The fluid 4 is represented by arrows 4.

As shown, the channels 7, 8 are comprised of perforations disposed in the wall of the catheter that defines each of the lumens 2, 3.

These channels allow either the delivery into the area surrounding the catheter of a fluid contained in a lumen of this catheter, or the entry into a lumen of this catheter of a surrounding fluid.

For example, at least one of the lumens is intended for perfusing a fluid and at least one other lumen is intended for extracting fluid.

Also as shown, the lumens 2, 3 for circulating the fluid 4 are for example comprised of juxtaposed lumens, but this is not limiting for the invention.

The dimensions and proportions of the catheter represented are not limiting for the invention.

At its proximal end 6, the catheter has elements 10, 11 for connecting each of the lumens 2, 3 it comprises to the means 9 for circulating fluid 4.

As neither the circulating means 9 nor the elements 10, 11 for connecting to this means 9 are subjects of the invention, these elements 10, 11 and the means 9 are not represented in detail.

It is at the distal end 5 that the catheter of the invention is noteworthy.

In effect, in order to constitute its distal end, the catheter comprises, beyond a so-called dividing point 12 located at a predetermined distance D1 from its proximal end 6, at least two distinct elongated end portions 13, 14 which:

in at least one rest position of the catheter, extend substantially parallel to the longitudinal axis of this catheter, each over a predetermined length L1, L2 measurable between a free end 13A, 14A, and the dividing point 12.

are each made of flexible material so as to be flexible at least under the effect of a lateral action due to the displacement of a fluid,

contain at least one segment of at least one of the lumens 2, 3 and has at least one channel 7, 8 for delivering and/or sampling the fluid.

These technical characteristics, when the distal end of the catheter is placed on the axis of a fluid flow such as a bodily fluid flow, allow the end portions, due to their flexibility and independence, to act like a sail set parallel to the wind and thus are practically not subject to obstructing.

In effect, the agitation and flexion of these end portions considerably reduces the risk of clogging substances being deposited on the surfaces of the perfusing and/or extracting channels with which these end portions are equipped.

According to another noteworthy characteristic, the end portions have different lengths L1, L2, and the channels with which these end portions are equipped are disposed so that each of them emerges at a different level of the catheter.

According to another characteristic of the invention, the channels with which the end portions are equipped are disposed in a group on each end portion, and these groups are disposed at different levels of the catheter.

I claim:

1. A multilumen catheter (1) comprising:

at least two inner lumens (2, 3), defined by a wall (2A, 3A), each of said inner lumens being adapted to guide

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at least one fluid (4), said wall isolating said at least two inner lumens from one another along an entire length of said catheter, to define at least two separate fluid flow passages,

two opposite ends (5, 6), a first one of which (5) is a distal end, said distal end specifically intended to be placed in a cavity of a patient's body and adapted to deliver and/or sample the fluid (4) to or from said distal end through at least one channel (7,8), a second end (6) being a proximal end, said proximal end adapted to be connected to a means (9) for circulating fluid (4),

said distal end of said catheter having a dividing point (12) located at a fixed predetermined distance D1 from said proximal end (6), and having at least two distinct elongated end portions (13, 14) extending from said dividing point, said dividing point being nearer to said distal end than to said proximal end,

wherein said at least two end portions, in at least one rest position of the catheter, extend substantially parallel to a longitudinal axis of said catheter, each over a predetermined length (L1, L2) measurable between a free end of said distal end (13A, 14A) and the dividing point (12),

wherein said at least two end portions are each made of flexible material so as to be flexible at least under the effect of a lateral action due to the displacement of a fluid, and

wherein each of said at least two end portions contains at least one segment of at least one of the lumens (2, 3) and has at least one channel (7, 8) for delivering and/or sampling the fluid.

2. The multilumen catheter according to claim 1, wherein:

each of said at least two end portions has a different length (L1, L2), and

the channels with which each of said at least two end portions are equipped are so constructed and arranged such that each emerges at a different position along the catheter.

3. The multilumen catheter according to claim 2, wherein the channels with which the at least two end portions are equipped are disposed in a group on each end portion, and wherein said groups are disposed at different positions along the catheter.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,001,079
DATED : December 14, 1999
INVENTOR(S) : Thierry Pourchez

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page,
Item [87], "§371 Date: Mar. 9, 1998" should be -- §371 Date: Mar. 5, 1998 --.
Item [87], "§102 (e) Date: Mar. 9, 1998" should be -- §102(e) Date: Mar. 5, 1998 --.

Column 4,
Line 17, "chatheter" should be -- catheter --.

Signed and Sealed this

Fourth Day of June, 2002

Attest:

Attesting Officer

JAMES E. ROGAN
Director of the United States Patent and Trademark Office

Pourchez v. Diatek, Inc.

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