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

MEDINOL LTD,
Plaintiff.
v.
GUIDANT CORP. and Advanced Cardiovascular Systems, Inc,
Defendants.

No. 03 Civ. 2604(SAS)

Sept. 30, 2004.

Keith R. Hummel, Rory O. Millson, Fabian D. Gonell, Cravath, Swaine & Moore LLP, New York, NY, Christopher A. Hughes, Richard C. Komson, Dorothy R. Auth, Morgan & Finnegan, LLP, New York, NY, for Plaintiff.

J. Michael Jakes, Christine E. Lehman, Robert F. Shaffer, Finnegan, Henderson, Farabow, Garrett & Dunner LLP, Washington, DC, Shari L. Steinberg, Yun G. Lee, Swidler Berlin Shereff Friedman LLP, New York, NY, for Defendants.

OPINION AND ORDER

SCHEINDLIN, J.

Medinol Ltd. ("Medinol") alleges that Guidant Corp. ("Guidant") and its subsidiary Advanced Cardiovascular Systems, Inc. ("ACS") (collectively "defendants") infringed (and continue to infringe) certain of Medinol's patents directed to balloon-expandable stents. Specifically, Medinol contends that the asserted claims of United States Patent Nos. (1) 5,733,303 (" '303 Patent"); (2) 5,843,120 (" '120 Patent"); (3) 5,972,018 (" '018 Patent"); (4) 6,443,982 (" '982 Patent"); and (5) 6,461,381 (" '381 Patent") (collectively "patents-in-suit") FN1 are infringed by defendants' manufacture, use, offer for sale, sale, and/or importation of the MULTI LINK PENTA(R) and MULTI LINK ZETA(TM) systems. FN2 Although the parties have agreed on definitions for seven terms contained in the asserted claims, twelve terms are in dispute. A *Markman* Hearing was held on September 2, 2004.FN3 The Court's construction of the disputed terms follows.

FN1. *See* Exs. 1-5 to 8/20/04 Affirmation of Yun G. Lee, counsel for Guidant ("Lee Aff.").

FN2. *See* Complaint ("Compl.") para.para. 24-26, 30-32, 36-38, 42-44, 48-50. Guidant counterclaims pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. s.s. 2201-2202, and U.S. patent law, 35 U.S.C. s. 100, et seq.

FN3. *See* Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996).

I. BACKGROUND

My previous opinion in this case described the underlying facts and procedural history, which I will not repeat here, except to summarize those points that are relevant to the instant dispute over claim terms.FN4

FN4. *See* Medinol Ltd. v. Guidant Corp., No. 03 Civ. 2604, 2004 WL 1243605 (S.D.N.Y. June 4, 2004).

A. The Parties

Medinol, which designs and manufactures coronary stents, maintains its principal place of business in Tel Aviv, Israel.FN5 Guidant, an Indiana-based company, develops, markets, and sells cardiovascular medical products. ACS has its principal place of business in California.FN6

FN5. Compl. para. 5.

FN6. *Id*. para.para. 6-7.

B. History of Stent Development

Balloon-expandable stents were developed to improve the success rate of percutaneous transluminal coronary angioplasty ("PTCA" or "balloon angioplasty").FN7 PTCA is a procedure during which the narrowed, diseased arteries are dilated to restore blood flow. This is accomplished by inserting and maneuvering into place a catheter to which a deflated balloon is attached. Once properly positioned, the balloon is inflated, compressing the fatty deposits, or plaque, against the artery wall. The catheter and balloon are then removed from the artery.

FN7. Stents are also "used to treat diseased blood vessels in ... other areas of the body ('peripheral arteries')." Scimed Life Sys ., Inc. v. Johnson & Johnson, 225 F.Supp.2d 422, 425 (D.Del.2002), *aff'd,* 87 Fed.App. 729 (unpublished decision) (Fed.Cir. Jan. 14, 2004).

Despite the benefits associated with PTCA, approximately thirty-five percent of patients experienced renarrowing of the arteries, a problem that stents are designed to address.FN8 Stents are, in essence, miniature scaffolding devices that prop open constricted arteries. They are delivered into the vessels on a balloon via a catheter. When the balloon is "at the area of blockage, it is inflated, [causing] the stent to expand and press against the vessel wall, thereby opening the artery. The balloon is then deflated and removed...." FN9 In light of the foregoing, it is desirable for stents to possess the following characteristics: (1) flexibility, which permits the stent to negotiate the curves of the artery; (2) strength or rigidity; and (3) uniform coverage, *i.e.,* relatively few gaps so that portions of the vessel do not press between the struts into the lumen.FN10

FN8. The major complications associated with balloon angioplasty are: (1) dissection, where the plaque "cracks" during the procedure, resulting in a flap that falls into the lumen creating a complete occlusion of the artery; (2) recoil of the vessel wall; and (3) restenosis, or renarrowing of the involved arteries, caused by a buildup of scar tissue created by the procedure. *See* Transcript of 9/2/04 *Markman* Hearing ("Tr.") at 6-8 (statements of Dr. Jacob Richter, Chief Technology Officer and Chairman of the Board for Medinol). However, PTCA is generally less traumatic and expensive than the alternative-coronary artery bypass surgery. *See* Medinol's Memorandum of Law Regarding Claim Construction ("Pl.Mem.") at 2.

FN9. Scimed Life Sys., 225 F.Supp.2d at 425.

FN10. *See* Tr. at 10 (Richter).

1. Early Stent **Designs: Slotted Tube and Coil**

The "first generation" stents were of two varieties: slotted tube and coil. Developed by Julio Palmaz in the 1980s,FN11 the slotted tube stents had a "plurality of slots ... disposed substantially parallel to the longitudinal axis of the tubular member" that, when expanded, had a honeycomb appearance.FN12 Because the Palmaz stent was very rigid, it provided significant radial strength, but lacked flexibility.FN13 By contrast, the coil stent was designed by Cesare Gianturco and comprised "wire formed into a serpentine configuration including a series of straight sections and a plurality of bends." FN14 As such, it was highly flexible but lacked rigidity and hence strength.

FN11. *See* U.S. Patent Nos. 4,739,762 ("Palmaz '762 Patent") [assigned to Expandable Grafts P'ship] (Apr. 26, 1988), Ex. 11 to Lee Aff.; 5,102,417 ("Palmaz '417 Patent") [Expandable Grafts P'ship] (Apr. 7, 1992), Ex. 12 to Lee Aff.

FN12. Palmaz '762 Patent, col. 3, ll. 38-40. *See also* id. Figures 1A, 1B.

FN13. *See* Tr. at 11 (Richter); id. at 29 (statement of Dr. Jerome Segal, expert witness for Guidant).

FN14. U.S. Patent No. 5,041,126 [Cook Incorporated] (Aug. 20, 1991), Ex. 10 to Lee Aff., col. 2, ll. 5-7. This design was the basis for the Gianturco-Roubin stent.

2. Articulated Stents

The next generation of stents addressed some of the weaknesses of the early devices. Specifically, the Palmaz-Schatz stent, based on the slotted cell design,FN15 dealt with the inflexibility of its predecessor through the incorporation of a one-millimeter straight flexible connector joining two seven-millimeter tubular members.FN16 This yielded a device that was more maneuverable, although the tubular members were still inflexible. Moreover, the straight connector that created an articulation point and allowed the stent to bend also caused a large gap to form in middle of the device.FN17 Johnson & Johnson attempted to

remedy this problem by inserting not one, but six, helical connectors between the rigid members. Nonetheless, the stent still lacked flexibility and presented new hazards, *e.g.,* upon expansion, the helical connectors caused the rigid portions to twist, risking damage to the vessel. FN18

FN15. *See* U.S. Patent No. 5,195,984 [Expandable Grafts P'ship] (Mar. 23, 1993), Ex. 13 to Lee Aff.

FN16. *See* id. col. 4, ll. 2-5; *see also* id. Figure 7.

