United States District Court,
D. Arizona.

BARD PERIPHERAL VASCULAR, INC.; David Goldfarb, M.D,
Plaintiffs.
v.
W.L. GORE & ASSOCIATES, INC,
Defendant.
W.L. GORE & ASSOCIATES, INC,
Counterclaimant.
v.
BARD PERIPHERAL VASCULAR, INC., David Goldfarb, M.D., and C.R. Bard, Inc,
Counterdefendants.

No. CV 03 0597 PHX MHM

Sept. 16, 2006.

Katherine R. Saunders, Latham & Watkins LLP, Washington, DC, Lawrence M. Green, Wolf Greenfield & Sacks PC, Boston, MA, Matthew B. Lehr, Latham & Watkins LLP, Menlo Park, CA, for Plaintiffs.

Arnold I. Rady, David H. Pfeffer, James W. Gould, Matthew Kemp Blackburn, Morgan & Finnegan LLP, New York, NY, Brett L. Dunkelman, William J. Maledon, Osborn Maledon PA, Phoenix, AZ, John S. Campbell, WL Gore & Associates Inc., Newark, DE, for Defendant and Counterclaimant.

Bhavana Joneja, Christine Willgoos, Jane A. Massaro, Jesse J. Jenner, Pablo D. Hendler, Robert B. Wilson, Fish & Neave, Steven C. Cherny, Latham & Watkins LLC, New York, NY, James F. Polese, Polese Pietzsch Williams & Nolan PA, Phoenix, AZ, Katherine R. Saunders, Maximilian A. Grant, Latham & Watkins LLP, Washington, DC, Marc K. Temin, Peter B. Ellis, Vickie L. Henry, Foley Hoag LLP, Boston, MA, Matthew B. Lehr, Latham & Watkins LLP, Menlo Park, CA, Shawn E. McDonald, Latham & Watkins LLP, Los Angeles, CA, for Counterdefendants.

ORDER

MURGUIA**, J.**

Currently before the Court are the parties' objections and comments (Doc.315-16, 329-34) to the Special Master's Report and Recommendations on Claim Construction ("Report"). (Doc. 314). The Court heard oral argument on the issues on May 12, 2006. The Court has reviewed the parties' filed objections and comments, the transcript of the claims construction hearing before the Special Master, and all relevant documents that have been submitted, including the additional case law cited at the hearing.

Defendant W.L. Gore & Associates, Inc. ("Gore") has filed objections to three specific portions of the Special Master's Report and Recommendation. Plaintiffs ("Bard") have filed comments to the Special Master's Report and Recommendation but have not submitted any objection for review by this Court.

In its first objection, Gore has cited paragraph 55 of the Report wherein the Special Master recommends that "all claims mentioning 'ingrowth' in the body or the whereby clause require that the ePTFE structure, at a

minimum, allows fibroblasts and red blood cells to enter the pores of the node and fibril microstructures of the ePTFE component of the graft." It is further stated in this paragraph that "the Special Master recommends that for those claims that recite that the ePTFE structure 'permits tissue 'ingrowth,' i.e., claims 20-24 and 27, the structure must allow organized host tissue to grow into the pores of the node and fibril microstructure." Gore contends that this proposed construction is partially erroneous because it does not add that all such ingrowth must be "transmural", i.e., through the wall. Gore argues in support of this contention that the Special Master failed to apply clear and consistent teaching of the patent specification describing ingrowth as "transmural" and that Dr. Goldfarb asserted "transmural" ingrowth to overcome a rejection by the patent examiner.

As to the first prong of its argument, Gore refers to a recitation in the specification at Col. 3, lines 40-55 which states as follows:

... the invention constitutes a prosthetic vascular device formed from a small bore tube of polytetrafluoroethylene which has been heated, expanded and sintered so as to have a microscopic superstructure of uniformly distributed nodes interconnected by fibrils and characterized by: (a) an average internodular distance which is (i) large enough to allow transmural migration of typical red cells and fibroblast, ...

Gore claims that this language indicating that the invention "constitutes" a prosthetic vascular device that "allow[s] transmural migration of typical red cells and fibroblast" refers to required "transmural ingrowth" since that is the description of what the invention "constitutes."

The Court concludes that the Special Master's recommended findings are not erroneous on this issue. The specification does not require complete transmural ingrowth as indicated by the words "to allow" which is permissive rather than restrictive. The Special Master indicated that the specification actually discloses that the objective is that the invention provides a structure that "will allow" transmural cellular ingrowth and assure the establishment of a viable neointima. (Report, para.46). As noted by the Special Master, Gore made this argument even though claims 1-6, 8-11 and 17-19 mention ingrowth in the "whereby" clause; claims 20-24 and 27 recite "which permits tissue ingrowth"; and claims 14-16 and 25-26 do not mention ingrowth at all. (Report, para.39). The Special Master further based his recommended finding on the recitation in claim 20 that the structure "prevent transmural blood flow" indicating that the applicant knew how to use the term "transmural" when he wanted to but did not use it when describing ingrowth in the claims. (Report, para.44). As discussed by the Special Master, providing objectives in a specification does not create claim limitations, citing Phillips v. AWH Corp., 415 F.3d 1303, 1327 (Fed.Cir.2005). (Report, para.45).