FN17. *See* Tr. at 13 (Richter).

FN18. *See* id.

3. Guidant's Multi-Link Stent

Guidant's Multi-Link stent, based on U.S. Patent 5,421,955 ("Lau '955 Patent") was among the next generation of stents, for which the primary innovation was the ability to be uniformly flexible at any point along the stent.FN19 The Lau '955 Patent disclosed an invention comprising serpentine rings with straight connectors.FN20 The rings may be connected in two ways: out of phase (connecting adjacent crowns of rings that face each other) and in phase (crowns pointing in one direction).FN21 The in-phase arrangement was commercialized as the Multi-Link stent. Although the straight connectors are inflexible, serving to "provide increased stability and ... prevent warping of the stent upon expansion," the rings themselves permit flexibility.FN22 Consequently, the rings could become deformed, resulting in large, irregular gaps, thereby compromising vessel wall support. Medinol dubbed this as an "open cell" FN23 design, as opposed to a "closed cell" design, which is associated with stents that have flexible links permitting the "cells on the outside of the curve to elongate uniformly and the cells on the inside of the curve to shorten uniformly." FN24

FN19. Lau '955 Patent (June 6, 1995), Ex. 14 to Lee Aff.

FN20. *See* Tr. at 32-33 (Segal).

FN21. *See* Lau '955 Patent, Figures 5 (in phase), 11 (out of phase).

FN22. *See* id. col. 1, ll. 65-68.

FN23. Tr. at 15 (Richter).

FN24. Pl. Mem. at 9. Medinol's stent design, which served as the basis for the NIR stent, features a "closed

cell" design. *See* id .

C. Medinol's Patents

Medinol is the assignee of the '303, '018, '120, '381, and '982 Patents, a family of flexible, expandable stents developed by Henry Marshall Israel and Gregory Pinchasik. Medinol asserts thirty-three claims from the patents-in-suit: 13, 16, 18, 27, and 28 of the '120 Patent; 1, 2-15, and 17 of the '982 Patent; claim 28 of the '303 Patent; claim 51 of the '018 Patent; and claims 56-58, 61, 63, 65-66, and 68-70 of the '381 Patent.FN25

FN25. For the text of these claims, see Medinol, 2004 WL 1243605, at *2-*6. In the Complaint, Medinol also asserted claims 24 of the '303 Patent and 64 of the '018 Patent. However, this Court granted Guidant's motion for summary judgment on the basis of collateral estoppel as to those two claims. *See id*. at *17.

The patents-in-suit all share the same drawings and essentially the same specification, and are continuations of Application Serial No. 282,181 (filed on July 28, 1994) and continuations-in-part of Application Serial No. 213,272 (filed on March 17, 1994), issued as U.S. Patent No. 5,449,373 ("Pinchasik '373 Patent").FN26 The specification of the patents-in-suit describes the stent design as comprising: (1) claims that describe stents in terms of two types of intertwined meander patterns and (2) claims that describe stents in terms of the structural elements of its flexible cells.FN27 The "key to the flexibility of the stents" based on Medinol's patents, is the "capacity for loops in the flexible links (or in the second meander patterns) to elongate differentially when the stent goes around a curve." FN28 The pattern for the stent is further explained in terms of three embodiments, represented pictorially in eight figures (Figures 1-5 [first preferred embodiment], 6 [second embodiment], and 7-8 [third embodiment]).

FN26. *See* Pinchasik '373 Patent, Ex. 6 to Lee Aff. The Pinchasik '373 Patent features "lighting bolt"-shaped, Pl. Mem. at 5, or "kink [ed]," Pinchasik '373 Patent, col. 2, ll. 16-18, connectors linking substantially rigid segments. *See* id. This design is an attempt to "improve" the Palmaz-Schatz stent by minimizing twisting on expansion and articulation-point gaps. Pl. Mem. at 5.

FN27. *See* Pl. Mem. at 7-8.

FN28. Id. at 8.

D. *Cordis* Litigation

In December 1999, Medinol and its licensee, Scimed Life Systems, Inc., filed a patent infringement action in the district of Delaware, alleging that Cordis Corp., Johnson & Johnson, and Johnson & Johnson Interventional Systems, Inc. had infringed certain claims of Medinol's '303, '120, and '018 patents. FN29 During those proceedings, the district court construed various claim terms, including: "stent"; "cell"; "member having a longitudinal component"; "loop"; "first loop" and "second loop"; "disposed between"; "disposed generally opposite"; "flexible compensating member or flexible link"; "area of inflection"; "uniform cellular structure"; "meander," "first meanders," and "second meanders"; "said loops adapted so that said stent prior to expansion is substantially uniformly flexible along its longitudinal axis"; "stent which

is substantially uniformly flexible with respect to its longitudinal axis by the flexibility of its cells with respect to said axis"; "apices"; and "plurality of flexible links." FN30

FN29. In *Cordis,* Medinol asserted that claims 12 of the '303 Patent; 13 of the '120 Patent; and 35, 47, and 60 of the '018 Patent were infringed.

FN30. *See* 8/15/01 Order Construing Disputed Claim Terms, No. 99 Civ. 904 (D.Del.) ("*Cordis* Order"), Ex. 3 to Pl. Mem.

II. APPLICABLE LAW

A. Principles of Claim Construction

Determination of infringement in a patent case involves two steps: (1) construction of the terms of the asserted claims ("claim construction") and (2) a determination of whether the accused device infringes the claims, as construed.FN31 Claim construction is a question of law,FN32 the purpose of which is to determine what is covered by the claims of a patent. In other words, " '[t]he construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims." ' FN33 Claim disputes often turn on the meaning of a phrase, a word, or a single functional or structural aspect of the patented device.

FN31. *See* Metabolite Labs., Inc. v. Laboratory Corp. of Am. Holdings, 370 F.3d 1354, 1360 (Fed.Cir.2004).

FN32. *See* Markman, 517 U.S. at 384, 390-91.

FN33. DeMarini Sports, Inc. v. Worth, Inc., 239 F.3d 1314, 1322 (Fed.Cir.2001) (quoting Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1347 (Fed.Cir.2000)).

Courts confronted with the task of construing patent claims are guided by well settled principles of interpretation. Of primary importance is the "intrinsic evidence of record, *i.e.,* the patent itself, including the claims, the specification and, if in evidence, the prosecution history." FN34 Additionally, courts may, as a discretionary matter, receive extrinsic evidence, such as expert testimony, to understand the technical aspects of a patent.FN35 However, extrinsic evidence cannot be used to "arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." FN36

FN34. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). Intrinsic evidence is the "most significant source" in ascertaining the "legally operative meaning of disputed claim language." *Id.*

FN35. *See* Metabolite Labs., 370 F.3d at 1360.

FN36. Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 977 (Fed.Cir.1999). *See also* Markman v. Westview Instruments, Inc., 52 F .3d 967, 981 (Fed.Cir.1995), *aff'd,* 517 U.S. 370.

Courts first consider the "words of the claims themselves ... to define the scope of the patented invention." FN37 A claim term is presumed to possess its ordinary and customary meaning, in view of both the temporal and technological context in which it arose. That is, the critical inquiry for purposes of claim construction relates to how "artisans of ordinary skill in the relevant art at the time of invention" understood the claim terms. FN38 In ascertaining the "ordinary and customary meaning" of particular words, the Federal Circuit has counseled that "dictionaries, encyclopedias and treatises [publicly available at the time the patent is issued] are particularly useful resources" as they are objective "reflections of common understanding not influenced by expert testimony or events subsequent to the fixing of the intrinsic record by the grant of the patent, not colored by the motives of the parties, and not inspired by litigation." FN39 Nonetheless, courts must exercise caution in relying on non-scientific dictionaries when confronted with technical terms.FN40

FN37. Vitronics, 90 F.3d at 1582.

FN38. Metabolite Labs., 370 F.3d at 1360 ("Indeed, normal rules of usage create a 'heavy presumption' that claim terms carry their accustomed meaning in the relevant community at the relevant time.").

FN39. Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202, 1203 (Fed.Cir.2002), *cert. denied,* 538 U.S. 1058 (2003). These resources are not properly classified as extrinsic evidence. *See* id. at 1203. Rather, they are best used in conjunction with the intrinsic record. For example, where a word is defined variously in a dictionary,
the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor. 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.

Id. (citations omitted).
FN40. *See* Revlon Consumer Prods. Corp. v. Estee Lauder Cos., No. 00 Civ. 5960, 2003 WL 21751833, at & n. 15 (S.D.N.Y. July 30, 2003) (citing cases).

The presumption favoring the general usage of particular terms can be rebutted by evidence in the intrinsic record. For instance, "a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." FN41 Accordingly, courts also review the patent specification, which is perhaps the "single best guide to the meaning of a disputed term" FN42 and demonstrates whether the patentee "used terms in a manner inconsistent with their ordinary meaning." FN43 The specification contains a "written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it." FN44 The presumption of ordinary meaning is overcome by the specification where the patentee "has set forth a definition for the term different from its ... customary

meaning or where the patentee has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." FN45

FN41. Vitronics, 90 F.3d at 1582.

FN42. *Id*.

FN43. DeMarini Sports, 239 F.3d at 1323.

FN44. Vitronics, 90 F.3d at 1582. *See also* 35 U.S.C. s. 112.

FN45. International Rectifier Corp. v. IXYS Corp., 361 F.3d 1363, 1370 (Fed.Cir.2004).

Courts also examine the prosecution history of the patent to assess whether the patentee made express representations regarding the scope and meaning of the claims to obtain the patent.FN46 The prosecution history includes the record of all proceedings relating to the patent that took place before the Patent and Trademark Office ("PTO"), including "any express representations made by the applicant regarding the scope of the claims," and possibly an examination of the prior art.FN47

FN46. *See* DeMarini Sports, 239 F.3d at 1323.

FN47. Vitronics, 90 F.3d at 1582. *See also* Middleton, Inc. v. Minnesota Mining & Mfg. Co., 311 F.3d 1384, 1388 (Fed.Cir.2002) ("This court also considers the prosecution history ... to determine whether the applicant clearly and unambiguously disclaimed or disavowed [any interpretation] during prosecution in order to obtain claim allowance.") (quotation marks and citation omitted).

"As in the case of the specification, the patent applicant's consistent usage of a term in prosecuting the patent may enlighten the meaning of that term." FN48 In particular, under the doctrine of prosecution disclaimer, the prosecution history " 'limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." ' FN49 Indeed, it is a "fundamental precept" in claim construction jurisprudence that patentees cannot "recaptur[e] through claim interpretation specific meanings disclaimed during prosecution." FN50 This "promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution." FN51 Although prosecution disclaimer does not attach where the "alleged disavowal of claim scope is ambiguous," FN52 an unequivocal disavowal of a particular meaning advanced by the patentee to overcome the prior art and obtain the patent narrows the "ordinary meaning of the claim congruent with the scope of surrender." FN53 Notably, "[w]hen multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." FN54

FN48. Metabolite Labs., 370 F.3d at 1360.

FN49. Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1325 (Fed.Cir.2002) (quoting Digital Biometrics, Inc. v. Identix, Inc., 149 F .3d 1335, 1347 (Fed.Cir.1998)).

FN50. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323 (Fed.Cir.2003).

FN51. Id. at 1324.

FN52. *Id*. *See also* Gemstar-TV Guide Int'l, Inc. v. International Trade Comm'n, No. 03 Civ. 1052, 2004 WL 2059279 (Fed.Cir. Sept. 16, 2004).

FN53. Omega Eng'g, 334 F.3d at 1324. *See also* id. at 1325 ("To balance the importance of public notice and the right of patentees to seek broad patent coverage, we have thus consistently rejected prosecution statements too vague or ambiguous to qualify as a disavowal of claim scope.").

FN54. Elkay Mfg., 192 F.3d at 980.

B. Claim Definiteness

"If the court finds that a claim is not 'amenable to construction,' then the claim is invalid as indefinite under section 112 of the Patent Act," FN55 which requires the claims of a patent to "particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention." FN56 The definiteness inquiry is directed to whether persons with ordinary skill in the art would comprehend the scope of the claim when read against the specification.FN57 Because a claim is statutorily presumed to be valid, it does not fail for indefiniteness simply "because it poses a difficult issue of claim construction." FN58 Rather, "if the claim is subject to construction, i.e., it is not insolubly ambiguous, it is not invalid for indefiniteness." FN59 Thus, even where a court's construction of the claim is one over which reasonable minds will disagree, the claim is, nonetheless, clear enough to survive the test of invalidity for indefiniteness.FN60 Where the question of validity under section 112 is close, it is resolved in favor of the patentee.FN61

FN55. Honeywell Int'l, Inc. v. International Trade Comm'n, 341 F .3d 1332, 1338 (Fed.Cir.2003) (quoting Exxon Research and Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed.Cir.2001)). Whether a claim satisfies this "definiteness" requirement is a question of law. *See* Bancorp Servs., L.L.C. v. Hartford Life Ins. Co., 359 F.3d 1367, 1371 (Fed.Cir.2004).

FN56. 35 U.S.C. s. 112, para. 2.

FN57. *See* Union Pac. Res. v. Chesapeake Energy Corp., 236 F.3d 684, 692 (Fed.Cir.2001).

FN58. Bancorp Servs., 359 F.3d at 1371.

FN59. *Id*.

FN60. Exxon Research and Eng'g, 265 F.3d at 1375 ("If a claim is insolubly ambiguous, and no narrowing construction can properly be adopted, we have held the claim indefinite. If the meaning of the claim is discernible, even through the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds."). *See also id*. (noting that the court "protect[s] the inventive contribution of patentees, even when the drafting of their patents has been less than ideal").

FN61. *See* Bancorp Servs., 359 F.3d at 1371; *see also* Union Pac. Res., 236 F.3d at 692 (noting that to rebut the presumption of validity, the burden of proof is clear and convincing evidence of patent invalidity).

III. DISCUSSION

The parties have agreed on definitions for: (1) apices ("[p]oints at the two longitudinal ends of a cell of a stent"); (2) arc ("[a] curved line or segment of a circle"); (3) area of inflection ("[a] portion of a stent element that is bent, i.e., a loop"); (4) disposed apart and generally opposite to ("[s]tructural elements positioned across from and approximately aligned with each other"); (5) disposed between ("[p]ositioned in the space that separates structural elements"); (6) member ("[a] structural element"); and (7) stent ("[a] device made of a body-compatible material, used to widen a blood vessel or other body opening (also called a 'lumen'), and to maintain the resultant size of the blood vessel or lumen").FN62 This leaves twelve terms to be construed, which I will discuss seriatim.

FN62. Proposed Claim Terms for Construction and Proposed Definitions ("Claim Chart"), Ex. 1 to Medinol's Memorandum of Law in Response to Guidant's Memorandum of Law on Claim Construction ("Pl.Reply").

A. "Meander" or "Meander Pattern," "First Meander" or "First Meander Pattern," "Second Meander" or "Second Meander Pattern"

The meander terms appear in claims: 13, 16, 27, and 28 of the '120 Patent; and 1, 2-15, and 17 of the '982 Patent.FN63 Medinol contends that "meander" or "meander pattern" should be defined as "a periodic or repeating pattern about a center line," and that first and second meanders "identify and differentiate two sets of meanders (or meander patterns)." FN64 Guidant (1) defines "first meander" as "[a] periodic sinusoidal pattern that is uniformly distributed about a center line and extends circumferentially [equivalent to vertically in Medinol's patent figures] around a stent" FN65 and (2) finds "second meander" to be indefinite.FN66 The parties agree that there is no customary meaning for these terms and that Medinol, in using them, has acted as its own lexicographer.FN67 Accordingly, the Court looks to the patent

specification and file history for guidance.