In support of its objection, Gore relies on Nystrom v. Trex Co., Inc., 424 F.3d 1136 (Fed.Cir.2005), as holding that the true test is what the patentee actually described in his specification as his invention. In *Nystrom,* in the Summary of Invention, the patent described the invention as a "decking board ... which also yields a superior product when cut from a log, ..." Id., 424 F.3d at 1139. The Federal Circuit affirmed the district court's claim construction that the word "board" in independent claim 1 meant a "piece of elongated construction material made from wood cut from a log." Id., at 1142-46. After noting that the claims at issue did not include any language describing the "board" as cut from a log or necessarily being made of wood, the court examined the term "board" in the context of the written description and prosecution history of the patent and concluded that the term "board" must be limited to wood cut from a log. Id., at 1143. It was determined that the patentee had consistently used the term "board" to refer to wood cut from a log. Id., at 1145. In the other cases Gore has cited, Kinik Co. v. Int'l Trade Comm'n, 362 F.3d 1359 (Fed.Cir.2004), and Lizardtech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336 (Fed.Cir.2005), the patentee's repeated references in the specification limited the construction of the claims.

As discussed above, however, the description at issue in the case at bar does not require complete

transmural ingrowth as indicated by the words "to allow" which is permissive rather than restrictive. The Court agrees with the Special Master that the applicant did not use the term "ingrowth" in a manner consistent with only one meaning. The Court also agrees with the Special Master that the reference to transmural ingrowth and neointima formation as objectives in the specification does not create a claim limitation. See Col. 3, lines 27-30 ("... it is a major objective of the present invention to provide a homogeneously porous vascular prosthesis characterized by small nodes interconnected by extremely fine fibrils to form an open superstructure which will allow uniform, controlled transmural cellular ingrowth and thereby assure the establishment and maintenance of a thin, viable neointima ...").

As for the second part of Gore's objection, Gore cites Seachange Intern., Inc. v. C-COR, Inc., 413 F.3d 1361 (Fed.Cir.2005), which involved a method and apparatus for redundantly storing video data in "distributed computer systems." Claim 1 of the patent was said to require "interconnecting each one of said processor systems in a point-to-point two way channel interconnection with each other one of said processor systems." Id., at 1369. Claim 37 was identical to claim 1 except that claim 37 required only that the interconnection be through a "network for data communications." *Id*. The applicant argued during the prosecution to overcome and to distinguish references that the prior art did not suggest connecting each processor via point-to-point, two-way channel interconnections. The Federal Circuit agreed with C-COR that the "[a]] pplicant's arguments made during the prosecution narrowed the scope of the 'network for data communications' limitation in claim 37(40) to cover only a point-to-point network." *Id.,* at 1372. The Federal Circuit set forth the applicable principles as follows:

Where an applicant argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of otherwise broad claim language. [Rheoux, Inc. v. Entact, Inc., 276 F.3d 1319, 1325 (Fed.Cir.2002)] ("Explicit arguments made during prosecution to overcome prior art can lead to narrow claim interpretations"); Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed.Cir.1997)("[S]ince, by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is by implication surrendering such protection."). A disclaimer must be clear and unambiguous.

Id., 413 F.3d at 1372-73.

In this case, the Special Master has recommended that the applicant distinguished the prior art on the basis that it had no ingrowth at all, not on the degree of the ingrowth. (Report, para.53). The Special Master found no unambiguous statement that the ingrowth in the patented invention must be complete and transmural, even though that is an objective of the invention. (*id*.). The Special Master based his recommended conclusion on a thorough review of the record and applicable case law. The Court agrees with the Special Master's recommendation and does not find this recommended conclusion erroneous in light of Gore's argument or the case law cited in support. Gore's objections regarding the Special Master's recommended construction of the phrase "which permits transmural ingrowth" are overruled.

Next, Gore contends that the Special Master erred in failing to construe claims 20-27 as requiring a uniform distribution of nodes. Gore states that it does not challenge the Special Master's recommended construction that all claims that recite a "substantially uniform distribution of nodes" as needing to satisfy that element but that claims 20-27 should have been included in that recommended construction even though the requirement is not expressly stated in those claims. Gore argues that the Special Master's rationale for excluding claims 20-27 as requiring a uniform distribution of nodes, that is, that these claims were added some time after Dr. Goldfarb's reliance on the requirement to overcome the prior art, does not withstand scrutiny. Gore refers the Court to paragraph 54 of the Report and Recommendation in which the Special Master discussed the case law relevant to the applicability of earlier arguments to later-added claims as generally requiring the presence of the same limitation or term addressed in or relevant to the prior arguments. The Special Master further noted in paragraph 54 that in limited cases the totality of the prosecution history may require such restriction even when the relevant term or limitation has been

excluded from the language of a later claim, citing Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1372 (Fed.Cir.2003). Gore relies on *Alloc* in support of its present objection. The Special Master recommended in paragraph 54 that the prosecution history of the present case, unlike that in *Alloc,* does not contain arguments accompanying the later claims indicating that the "ingrowth" requirement remained a basis of patentability.

With respect to his discussion regarding the construction of the terms "substantially uniform distribution of nodes" at section E of the Report, the Special Master observed that the phrase appears in claims 1-6, 8-11, and 14-19 but that Gore had asserted that the limitation should apply to all of the asserted claims. (Report, para.63). At paragraph 67 of the Report, the Special Master rejected Gore's argument, stating his recommendation as follows:

However, the Special Master does not agree with Gore that the specification or the prosecution history lend some special meaning to the phrase. Though both contain statements as to the importance of uniform distribution of nodes, none provides the sort of unambiguous disclaimer or definition required to depart from the words of the claim themselves. Thus, the Special Master's construction of the phrase applies only to those particular claims in which it appears, i.e., claims 1-6, 8-11, and 14-19.

(Doc. 314, para.67).

Gore's present objection relies on language recited from the specification at Col. 3, lines 40-44, to the effect that the "invention constitutes a prosthetic vascular device formed ... so as to have a microscopic superstructure of uniformly distributed nodes interconnected by fibrils ..." As the Special Master has recommended, the specification and prosecution history "[b]oth contain statements as to the importance of uniform distribution of nodes, none provides the sort of unambiguous disclaimer or definition required to depart from the words of the claim themselves." (Report, para.67). Claims 20-27 do not recite the phrase "uniform distribution of nodes" at all much less as a requirement. While claims must be interpreted in light of the specification, the Court must avoid impermissibly importing limitations from the specification. Alloc, 342 F.3d at 1370 (cited references omitted). *See,* Callicrate v. Wadsworth Mfg., Inc., 427 F.3d 1361, 1368 (Fed.Cir.2005)(it is improper to import limitations from the specification into the claims, and thereby restrict the claims to coverage of a limited embodiment). Gore's objection is overruled.

As to Gore's third objection, Gore states that the parties and the Special Master have agreed that an identical construction should be given to each of the introductory terms in each of the claims, that is, "prosthetic vascular structure," "prosthetic vascular graft", and "artificial vascular prosthesis". (Doc.315, at p. 11). The Special Master has recommended that these terms be defined as "a structure used to replace, repair, augment, or bypass blood vessels." (Report, para.26). Gore contends that the proposed construction is improper to the extent that it includes "augment" or "repair." Gore contends that the operative word is "prosthesis" or its adjective form "prosthetic" as referring to "an artificial device to replace a missing part of the body." In support of this definition, Gore refers to the definition set forth in *Webster's Third New International Dictionary* (1972 ed.), noting that medical dictionaries published in 1981, 1985 and 1993 were in accord. Gore challenges Bard's reference in its opening *Markman* brief that the meaning of the term "prosthesis" has been expanded in or about 2003 to include "an artificial device to replace or *augment* a missing or impaired part of the body." (emphasis supplied). (Doc. 315, at p. 12).

As part of its objection, Gore contends that the Special Master was incorrect when he stated at paragraph 13 of his Report that "Gore does not dispute that these terms' generally understood meaning in the art would extend to structures used to repair or augment blood vessels ..." Gore contends that it has expressly denied that "augment" was part of a 1974 definition of prosthesis and that it has never asserted any argument about "repair" in the proceedings. (Doc. 315, at p. 12).

At paragraph 14 of the Report, the Special Master noted that Gore had disagreed that it had conceded that

any relevant dictionary definition of prosthesis, prosthetic structure or graft includes devices used to repair or augment blood vessels. The Special Master went on to note in paragraph 14 that at the claims construction hearing, Gore had specifically acknowledged that there are such things as "patch grafts" or "patch prostheses" but had argued that the claims could not cover such structures because "there is no disclosure of a flat patch ... [and][t]he only description is tubular", citing the hearing transcript. The Special Master further observed that Gore had stressed that the claims cover structures used to "replace and bypass but not repair" "because of the specification", again citing the hearing transcript.

As part of this present objection, Gore further argues that there is nothing in the intrinsic record, or the 1974 extrinsic record, which supports the Special Master's recommended conclusion that his construction "reflects the understanding of the meaning of these phrases to one skilled in the art based on the patent and the rest of the intrinsic record", as set forth at paragraph 25 of the Report. Gore therefore contends that there is no support in the intrinsic record, or in the 1974 extrinsic record, for "prosthesis" to be construed to include devices which "repair" or "augment."

In paragraph 14, the Special Master recommended that, despite whether Gore's statements at the hearing can be considered concessions, "intrinsic evidence from the patent's prosecution history contains references that indicate that one skilled in the art of the invention at the time of the application would understand the terms 'graft' and 'prosthesis' to include devices used to patch, and thus repair or augment, a blood vessel." The Special Master in support of the recommended finding cited four scientific articles which were prior art references listed on the first few pages of the patent. These articles indicated that patches or patch grafts were known in the prior art by 1974.

The Special Master analyzed the issue based on a thorough discussion set forth in several paragraphs of his Report. (Report, paras.16-25). The Special Master considered whether the words should be accorded their ordinary meaning in the art or whether this meaning should be narrowed by the disclosure of the patent specification. (Report, para.16). As part of his proposed findings, the Special Master, after citing relevant case law, recommended that the embodiments are exemplary and not restrictive. (Report, para.21). The Special Master also found in part that "there was no disclaimer of non-tubular or non-sutured embodiments, or of embodiments used to repair or augment a blood vessel." (Report, para.23). The Special Master specifically noted that "[t]he patent also expressly states that the claimed prosthesis 'may assume many embodiments and configurations other than those specifically set forth and described' in the specification, providing examples," referring to Col. 9, lines 20-28. (Report, para.21). The Special Master supported his recommended conclusion with a thorough analysis of the issue and case law. The Special Master has recommended that the phrases be construed as "a structure used to replace, repair, augment or bypass blood vessels" (Report, para.26), stating that he has "articulated the construction using language that he believes more simply reflects the understanding of the meaning of these phrases to one skilled in the art based on the patent and the rest of the intrinsic record." (Report, para.25).