FN63. *See* '120 Patent, col. 7, ll. 16-17, 19, 21-25, 41-42, col. 8, ll. 45-51; '982 Patent, col. 6, ll. 32-33, 35-36, 37, 40-43, 45-48.

FN64. Pl. Mem. at 13. In the Claim Chart, Medinol words this slightly differently, equating "meander" with "[a] periodic or repeating pattern of structural elements oriented about a center line" and first and second meanders that "[i]dentify and differentiate two different patterns." Claim Chart at 4.

FN65. Guidant's Memorandum of Law on Claim Construction (filed under seal) ("Def.Mem.") at 12.

FN66. *See id*. at 14; *see also* 35 U.S.C. s. 112, para. 2. Guidant adds that "to the extent that this term can be construed ... it should be construed as a periodic pattern that is uniformly distributed about a center line from one longitudinal end of the cell to the other." *See* Claim Chart at 4.

FN67. *See* Pl. Mem. at 13 ("For these terms, the patentees acted as their own lexicographer and clearly set forth a different definition than the plain meaning.") (quotation marks and citation omitted); Def. Mem. at 13 ("It cannot be disputed that the term 'meander' has no ordinary meaning in stent design."); *see also* Tr. at 43 (statement of Dorothy Auth, counsel for Medinol).

The specification for the '303 Patent provides that "[t]he term 'meander pattern' is taken herein to describe a periodic pattern about [a] center line and 'orthogonal meander patterns' are patterns whose center lines are orthogonal to each other." FN68 The summary of the invention explains:

FN68. '303 Patent, col. 2, ll. 57-60.

The stent of the present invention is formed of a tube ... which has first and second meander patterns having axes extending in first and second directions wherein the second meander patterns are intertwined with the first meander patterns. The first and second directions *can be* orthogonal to each other.FN69
FN69. *Id*. col. 1, ll. 55-60 (emphasis added).

In the description of the preferred embodiments, it is further explained that "the present invention encompasses all stents manufactured with a pattern formed of two meander patterns, orthogonal *or otherwise*." FN70 Accordingly, while the first and second meanders can be orthogonal to one another, the patentee also contemplates that the meander patterns could be "otherwise" oriented. The inclusion in the patent specification of a non-orthogonal arrangement of the first and second meander patterns forecloses Guidant's suggestion that circumferential and longitudinal directions be assigned to the meanders.FN71

FN70. *Id*. col. 4, ll. 36-38 (emphasis added).

FN71. Moreover, to so limit the meanders would render some of the claims redundant, violating the canon of "claim differentiation." Karlin Tech. Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 972 (Fed.Cir.1999). This principle is not a "rigid rule" and is "ultimately based on the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope [and] normally means that the limitations stated in dependent claims are not to be read into the independent claim from which they depend." *Id*.
For example, claim 1 of the '982 Patent describes:

1. An expandable stent for supporting a vessel, wherein in the expanded and deployed state, the stent consists of:

(a) first meander patterns having loops, the first meander patterns being longitudinally spaced from each other and having axes extending in a first direction; and
(b) second meander patterns having loops, the second meander patterns having axes extending in a second direction, different than the first direction....
[(c)-(e) omitted]

'982 Patent, col. 6, ll. 29-36. Claim 3 asserts a "stent according to claim 2 and wherein said first direction extends in a circumferential direction." *Id*. col. 6, ll. 51-52. Claim 4 discloses a "stent according to claim 3, wherein the second direction extends in a longitudinal direction." *Id*. col. 6, ll. 53-54. To ascribe circumferential and longitudinal directions to the first and second meanders would render the words "circumferential" and "longitudinal" in claims 3 and 4 irrelevant.
However, the written description of the patent clearly provides that the first meander is sinusoidal about a center line. The written description states that "[m]eander pattern 11 is a vertical sinusoid having a vertical center line 9." FN72 Accordingly, the term "first meander" is construed as follows: a periodic sinusoidal pattern about a center line.FN73 The phrase "second meander" is not indefinite. Rather, it is defined as a periodic pattern about a center line oriented in a direction different from the axis of the first meanders.FN74

FN72. '303 Patent, col. 2, ll. 63-64 (referencing Figures 1-4).

FN73. Guidant would also include the phrase "uniformly distributed" in the definition of a first meander, arguing that the ordinary meaning of "center line" is a "real or imaginary line that is equidistant from the surface or sides of something." Webster's Ninth New Collegiate Dictionary (1991), *cited in* Guidant's *Markman* Hearing Slide Presentation at 12. Thus, the phrase "about a center line" requires that the meander pattern be uniformly distributed about the line. But the meaning of "uniformly distributed" is adequately captured by the words "center line." To use both "uniformly distributed" and "center line" would be needlessly redundant.

FN74. *See* '303 Patent, col. 3, ll. 3-4.

B. "Loop"

Loop is contained in claims: 13, 16, 18, 27, and 28 of the '120 Patent; 1, 2-15, and 17 of the '982 Patent; and 61 and 68 of the '381 Patent.FN75 Medinol proposes the following plain meaning definition for "loop": "[a] structural element[ ] that turn[s] back on [itself]." FN76 Guidant submits that Medinol did not use the word consistently with its ordinary meaning and defines "loop" as a "C- or U-shaped structure." FN77

FN75. *See* '120 Patent, col. 7, ll. 19-20, 23, 42-43, col. 8, ll. 14, 20, 46; '982 Patent, col. 5, ll. 31, 34, 40, 46, 49, 60; '381 Patent, col. 10, ll. 33, 35, col. 11, ll. 18, 20.

FN76. Pl. Mem. at 16.

FN77. Def. Mem. at 16.

The intrinsic record makes clear Medinol's intent to define "loop" to mean a C-or U-shaped structure rather than simply a structural element that turns back on itself. *First,* the patents-in-suit neither describe nor depict a "loop" as an element that turns back on itself. Rather, "loop" is consistently used to identify structures that are either C- or U-shaped.FN78 *Second,* the Pinchasik '373 Patent, a predecessor to the patents-in-suit, tellingly does not use the word "loops," but uses "kinks" to describe its lightning bolt, or S-shaped, curves.FN79 By contrast, the '303 Patent provides that "[m]eander pattern 11 has two loops 14 and 16 per period wherein loops 14 open to the right while loops 16 open to the left." FN80 Loops 14 and 16 are clearly C-shaped structures and are dissimilar from the "kinks" presented in the Pinchasik '373 Patent.FN81 Thus, the designs disclosed in the patents-in-suit no longer contain "kinks," but "loops." But Medinol's proposed definition-a structural element that turns back on itself-would cover both kinks and loops as used in the patent specification. Based on the foregoing, Medinol imparted special meaning to the word "loop," using it to describe a structural element that is either C-shaped (loops associated with the first meander) or U-shaped (loops associated with the second meander).FN82

FN78. In some instances, the ends of the "loop" even turn outward. *See, e.g.,* '303 Patent, Figure 8 (depicting an expanded stent).

FN79. *See* Pinchasik '373 Patent, col. 4, ll. 63-68; *see also* id. Figures 3A, 3B, 3C.

FN80. '303 Patent, col. 2, ll. 64-66. *See also* id. Figures 1-4.

FN81. *See* id. Figures 1-4.

FN82. *See* id. col. 2, ll. 64-66 (describing meander pattern 11, which is the first meander pattern); id. col. 3,

ll. 4-7 (noting that meander pattern 12, the second meander, has loops that open downward (loop 18) and upwards (loop 20)); *see also* Figures 1-4. The same structure is disclosed in the other embodiments of the stent design. *See* id. col. 5, ll. 6-13 ("The stent also includes a first loop 63 defining a first angle 64 disposed between the first end 52 of the first member 51 and the first end 55 of the second member 54. A second loop 65 defining a second angle 66 is disposed between the second end 59 of the third member 57 and the second end 62 of the fourth member 60 and is disposed generally opposite to the first loop 63); col. 4, ll. 5-9 (describing loops); *see also* id. Figures 5A-5B, 7-8.