The Court has considered Gore's objection based on a recitation in the specification that "a principle objective of the invention" is to "provide a prosthetic vascular structure capable of replacing or bypassing natural blood vessels ...", citing Col. 1, lines 25-27, as well as Gore's objection based on the absence of any pre-1974 dictionary definition that included "repair" or "augment." The Court also has considered Gore's objection regarding the Special Master's consideration of pre-1974 scientific articles as indicating that the devices could be used "to patch" and "thus repair or augment" a blood vessel. The Special Master set forth his legal conclusions in part at paragraph 17, including that "[c]laims may cover such after-arising technology, which logically can never be described in the patent specification. (citation omitted)." See also the Report at paras. 18, 21-22 & 25. The Special Master gave the terms their ordinary meanings to persons of skill in the art at the time of the invention based on the patent and the rest of the intrinsic record. This recommended construction is consistent with Phillips, 415 F.3d at 1313 ("the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."). The

Court is in agreement with the recommendation of the Special Master. Gore's objection is overruled.

Bard has asked that the Court adopt the constructions in the Special Master's Report and Recommendation, subject to and reserving its rights on appeal as to the one objection it made to the Special Master's preliminary report. Bard objected to the Special Master's construction of the term "substantially uniform distribution of nodes" which appears in claims 1-6, 8-11, and 14-19. (Doc. 316, at page 5 n. 3). Bard has not raised this objection to this Court and therefore it has not been considered.

Accordingly,

IT IS ORDERED that Gore's objections to the Special Master's Report and Recommendation (Doc. 315) are overruled.

IT IS FURTHER ORDERED adopting the Report and Recommendation of the Special Master (Doc. 314) in its entirety as the Order of this Court.

SPECIAL MASTER'S REPORT AND RECOMMENDATIONS ON CLAIM CONSTRUCTION

AMEND, J.

1. Pursuant to the June 14, 2005 Order of District Judge Mary H. Murguia, the undersigned was appointed Special Master in the above-captioned case to receive a tutorial concerning the technology relating to, to hold a hearing on, and to report to the Court his recommendations for construction of certain disputed limitations of, the asserted claims of U.S. Patent No. 6,436,135 ("the '135 patent") under Fed.R.Civ.P. 53.

2. The Special Master conducted a hearing on August 5, 2005 at the United States Courthouse in Phoenix, Arizona, and this hearing was transcribed by a court reporter. Immediately before the hearing, both parties presented a tutorial on the technology involved in this case. The tutorial presentations were not transcribed, but were videotaped for future reference by the Special Master and/or the Court. Prior to the hearing, both parties filed initial and reply briefs and associated exhibits relating to claim construction. In addition, defendant W.L. Gore & Associates ("Gore") filed its Citation of New Case Relevant to the Proper "Markman" Construction of Claims, to which plaintiffs Bard Peripheral Vascular and David Goldfarb (collectively, "Bard") filed an objection. Bard also filed a Corrective Markman Submission, to which Gore responded. Further, at the Special Master's invitation, both parties filed briefs addressing the affects of the Federal Circuit's recent *en banc* decision in Phillips v. AWH Corp., 415 F.3d 1303 (Fed.Cir.2005), which issued after the parties' primary briefing but before the hearing. Both parties also tendered presentation materials during the tutorial and hearing. After the hearing, the Special Master prepared a Preliminary Report that was distributed to the parties for comment. This final Report has considered all additional arguments and comments made by the parties in response to the Preliminary Report.

The Patent-In-Suit

3. The '135 patent is titled Prosthetic Vascular Graft, and is generally directed to such a device with thin walls, made from expanded polytetrafluoroethylene (ePTFE), and with a particular microscopic superstructure of nodes and interconnecting fibrils. The application was filed by co-plaintiff David Goldfarb on October 24, 1974 and the patent issued on August 20, 2002, following lengthy proceedings at the U.S. Patent and Trademark Office ("PTO"). After a period of *ex parte* prosecution, an interference was initiated in 1983 to resolve a priority dispute between Goldfarb and Peter Cooper, who was an employee of defendant Gore. Ultimately, priority and rights in the invention were awarded to Goldfarb. *See generally* Cooper v. Goldfarb, 154 F.3d 1321 (Fed.Cir.1998).

4. The '135 patent includes 27 claims. Of these, Bard has charged Gore with infringing claims 1-6, 8-11, and

14-27. As reflected in the June 14 Order, the parties have agreed that there are eight different limitations that require construction by the Court. The claim limitations at issue and construed herein are (in the sequence listed in the June 14 Order):

1. Terms "prosthetic vascular structure"/"prosthetic vascular graft"/" artificial vascular prosthesis" [claims 1-6, 8-11, 14-27];

2. Terms "of" and "comprising" [claims 1-6, 8-11, 14-27];

3. Term "having" [claims 1-6, 8-11, 14-27];

4. Terms "substantially uniform distribution of nodes" [claims 1-6, 8-11, 14-19];

5. Terms "average distance between nodes" [claims 1-6, 8-11, 14-27];

6. The "whereby" clause [claims 1-6, 8-11, 17-19];

7. Terms "wall thickness" and "density" [the parties dispute which claims contain wall thickness and density limitations]; and

8. Terms "which permits tissue ingrowth" [claims 20-24 and 27].

At the hearing the limitations were addressed in a different sequence to facilitate the arguments, and the discussion sequence in this Report follows that of the hearing.

General Principles of Claim Construction Law

5. Claim interpretation is a matter of law for the Court. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995) (*en banc*), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "Courts construe claims by considering the evidence necessary to resolve disputes about claim terms and to assign a fixed, unambiguous, legally operative meaning to the claim." Liquid Dynamics Corp. v. Vaughan Co., 355 F.3d 1361, 1367 (Fed.Cir.2004). Comparison of the accused device and/or prior art with the construed claims is a task for the fact finder (here a jury) at later stages of the action. *See, e.g., N.* Am. Container, Inc. v. Plastipak Packaging, Inc., 415 F.3d 1335, 1344 (Fed.Cir.2005); In re Cruciferous Sprout Litig., 301 F.3d 1343, 1346 (Fed.Cir.2002). Accordingly, the Special Master has been careful to recommend claim constructions that the fact finder may readily and effectively apply.

6. "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude." ' Phillips, 415 F.3d at 1312 (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed.Cir.2004)). Generally, the words of a claim are given their "ordinary and customary meaning," *i.e.,* "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.,* as of the effective date of the patent application." Phillips, 415 F.3d at 1312-13; *see also* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). "The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." Phillips, 415 F.3d at 1313. Ultimately, "the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim." Research Plastics, Inc. v. Fed. Packaging Corp., 421 F.3d 1290, 1295 (Fed.Cir.2005) (quoting Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998)).

7. In some cases, the ordinary meaning of claim language as understood by a person of skill in the art involves little more than the application of the widely accepted meaning of commonly understood words.

Phillips, 415 F.3d at 1314. In other cases, however, claim construction requires examination of terms that have a particular meaning in a field of art. In such cases, a court "looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean," including "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id*. (internal quotations omitted).

8. In examining the words of the claims themselves, a court may need to consider the doctrine of claim differentiation. This doctrine "stems from '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." ' Seachange Int'l, Inc. v. C-Cor Inc., 413 F.3d 1361, 1368 (Fed.Cir.2005) (quoting Karlin Tech. Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 971-72 (Fed.Cir.1999)). The doctrine is at its strongest when a limitation sought to be "read into" an independent claim already appears in a dependent claim. Seachange, 413 F.3d at 1368-69. However, the doctrine only creates a presumption and "can not broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence." Id. at 1369 (quoting Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1480 (Fed.Cir.1998)).

9. The claims do not stand alone, but are part of an integrated written instrument including the specification. Phillips, 415 F.3d at 1315. Thus, claims "must be read in view of the specification, of which they are a part." *Id*. (quoting Markman, 52 F.3d at 979). The specification "is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." *Id*. (quoting Vitronics, 90 F.3d at 1582). The specification may reveal a special definition given to a claim term, or may reveal the inventor's intentional disclaimer or disavowal of claim scope. *Id*. at 1316. In both instances, the specification serves to express the correct claim scope as dictated by the inventor. *Id*. While the specification may define claim terms by implication, *id*. at 1321, the fact that the specification includes limited and specific embodiments is insufficient to define a term implicitly, and it is improper to confine the scope of the claims to the embodiments of the specification. *Id*. at 1323.

10. In addition, a full understanding of what the inventor actually invented requires consideration of the prosecution history, so to exclude any interpretation that was disclaimed during prosecution. Research Plastics, 421 F.3d at 1296. Like the specification, the prosecution history "provides evidence of how the PTO and the inventor understood the patent." Phillips, 415 F.3d at 1317. "Yet, because the prosecution represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id*. Thus, a court will hold an applicant's statements and arguments to make the claim scope narrower than it would otherwise be only when such statements represent a "clear and unmistakable disclaimer" or where the patentee has "unequivocally disavowed" a certain meaning. Liquid Dynamics, 355 F.3d at 1368 (quoting Anchor Wall Sys. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1311 (Fed.Cir.2003) and Omega Eng'g, Inc.v. Raytek Corp., 334 F.3d 1314, 1324 (Fed.Cir.2003)).

11. Finally, it is improper to construe claims in light of the accused device, or to allow the function and structure of the accused device to influence claim construction. Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC, 350 F.3d 1327, 1340 (Fed.Cir.2003); SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1118 (Fed.Cir.1985) (*en banc*). Although both parties at times made references to the structure and operation of the products accused of infringement in this case, the Special Master did not take this information into account when construing the claims.

Construction of Disputed Terms

A. Terms "prosthetic vascular structure"/"prosthetic vascular graft"/" artificial vascular prosthesis"

12. One of these three phrases appears in each of the asserted claims. The parties agree that, within the context of the asserted claims, there is no difference in scope among the three different phrases. The parties disagree, however, as to what that scope is.