C. "Spaced Apart" or "Longitudinally Spaced From"

"Spaced apart" or "longitudinally spaced from" is used in claims: 27 and 28 of the '120 Patent; and 1, 2-15, and 17 of the '982 Patent.FN83 Medinol defines "spaced apart" as "[s]eparated" and "longitudinally spaced from" as "[s]eparated along the longitudinal axis." FN84 Guidant, by contrast, submits that the terms mean "[t]he apices of adjacent cells along the longitudinal axis are separated from one another in space *by a flexible connector*." FN85

FN83. *See* '120 Patent, col. 8, l. 16; '982 Patent, col. 6, l. 32.

FN84. Claim Chart at 4.

FN85. Def. Mem. at 20 (emphasis added).

The words "spaced apart" and "longitudinally spaced from" are used in the asserted claims consistently with their accustomed meaning. In other words, "spaced apart" means "separated" and "longitudinally spaced from" means "separated along the longitudinal axis." FN86 For instance, claim 21 of the '120 Patent, upon which asserted claims 27 and 28 depend, discloses:

FN86. *See* Webster's New World Dictionary 1363 (2d Coll. ed. 1974 ("New World Dictionary"), Ex. I to the 8/20/04 Declaration of Fabian D. Gonell, counsel for Medinol ("Gonnell Decl.") (defining "spaced" as "to arrange with space or spaces in between"), *cited in* Medinol's *Markman* Hearing Slide Presentation ("Pl.Sl.") at 47; *see also id*. at 63 (defining "apart" as "separately or away in place or time), *cited in* Pl. Sl. at 47.

A stent formed of a tube having a patterned shape, the patterned shape comprising:
a. first meander patterns having axes extending in a first direction;

b. second meander patterns having axes extending in a second direction, different than said first direction, wherein said second meander patterns intersect with said first meander patterns;

c. wherein said first meander patterns have loops;

d. wherein said first meander patterns are spaced apart to leave a portion of said second meander patterns between each pair of adjacent first meander patterns;

e. wherein each of said second meander patterns has at least one loop between at least one pair of adjacent first meander patterns.FN87

FN87. '120 Patent, col. 8, ll. 6-20.

The claim language makes clear that the term "spaced apart" means separated- *i.e.*, that the first meanders are placed at some distance from one another. That part of the second meander pattern (a loop) is positioned in the space between first meanders is an *additional* limitation, independent from the words "spaced apart."

The prosecution history cited by Guidant fails to contradict this conclusion. Medinol argued to the PTO that "the claims have been amended to make clear that the first meander patterns are spaced from each other *and* that the loop is in the space between meander patterns, a limitation discussed at the interview as better defining the relationship." FN88 It follows from this statement that "spaced apart" is used to describe only the relative position of the first meander patterns, not the entire structure of the stent. Accordingly, there is no basis for requiring a loop of the second meander to fill the space between first meanders. Thus, Guidant has failed to demonstrate that Medinol intended for these terms to be used in a manner contrary to their plain and ordinary meaning and "spaced apart" and "longitudinally spaced from" are thus respectively defined as "separated" and "separated along the longitudinal axis."

FN88. 4/8/02 Response to Office Action Under 37 C.F.R. s. 1.111 from U .S. Application No. 09/489,362 (Paper # 15), Ex. 37 to Lee Aff. at 12 (emphasis added).

D. "Enclosed Spaces"

The phrase "enclosed spaces" appears in claims: 13, 16, and 18 of the '120 Patent; and 6 and 7 of the '982 Patent.FN89 Medinol contends that the phrase "enclosed spaces" is used consistent with its ordinary meaning, referring to "the area defined by the structural elements of a cell." FN90 Alternatively, Guidant construes this term as simply identifying "[a] cell." FN91

FN89. *See* '120 Patent, col. 7, l. 26; '982 Patent, col. 6, ll. 59, 61-62.

FN90. Pl. Mem. at 16. Medinol notes that the "plain meaning of 'enclose' is to 'close in' or 'surround,' " *id.* (citing Webster's Third International Dictionary 746 (1976) ("Webster's Third"), Ex. J to Gonnell Decl., and New World Dictionary at 460), and "space" is ordinarily defined in contexts such as this as "the distance, expanse, or area ... within ... things," *id.* (citing Webster's Third at 2180 (definition 2a) and New World Dictionary at 1363 (definition 2a).

FN91. Def. Mem. at 24.

Guidant's proposed definition is improper for at least two reasons. *First,* "enclosed space" is distinguished from "cell" in the patent specification. For instance, in describing Figure 4 of the '303 Patent, the patentee

includes the following language: "When the stent expands, both meander patterns 11 and 12 expand (i.e. all loops 14-20 open up). As can be seen, the expanded stent has two types of enclosed spaces, a large space 42 between meander patterns 12 *o* and 12 *e* and a small space 44 between meander patterns 12 *e* and 12 *o*." FN92 As depicted in Figure 4, "enclosed spaces" refers to the area contained within first and second meander patterns. By contrast, the word "cell" is used to refer to the structural elements outlining the enclosed spaces. For example, in Figure 8, the invention is described as "an expandable stent defining a longitudinal aperture 80 having a longitudinal axis or extension 79 and a circumferential axis or extension 105, including a plurality of flexible connected *cells* 50.... Each *cell* 50...." FN93

FN92. '303 Patent, col. 3, ll. 51-55. *See also id*. Figure 4.

FN93. *Id*. col. 4, ll. 57-62 (emphasis added).

Second, the language cited by Guidant as supportive of its definition does not amount to an unambiguous disavowal of the claim scope, justifying a departure from Medinol's plain meaning definition for "enclosed spaces." That is, the specification states:

FIG. 8 illustrates the pattern of FIG. 7 in an expanded format. Since there are no even and odd horizontal meander patterns, in the expanded format of FIG. 8, there are no large and small spaces. Instead, all spaces are of the same size, i.e., the stent is comprised of a plurality of spaces or cells 50 defining a uniform cellular structure.FN94

FN94. *Id*. col. 4, ll. 50-55.

But this passage does not clearly indicate that "enclosed spaces" and "cells" are interchangeable terms used to identify the same structure. One skilled in the art could have read the cited passage as suggesting that the uniform cellular structure is described as comprising either enclosed spaces or cells. FN95 Because the cited language is not a clear disclaimer of the customary meaning of the word "enclosed spaces," and because this term is used consistently with its ordinary meaning in the specification, "enclosed spaces" is defined to mean the area enclosed by the structural elements of a cell.

FN95. Moreover, the identifier "50" is placed on Figure 8 close to the perimeter of the structure; whereas on Figure 4, "42" is placed directly in the center of the area. This further suggests that "50" refers to the structure around the enclosed space, while "42" references the enclosed space itself. *See id*. Figures 4, 8.

E. "Cell"

"Cell(s)" is (are) used in claims: 28 of the '303 Patent; 51 of the '018 Patent, 56-58, 61, 63, 65-66, 68-70 of the '381 Patent.FN96 Medinol asserts that "cell" and "cells" mean "an arrangement of structural elements that defines an enclosed space." FN97 Guidant proposes the following definition for these terms: "A first and second loop at the two longitudinal ends and a first and second flexible link that define a small enclosed space." FN98

FN96. *See, e.g.,* '303 Patent col. 10, ll. 16, 23; '018 Patent col. 13, ll. 13, 18; '381 Patent, col. 10, ll. 11, 15, 31, 34, col. 11, ll. 2, 16, 19.

FN97. Pl. Mem. at 17. *Accord Cordis* Order at 2.

FN98. Def. Mem. at 21.