13. Gore contends that these phrases require: (i) that the claimed structure be tubular; (ii) that it be used only to replace or bypass blood vessels (and not to repair, augment or support them); and (iii) that it be implanted by suturing. With respect to the suturing limitation, Gore argues that the specification of the '135 patent describes only this means of utilization. Gore argues that the patentee must be bound by his own description, and under *Phillips* the claims cannot be broader than what is described as the invention in the specification. Similarly, Gore asserts that the patent specification contains what it describes as "global statements" that describe, and thus limit, the invention to a tube of ePTFE that is used only to either replace or bypass a blood vessel. From this, argues Gore, it must necessarily follow that the device must be tubular because blood must flow through it. Though Gore does not dispute that these terms' generally understood meaning in the art would extend to structures used to repair or augment blood vessels, it contends that this meaning is constrained by the limited disclosure of the specification.

14. Gore disagrees that it ever conceded that any relevant dictionary definition of prosthesis, prosthetic structure, or graft includes devices used to repair or augment blood vessels. At the August 5, 2005 hearing, however, Gore specifically acknowledged that there are such things as "patch grafts" or "patch prostheses," but argued that the claims could not cover such structures because "there is no disclosure of a flat patch ... [and][t]he only description is tubular." Tr. at 14. Moreover, Gore stressed that the claims cover structures used to "replace and bypass but not repair" "because of the specification." Tr. at 27. The treatment of these terms during the hearing addressed whether, as Gore argued, the specification must *narrow* what would otherwise be the scope of the terms. However, regardless of whether or not Gore's statements at the hearing are considered concessions, intrinsic evidence from the patent's prosecution history contains references that indicate that one skilled in the art of the invention at the time of the application would understand the terms "graft" and "prosthesis" to include devices used to patch, and thus repair or augment, a blood vessel. *See* Wesolowski *et al*. (FH00074, FH00085, X00076, X00087); Sharp *et al*. (FH00091, FH00092-93, X00093, X00094-95); Dale & Lewis (FH00098, FH00107, X00100, X00109); Matsumoto *et al*. (FH00693, FH00694-95, X00699, X00700-01).

15. Bard contends that the terms should be interpreted more broadly, to include any structure used to repair or augment, in addition to replace or bypass, a blood vessel. Therefore, Bard asserts that the structure need not be tubular, need not be implanted only by suturing, and that the terms "structure," "prosthetic" and "graft" also include devices that are used for repair, such as a patch. (Bard does agree that the repair or augmentation must be of a blood vessel, which is tubular.) In support of this argument Bard points to dictionary definitions, usage by Gore and others in prior art and later patents, as well as use of the terms within the PTO Manual of Patent Classification. Moreover, Bard invokes the doctrine of claim differentiation, arguing that some of the claims expressly recite that the claimed structure itself be tubular, and that this language becomes redundant if the tubular limitation is broadly read into all the claims based on the specification.

16. The primary issue for the Court to resolve with respect to these terms is whether the words should be accorded their ordinary meaning in the art, or whether this meaning must be narrowed by the disclosure of the patent specification.

17. The embodiments disclosed in the specification are limited to ePTFE devices that are tubular and that are used either to replace or bypass blood vessels. However, claims may embrace "different subject matter than is illustrated in the specific embodiments in the specification." Nazomi Communications, Inc. v. ARM Holdings, PLC, 403 F.3d 1364, 1369 (Fed.Cir.2005). Even when only a single embodiment is disclosed in the specification, it ordinarily does not serve to limit the otherwise broader language of the claims to that embodiment. Gemstar-TV Guide Int'l, Inc. v. United States Int'l Trade Comm'n, 383 F.3d 1352, 1366

(Fed.Cir.2004). This is consistent with the different purposes of the specification and the patent claims: While the claims themselves define the metes and bounds of the invention, the specification is meant to enable its use and to provide a best mode for doing so. Phillips, 415 F.3d at 1323. Moreover, it does not matter that any particular embodiment within the scope of the claims *could not* have been described in the specification because the particular technology had not yet been developed. Claims may cover such after-arising technology, which logically can never be described in the patent specification. Superguide Corp. v. DirecTV Enters., Inc., 358 F.3d 870, 878-79 (Fed.Cir.2004); SRI, 775 F.2d at 1121 (the law "does not require that an applicant describe in his specification every conceivable and possible future embodiment of his invention"); A.B. Dick Co. v. Burroughs Corp., 713 F.2d 700, 703 (Fed.Cir.1983) ("[A] pencil structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what the pencil can write. Neither would infringement be negated simply because the patentee failed to contemplate use of the pencil in that environment.").

18. Gore asserts that under the Federal Circuit's recent *en banc* decision in *Phillips,* the claims of the patent cannot be construed broader than the disclosure of the specification. *Phillips* states that "the principal question that this case presents to us is the extent to which we should resort to and rely on a patent's specification in seeking to ascertain the proper scope of its claims." *Id*. at 1312. That is also the question here. However, Gore overstates the holding of *Phillips*. The *Phillips* decision makes clear that "although the specification often describes very specific embodiments of the invention, [the Federal Circuit has] repeatedly warned against confining the claims to those embodiments." *Id*. at 1323. Moreover, the decision made clear that it did not change the basic principles regarding the relationship between the specification and the claims set forth in Markman, 52 F.3d 967, Vitronics, 90 F.3d 1576, and Innova, 381 F.3d 1111. Phillips, 415 F.3d at 1312. Indeed, over a dissenting opinion, the *en banc* majority in *Phillips* construed the term at issue, "baffle," to include embodiments that were not disclosed in the specification. *Id*. at 1329. Thus, *Phillips* clearly rejects the contention that when words have an ordinary meaning in the art, the scope of claims that use these words must nonetheless be limited to the examples of the specification. What a court must do instead is, based on the manner in which a patentee uses a term within the specification and claims, determine whether a "person of skill in the art would understand the embodiments to define the outer limits of the claim term or merely to be exemplary in nature" within the context of a particular patent. *Id*. at 1323.