The plain meaning of "cell" is, as the *Cordis* court found, an arrangement of structural elements that defines an enclosed space .FN99 Guidant's suggested construction cannot be adopted because it is overly restrictive. This definition only relates to the preferred embodiment depicted in Figures 7 and 8, and excludes the preferred embodiment reflected in Figures 1-4. Specifically, Figure 4 contemplates a cell that has four loops at the longitudinal ends, two interior longitudinal loops, and two flexible links. FN100 The text of the patent itself indicates that Figures 4, 7, and 8 collectively represent two different "preferred embodiments" of the invention. FN101 Accordingly, to restrict the term "cell" to the manner in which it is represented for purposes of Figures 7 and 8 would improperly exclude another preferred embodiment of the invention.FN102 Accordingly, the term "cell" is defined as an arrangement of structural elements that defines an enclosed space.

FN99. *See Cordis* Order at 2.

FN100. *See* '303 Patent, Figure 4; *see also* Pl. Sl. at 79.

FN101. '303 Patent, col. 2, ll. 24-26, 32-33, 38-41.

FN102. *See* Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1347 (Fed.Cir.2004) ("Apotex's construction also violates the principle that claims should rarely, if ever, be construed to exclude a preferred embodiment.").

F. "Flexible Cells"

The words "flexible cells" must be construed for purposes of claims: 28 of the '303 Patent; 51 of the '018 Patent, 56-58, 61, 63, 65-66, 68-70 of the '381 Patent.FN103 Medinol proposes that "flexible cell" should be defined as "an arrangement of structural elements that defines an enclosed space and that is capable of being bent or flexed." FN104 Guidant interprets "flexible cells" as follows: "A first and second loop at the two longitudinal ends and a first and second link that define a small enclosed space. The cells must be substantially flexible prior to expansion of the stent and substantially rigid after expansion of the stent." FN105

FN103. *See* '303 Patent, col. 10, ll. 16-17, 20, 23; '018 Patent, col. 13, ll. 11, 14; '381 Patent, col. 9, ll. 59-61, col. 10, ll. 21, 39, 46, col. 11, ll. 3, 11, 25.

FN104. Pl. Mem. at 18.

FN105. Def. Mem. at 23.

As Guidant argues, Medinol's stent design "hinges on 'flexible cells' being flexible before expansion and rigid afterward." FN106 Indeed, during prosecution, Medinol unambiguously imparted a particular meaning to "flexible cell." For example, Medinol distinguished its invention from the prior art, stating:

FN106. Guidant's Reply Brief on Claim Construction ("Def.Reply") at 14.

[T]he articulated stent disclosed in the '373 patent is flexible only at the articulation points where the connectors connect the substantially rigid segments. In contrast, the Applicant's invention and the pending claims are directed to a flexible expandable stent whose unique meander patterns and structure define a plurality of flexible expandable cells that are substantially flexible prior to expansion of the stent and substantially rigid after expansion of the stent that permit the stent to be substantially uniformly flexible along its entire length prior to expansion of the stent. FN107

FN107. 3/20/98 Response Under 37 C.F.R. s. 1.111 from U.S. Application No. 08/881, 594 (Paper # 5), Ex. 23 to Lee Aff., at 8. *See also* 1/4/01 Supplemental Information Disclosure Statement ("IDS") from U.S. Application No. 09/337, 629 (Paper # 12), Ex. 38 to Lee Aff., at 7 ("These deficiencies in scaffolding are attributable to the fact that the Burmeister Figure 14 design is not a flexible 'closed cell' design, as claimed in the Medinol patents."). Contrary to Medinol's arguments, this language plainly reveals that Medinol intended this disclaimer to apply to the entire stent design, not just the particular claims then in dispute. *See* Digital Biometrics, 149 F.3d at 1347 ("The public has a right to rely on such definitive statements made during prosecution. Notice is an important function of the patent prosecution process, as reflected by [35 U.S.C. s. 112, para. 2] and recently confirmed by the Supreme Court. Absent qualifying language in the remarks, arguments made to obtain the allowance of one claim are relevant to interpreting other claims in the same patent.") (citations omitted).

This explanation makes quite clear that Medinol intended for the phrase "flexible cell" to have a meaning altogether different from a compilation of dictionary definitions for the words "flexible" and "cell." A significant aspect of the invention, "flexible cell" has a special meaning, referring to cells that are flexible prior to expansion and rigid upon expansion. Thus, flexible cell is construed as follows: An arrangement of structural elements that defines an enclosed space. The cells must be substantially flexible prior to expansion of the stent and substantially rigid after expansion of the stent.

G. "Flexible Link"

The following claims incorporate the phrase "flexible link": 28 of the '303 Patent; 51 of the '018 Patent, 56-58, 61, 63, 65-66, 68-70 of the '381 Patent. FN108 For Medinol, "flexible link" means "a structural element that is flexible with respect to the stent's longitudinal axis and must be aligned along the longitudinal axis of the stent." FN109 Guidant views a "flexible link" as "[a] structural element connecting the apices of

adjacent cells, that is flexible and aligned with respect to the stent's longitudinal axis." FN110

FN108. *See* '303 Patent, col. 10, ll. 23-24; '018 Patent, col. 13, ll. 15-16, 19, 24-25, 27; '381 Patent, col. 9, ll. 66-67, 69-70, col. 10, ll. 2-3, 6, 8, 21, 24, 49, 52, 56-57, 61, 63, col. 11, l. 22.

FN109. Pl. Mem. at 19. *Accord Cordis* Order at 3 (defining "flexible compensating member or flexible link").

FN110. Def. Mem. at 24.

The parties' disagreement over this term arises from Guidant's proposed inclusion of a requirement that the flexible links connect the "apices of adjacent cells." FN111 During prosecution, the patentee distinguished the Palmaz '417 Patent by explaining that:

FN111. *Id*. *See also* Pl. Sl. at 93.

Applicants have also amended Claim 1 to include the limitations of Claim 3 to adjacent cells of adjacent rigid segments. This is in contrast to Palmaz '417 and Cardon whose links are spiral-shaped and therefore, do not connect the apices of adjacent segments. Instead, they connect the apex of a first cell on one segment with the apex of a second cell (of the second segment) which is shifted from the one which is adjacent to the first cell. FN112
FN112. 2/17/95 Amendment Under Rule 116 from U.S. Application No. 08/213,272 (Paper # 9), Ex. 20 to Lee Aff., at 2-3.

This statement reveals that (1) the Palmaz '417 and the "Cardon" Patents connect the apices of non-adjacent cells and (2) the key distinction between claim 1 of the Pinchasik '373, as amended, and the prior art, was the requirement that the flexible links connect the apices of *adjacent* cells. FN113 The amendment related not to the "apices" of the cells, but to the relative location of the connected cells (adjacent versus non-adjacent). The use of flexible links to connect adjacent segments was intended to improve upon designs based on the prior art by avoiding twisting on expansion. It is therefore logical to impart the following definition to the term "flexible link": a structural element connecting adjacent cells that is flexible and aligned with respect to the stent's longitudinal axis.

FN113. The *Cordis* court found that this language clearly indicated that although "neither the prosecution history nor the specification require that the physical connection be made at points directly opposite" to one another, "a flexible compensating member or flexible link must connect adjacent cells." *Cordis* Order at 3 n. 2.

H. "Substantially Uniform Structure of Flexible Cells"

The words "substantially uniform structure of flexible cells" are used in claim 28 of the '303 Patent.FN114

Medinol argues that this term refers to "a stent structure that has a largely repeating distribution of flexible cells that have nearly the same structure." FN115 Guidant contends it means "[a]ll of the cells of the stent have substantially the same structure." FN116

FN114. *See* '303 Patent, col. 10, l. 17.

FN115. Pl. Mem. at 27.

FN116. Def. Mem. at 25.