19. In that regard, Gore asserts that the embodiments described in the specification are definitional, not exemplary, because the specification uses what Gore describes as "global statements" that explain the described embodiments as covering the complete scope of the invention. Gore places particular emphasis on a statement at col. 3, ll. 40-42, stating that the "invention constitutes a prosthetic vascular device formed from a small bore tube of polytetrafluoroethylene."

20. Bard counters that although an objective of the patented invention is to "replace" and "bypass" blood vessels, recitations of objectives to not constitute claim limitations. Bard further argues that Gore is unable to point to any portion of the specification that states that the patented structure is limited to "replacing" or "bypassing" tubular blood vessels, or to tubular or sutured structures, and that a clear disclaimer of subject matter is required to narrow the scope of the claims.

21. The Special Master's analysis of the specification and the claims leads to the conclusion that the embodiments are exemplary and not restrictive. Most of the passages that Gore cites involve discussions and description of illustrative figures with no accompanying limiting language. Other portions merely state objectives of the invention, which also are insufficient to narrow the scope. Phillips, 415 F.3d at 1326-27; Brookhill-Wilk I, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1300-02 (Fed.Cir.2003); Northrop Grumman Corp. v. Intel Corp., 325 F.3d 1346, 1355 (Fed.Cir.2003). The patent also expressly states that the claimed prosthesis "may assume many embodiments and configurations other than those specifically set forth and described" in the specification, providing examples. Col. 9, ll. 20-28. Even though stated in broad terms, this demonstrates that the inventor did not intend to limit his invention to the particular embodiments shown. *See* Northrop Grumman, 325 F.3d at 1355-56.

22. While the specification beginning at column 3, line 30 does state "the invention constitutes ...," this alone is insufficient to narrow the scope of the claims to that described in the specification, and is distinguishable from cases where the specification has been held to define the complete scope of the invention and thus narrow the otherwise broader meaning of the claim language. In SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337 (Fed.Cir.2001), for example, the Federal Circuit held that the patentee had limited the scope of the term "lumen" to mean a "coaxial lumen" because the specification specifically distinguished the prior art's use of "dual lumens" and stated that "all embodiments of the present invention *contemplated* and disclosed herein" employed coaxial lumens. 242 F.3d at 1343-44 (emphasis added). Subsequent cases have emphasized the specificity and extent of the disclaimer present in *SciMed* and similar cases necessary to limit the scope of the claims, and have held that less clear statements do not have such effect. *See, e.g.,* Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 1340-41 (Fed.Cir.2004); CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1368 (Fed.Cir.2002); Honeywell Inc. v. Victor Co. of Japan, Ltd., 298 F.3d 1317, 1325 (Fed.Cir.2002). Likewise, in C.R. Bard, Inc. v. United States Surgical Corp., 388 F.3d 858, 866 (Fed.Cir.2004), the Federal Circuit held that the specification was narrowing because it "clearly defined" particular terms as requiring a pleated surface. But again, less clear statements do not have the same effect. *See* Lucent Techs., Inc. v. Extreme Networks, Inc., 367 F.Supp.2d 649, 654-55 (D.Del.2005) (distinguishing *U.S. Surgical*); Swimways Corp. v. Overbreak, LLC, 354 F.Supp.2d 637, 645-46 (E.D.Va.2005) (same).

23. Here, the specification states not that the invention *is* a tube of ePTFE, but that it is "formed from a small bore tube of polytetrafluoroethylene which has been heated, expanded and sintered." Col. 3, ll. 41-42. But a patch, as an example, could be made from such a tube, even though the final product is not tubular. In any event, the claims are directed to a device, not a method of manufacture. Moreover, there was no disclaimer of non-tubular or non-sutured embodiments, or of embodiments used to repair or augment a blood vessel. Nor was tubularity or suturing used to distinguish the prior art. Nor is there a clear definition as present in *U.S. Surgical*. The statements in the specification do not rise to the level necessary to effect a disclaimer under Federal Circuit case law.

24. This conclusion is supported by the fact that one dependent claim (15) uses the term "tubular" to further narrow the meaning of "prosthetic vascular graft," and in other claims the limitation that the patented structure be "tubular" is expressly recited in the claim text as a further limitation on a "prosthetic vascular structure." In this latter regard, if a prosthetic vascular structure was inherently tubular, the further recited limitation of "tubular" would be redundant. Though not dispositive, the claim language creates a presumption that the terms themselves are not inherently limited to tubular structures. *See, e.g.,* Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed.Cir.1998). Moreover, this usage further supports the conclusion that the tubular embodiments shown are exemplary. As the Federal Circuit explained in *Phillips* in an analogous situation, "the claim in this case refers to "steel baffles," which strongly implies that the term "baffles" does not inherently mean objects made of steel." 415 F.3d at 1314. Claims 14 and 20-27 do not recite the word "tubular" at all, and it is inappropriate to read limitations from other claims into these claims.