The phrase "uniform structure of flexible cells" was construed by the *Cordis* court for purposes of claim 12 of the '303 Patent. That court determined that the phrase means "[t]he flexible connected cells of claim 6 have the same structure." FN117 This construction draws from the patent specification, where the patentee states, with respect to Figure 8, that "all spaces are of the same size, i.e., the stent is comprised of a plurality of spaces or cells 50 defining a uniform cellular structure." FN118 The parties agree that this definition is the foundation upon which the meaning of the word "substantially," denoting approximation, must be built.FN119 Given that "uniform structure of flexible cells" means "[t]he flexible connected cells ... have the same structure," it is clear that the word "uniform" is taken to modify the structure, rather than the overall arrangement, of the flexible connected cells. The word "substantial," then, also modifies the structure of the cells- *i.e.,* as Guidant indicates, the phrase "substantially uniform structure of flexible cells" means that all of the flexible connected cells have approximately the same structure.FN120

FN117. *Scimed Life Sys.,* 87 Fed.App. at 735 (affirming the finding of the district court as to this claim term).

FN118. '303 Patent, col. 4, ll. 53-55.

FN119. *See* Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1360 (Fed.Cir.2003) ("The term 'substantially,' as used in this context, denotes approximation."), *cert. denied,* 124 S.Ct. 1426 (2004); *see also* Tr. at 91 (statement of Keith Hummel, counsel for Medinol) ("Judge Robinson did not construe our term, but she construed ... uniform cellular structure. And she said uniform cellular structure is the flexible connected cells of claim 6 have the same structure.... We have taken her language, have the same structure, and changed it to nearly the same structure, which is a term of approximation."); *id.* at 143 (statement of Christine Lehman, counsel for Guidant) ("Judge Robinson told us, uniform cellular structure means flexible connected cells of claim 6 have the same structure. So we know that. And this actually was the one claim construction issue that the federal circuit did address.").

FN120. Medinol's primary objection to Guidant's proposed construction of this term relates to the use of the word "including" in the claim language. Specifically, the claim reads, in relevant part: "An expandable stent, *including:* a plurality of connected cells having a longitudinal axis defining a substantially uniform structure of flexible cells having a longitudinal axis and a circumferential axis substantially perpendicular to said

longitudinal axis...." '303 Patent, col. 10, ll. 14-19 (emphasis added). Defining the word "including" to mean less than all, Medinol asserts that, according to the specification, not all of the cells can have substantially the same structure. But Medinol has explicitly made statements to the contrary, arguing that notwithstanding the patentee's use of the word "including" in claim 12 of the '303 Patent, the term "uniform structure of flexible cells," refers to "all cells of the stent." *See* Medinol's Brief in Support of Its Appeal in the *Cordis* Action (filed under seal), Ex. 48 to 9/9/04 Affirmation of Robert F. Shaffer, counsel for Guidant, at 37-39. Accordingly, Medinol's argument for a restrictive reading of "including" fails.

I. "Substantially Uniformly Flexible (with Respect to Its Longitudinal Axis)"

"Substantially uniformly flexible (with respect to its longitudinal axis)" is referenced in claim 51 of the '018 Patent.FN121 Medinol interprets this phrase to mean "the stent's flexibility is nearly the same as one moves along the longitudinal axis of the stent." FN122 Guidant defines it as follows: "The structural elements of the cells provide longitudinal flexibility, such that the flexibility of the stent is substantially uniform only prior to expansion, as one moves along the longitudinal axis of the stent." FN123

FN121. *See* '018 Patent, col. 13, ll. 4-6 ("A generally longitudinally extending tubular stent which is substantially uniformly flexible with respect to its longitudinal axis, said stent consisting essentially of....").

FN122. Pl. Mem. at 28.

FN123. Def. Mem. at 26.

The *Cordis* court construed two phrases similar to the term disputed here. *First,* "[s]tent which is substantially uniformly flexible with respect to its longitudinal axis by the flexibility of its cells with respect to said axis," FN124 was defined as: "The structural elements of the cells provide longitudinal flexibility such that the flexibility of the stent is substantially uniform as one moves along the longitudinal axis of the stent." FN125 *Second,* "[s]aid loops adapted so that said stent prior to expansion is substantially uniformly flexible along its longitudinal axis," FN126 was construed as: "The first loops and second loops must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction, to provide substantially uniform flexibility to the unexpanded stent as one moves longitudinally along the stent." FN127

FN124. '018 Patent, col. 12, ll. 25-28.

FN125. *Cordis* Order at 7.

FN126. '018 Patent, col. 10, ll. 66-67-col. 11, l. 1.

FN127. *Cordis* Order at 6.

The parties concur that the primary difference between their respective proposals is Guidant's assertion that the stent is substantially uniformly flexible only prior to expansion.FN128 But inclusion of the phrase "only prior to expansion" in the construction is needlessly repetitive. When used elsewhere in the patent, the phrase "substantially uniformly flexible" is coupled with the words "prior to expansion of the stent," suggesting that including "prior to expansion of the stent" in the definition of "substantially uniformly flexible" would be unnecessarily duplicative. FN129 Accordingly, the term is defined to mean: the flexibility of the stent is substantially uniform as one moves along the longitudinal axis of the stent.

FN128. *See, e.g.,* Pl. Reply at 20; Def. Reply at 17.

FN129. For instance, Claim 39 of the '018 Patent contains the following language: "a plurality of flexible cells provided with a plurality of first loops and a plurality of second loops, said loops adapted so that said stent *prior to expansion* is substantially uniformly flexible along its longitudinal axis...." '018 Patent, col. 10, ll. 65-67-col. 11, l. 1.

J. "Portion with a Substantial Longitudinal Component"

Claims 56-58, 61, 63, 65-66, and 68-70 of the '381 Patent contain references to "portion with a substantial longitudinal component." FN130 Medinol proposes that this term means "a part of a member that has ends at positions a discernable distance from each other with respect to the stent's longitudinal axis." FN131 Guidant suggests a different definition: "A stent element that is substantially more horizontal than vertical along the stent's horizontal [*i.e.,* longitudinal] axis." FN132 The *Cordis* court defined a similar term, "[m]ember having a longitudinal component," as follows: "A 'member' is a structural element that has its ends at different longitudinal positions with respect to the stent's longitudinal axis. A member's 'longitudinal component' is the distance between the longitudinal positions of the first and second ends of the member." FN133

FN130. '381 Patent, col. 10, ll. 12-13, 66-67.

FN131. Pl. Mem. at 23.

FN132. Def. Mem. at 27.

FN133. *Cordis* Order at 2.

The parties' dispute stems from their conflicting views as to the plain meaning of the word "substantial." FN134 Medinol suggests that the meaning of "substantial" as it relates to the disputed phrase, is captured by the construction, "a part of a member that has ends at positions a *discernable* distance from each other with respect to the stent's longitudinal axis." FN135 Because substantial means "of or having substance,"

Medinol's use of "discernable" to describe "of or having substance" in this context is consistent with the ordinary meaning of "substantial." Guidant counters that "substantial" means that the stent element must be more horizontal than vertical, with respect to the longitudinal axis. This argument lacks merit, however, because it imposes an additional restriction supportable by neither the ordinary meaning of the words or the patent specification. That is, Guidant's definition requires that a portion with a substantial longitudinal component has a greater longitudinal length, when compared with its circumferential length. But imparting special meaning to the phrase is not warranted by the intrinsic record. Thus, "portion with a substantial longitudinal component" means a part of a member that has ends at positions a discernable distance from each other with respect to the stent's longitudinal axis.

FN134. *See, e.g.,* Tr. at 150 (Lehman) (noting that the parties disagree as to the "plain meaning" of "substantial"); Pl. Sl. at 109 (presenting the "plain meaning" of the words); Def. Reply at 17 ("Medinol's definition is simply inconsistent with both the dictionary and any common understanding of 'substantial' and should be rejected."). Indeed, the specification uses these words in accordance with their accustomed meaning, and nothing in the intrinsic record suggests that Medinol intended for these words to have a special meaning for purposes of the asserted claims.

FN135. Pl. Mem. at 23 (emphasis added). Medinol notes that the plain meaning of: (1) " 'portion' is 'a part ... of anything,' " *id*. at 24 (quoting New World Dictionary at 1110-11); (2) " 'substantial' is 'having substance,' " *id*. (quoting New World Dictionary at 1420); (3) " 'longitudinal' is 'of or in length' or 'running or placed lengthwise,' " *id*. (quoting New World Dictionary at 834 (defs.1-2)); and (4) " 'component' is 'an element or ingredient,' " *id*. (quoting New World Dictionary at 291).

K. "Extension"

"Extension" must be defined for purposes of claims 28 of the '303 Patent and 51 of the '018 Patent.FN136 Medinol would define "extension" to mean "dimension." FN137 Guidant views this term as equivalent to "[a]n axis." FN138

FN136. *See* '303 Patent, col. 10, l. 25; '018 Patent, col. 13, ll. 7-9, 13, 18.

FN137. Pl. Mem. at 26.

FN138. Def. Mem. at 28.

Defining "extension" as an "axis" makes little sense in light of the claim language. Claim 51 of the '018 Patent recites, in relevant part:

A generally longitudinally extending tubular stent which is substantially uniformly flexible with respect to its longitudinal axis, said stent consisting essentially of: a plurality of flexible cells, each having a longitudinal *extension* parallel to said longitudinal *axis* and a circumferential extension parallel to an arc of a circle around the circumference of the stent.... FN139

FN139. '018 Patent, col. 13, ll. 4-10 (emphasis added).

The use of the words "axis" and "extension" in the same clause indicates that Medinol intended for these words to have different meanings.FN140 It is thus clear that "extension" does not mean "axis." The ordinary understanding of extension is "the property of a body by which it occupies space," or "dimension." FN141 Because this definition is consistent with the intrinsic record, there is no reason to depart from it and therefore, "extension" is defined as dimension.

FN140. *See* Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 93 F.3d 1572, 1579 (Fed.Cir.1996) ("Admittedly, the claim says little about the structure of the 'pusher assembly.' It does clearly imply, however, that whatever 'pusher assembly' means, it is not a synonym for 'pusher bar.' ... If the terms 'pusher assembly' and 'pusher bar' described a single element, one would expect the claim to consistently refer to this element as either a 'pusher bar' or a 'pusher assembly,' but not both, especially not within the same clause. Therefore, in our view, the plain meaning of the claim will not bear a reading that 'pusher assembly' and 'pusher bar' are synonyms."). Guidant cites the following language in support of its reading of "extension" as interchangeable with "axis": "As shown in FIGS. 3, 7 and 8, Applicants' invention can also be described as an expandable stent defining a longitudinal aperture 80 having a *longitudinal axis or extension* 79 and a circumferential axis or extension 105...." '018 Patent, col. 4, ll. 58-61 (emphasis added). Even if this language is taken to mean that the terms "axis" and "extension" are interchangeable in the specification, the patentee uses the terms in Claim 51 in a manner strongly suggesting that "extension" has a meaning apart from "axis." Accordingly, even accepting Guidant's interpretation of the written description, it cannot trump the plain meaning of the word "extension."

FN141. Pl. Sl. at 119 (quoting New World Dictionary at 495-96).

L. "Circumferential Member," "First Circumferential Member" and "Second Circumferential Member"

"Circumferential member" is used in claims 56-58, 61, 63, 65-66, and 68-70 of the '381 Patent.FN142 Medinol argues that "circumferential member" means "a structural element extending in the circumferential direction," noting that the first and second circumferential members "identify and differentiate two different circumferential members." FN143 By contrast, Guidant contends that the term "circumferential member" is indefinite under section 112, but to the extent that it can be construed, it should be defined as "a loop." FN144

FN142. *See* '381 Patent, col. 10, ll. 1, 5, 9-10, 13-14, 16-17, 22, 55, 59, 63-64, 67, col. 11, ll. 1, 12.

FN143. Pl. Mem. at 21.

FN144. Def. Mem. at 28, 30 n. 16.

The term "circumferential member" is not indefinite. The parties agree that the term "member" means a structural element.FN145 Circumferential, used in this context, relates to the circumferential direction. Nonetheless, Guidant submits that a circumferential member is merely a loop. This interpretation is rejected. *First,* Guidant does not identify any part in the intrinsic record limiting "circumferential member" to a loop. *Second,* as Medinol correctly notes, Guidant's proposed definition of "circumferential meander" suffers from overinclusiveness, as it would includes loops with "end points that are not displaced from each other with respect to the stent's circumferential axis, such as reference numerals 18 ... and 20 of Figures 1-4." FN146 Accordingly, the term "circumferential member" describes a structural element extending in the circumferential direction, and the first and second circumferential members identify and differentiate two different circumferential members.

FN145. *See* Claim Chart at 1. Indeed, the language of claim 56 clearly describes a circumferential member: 56. A balloon expandable stent for implantation into a lumen to support the lumen, said stent both in the unexpanded state and in the balloon-expanded state including: a plurality of flexible cells adjacent to one another both circumferentially and longitudinally each of said flexible cells comprising:

a) a first flexible link including an arc, the first flexible link having a first longitudinal end and a second longitudinal end;
b) a second flexible link including an arc, the second flexible link having a first longitudinal end and a second longitudinal end;
c) a first circumferential member disposed between said first longitudinal end of said first flexible link and said first longitudinal end of said second flexible link and;
d) a second circumferential member disposed between said second longitudinal end of said first flexible link and said second longitudinal end of said second flexible link,
e) at least one of said first circumferential member and said second circumferential member in each of said cells having a portion with a substantial longitudinal component that is also a portion with a substantial longitudinal component of a first circumferential member or a second circumferential member in a longitudinally adjacent cell,
wherein in the expanded state the first and second circumferential members have a substantial longitudinal component to provide coverage of the lumen.

'381 Patent, col. 9, ll. 56-57-col. 10, ll. 1-18.
FN146. Pl. Mem. at 23. *See also* '381 Patent, Figures 1-4.

IV. CONCLUSION

In sum, the disputed claim terms are defined as follows:

No.	Disputed Claim Term	Definition
1.	Meander or Meander Pattern	A periodic pattern about a center line.
	First Meander/First	A periodic sinusoidal pattern

		about a center
	Meander Pattern	line.
		A periodic pattern about a center line oriented
	Second Meander/Second	
		in a direction different from the axis of the
	Meander Pattern	
		first meanders.
2.	Loop	A C- or U-shaped structure.
	"Spaced Apart" or	"Spaced apart" means separated.
3.	"Longitudinally Spaced	"Longitudinally spaced from" means
	From"	separated along the longitudinal axis.
		The area enclosed by the structural elements
4.	Enclosed Space(s)	
		of a cell.
		An arrangement of structural elements that
5.	Cell(s)	
		defines an enclosed space.
		An arrangement of structural elements that
		defines an enclosed space. The cells must be
6.	Flexible Cells	substantially flexible prior to expansion of the
		stent and substantially rigid after expansion of
		the stent.
		A structural element connecting adjacent cells
7.	Flexible Link	that is flexible and aligned with respect to the
		stent's longitudinal axis.
	Substantially Uniform	All of the flexible connected cells have
8.		
	Structure of Flexible Cells	approximately the same structure.
	Substantially	The flexibility of the stent is

	Uniformly	substantially
9.	Flexible (with respect to its	uniform as one moves along the longitudinal
	longitudinal axis)	axis of the stent.
		A part of a member that has ends at positions
	Portion with a Substantial	
10.		a discernable distance from each other with
	Longitudinal Component	
		respect to the stent's longitudinal axis.
11.	Extension	Dimension.
		A structural element extending in the
12.	Circumferential Member	
		circumferential direction.
	First and Second	Identify and differentiate two different
	Circumferential Member	circumferential members.

A conference is scheduled for October 7, 2004 at 3:15 p.m. in Courtroom 15C.

SO ORDERED:

S.D.N.Y.,2004.
Medinol Ltd. v. Guidant Corp.

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