25. While the Special Master does not agree with Gore as to the effects of the specification on claim construction, he also finds that Bard's proposed constructions, which have varied from stage-to-stage of the proceedings and are overly tied to specific pieces of extrinsic evidence, do not present an appropriate construction for the fact finder to apply. Rather, the Special Master has articulated the construction using language that he believes more simply reflects the understanding of the meaning of these phrases to one skilled in the art based on the patent and the rest of the intrinsic record.

26. Accordingly, the Special Master recommends that these phrases be construed as: A structure used to replace, repair, augment, or bypass blood vessels. FN1

FN1. Bard concedes that only blood vessels are covered, and that vessels conveying other material such as lymphatic fluids or bile are not.

B. The "whereby" clause

27. Claims 1-6, 8-11, and 17-19 contain a concluding clause that recites, "whereby said structure may provide for the smooth flow of blood between at least two points in a living organism while controlling cellular ingrowth through the wall of the tubular configuration to promote and nourish a thin, viable neointima over the inner surface thereof and to firmly attach said prosthetic vascular structure to adjacent tissue of said living organism." The question to be decided is if this clause is a limitation and, if so, how does it limit the claims.

28. Bard argues that this clause states only a desirable and possible result of the structural limitations recited before the word "whereby," and therefore does not create additional limitations under controlling Federal Circuit law.

29. Gore, on the other hand, argues that this clause represents a separate and independent limitation in addition to those recited elsewhere in the claim. While acknowledging the precedent relied on by Bard addressing "whereby" clauses, which would appear to suggest that they are not a limitation, Gore contends that the cases are not applicable here because Goldfarb used the "whereby" clause as a basis to distinguish prior art during prosecution. Thus, according to Gore, the clause represents additional specific limitations that must be established factually to prove infringement.

30. Prior decisions have addressed the effect on claim scope of a "whereby" clause such as the one at issue here. In Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165 (Fed.Cir.1993), for example, the I.T.C. had determined that a "whereby" clause did not further limit a claim when it only expressed the necessary result of what was recited elsewhere in the claims, while the respondent asserted that the clause established specific further limitations. Id. at 1172. The Federal Circuit held that "a 'whereby' clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim." *Id*. The court found that the clauses at issue "merely describe the result of arranging the components of the claims in the manner recited in the claims." *Id*. Likewise, in Lockheed Martin Corp. v. Space Systems/Loral, Inc., 324 F.3d 1308, 1319 (Fed.Cir.2003), the Federal Circuit reiterated that "a whereby clause that merely states the result of the limitations in the claim adds nothing to the substance of the claim."

31. In Hoffer v. Microsoft Corp., 405 F.3d 1326 (Fed.Cir.2005), however, the Federal Circuit concluded that a "whereby" clause did create further limitations because "when a 'whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." Id. at 1329. There, the court concluded that the recited "interactive messaging" "is more than the intended result of a process step; it is part of the process itself." *Id*. The court further looked to portions of the specification and prosecution history describing the interactive element as an integral part of the invention in concluding that the clause could not be ignored.FN2

FN2. The *Hoffer* decision addressed a "whereby" clause in the context of a method claim, but the same principles apply to device claims. Lockheed, 324 F.3d at 1319.

32. Likewise, in Eltech Sys. Corp. v. PPG Indus., Inc., 710 F.Supp. 622 (W.D.Wisc.1988), the district court ruled that a "whereby" clause was an additional limitation. The court stated that because the recited "whereby" clause at issue "was relied upon to distinguish over the prior art during the prosecution of the patent," it "must be viewed as essential to the allowance of those claims and essential to the establishment

of infringement." Id. at 633.

33. In Thermalloy Inc. v. AAvid Eng'g, Inc., 935 F.Supp. 55, 60 (D.N.H.1996), the district court stated, relying on *Eltech,* that "terms contained in whereby clauses can evolve into essential features of the invention during prosecution of the patent and, once essential, they constitute necessary limitations." It concluded that because the applicant used the particular limitation in the "whereby" clause (a specific ratio of the size of two components) to overcome the prior art, it became an essential element. *Id*. The Federal Circuit affirmed, 121 F.3d 691 (Fed.Cir.1997), treating the limitation not as requiring special analysis because of the word "whereby," but rather simply treating it as an additional limitation. Though not expressly addressed in the opinion, this treatment appears to follow from the fact that the specific ratio recited was not a result of the preceding limitations, but rather was something additional.

34. The case law thus establishes a "rule" that, when a "whereby" clause states the results of the preceding limitations in the claim, it does not add any further limitation; but when the clause recites something that is not the result, or when it states a condition that is material to patentability, then it does create an additional limitation.

35. Looking to the patent and intrinsic record, the Special Master concludes that the "whereby" clause in this case is one that states the result of the prior limitations, rather than adds additional limitations. The specification explains that the neointima and other features listed in the clause are among the desired objectives that can be achieved with the structural limitations recited previously in the claims. Moreover, the "whereby" clause itself recites "whereby said structure *may* provide"-language that clearly indicates that the listed features are not required, but are a hoped for result of the recited *structural* limitations.

36. However, that does not end the inquiry. As Gore points out, Goldfarb arguably used at least some content of the "whereby" clause to distinguish prior art during prosecution of the patent, and if so this presents an independent, potential basis for limiting the scope of the claims. As a general matter, the Special Master agrees that arguments made during prosecution can have the effect of narrowing the scope of the claims of a patent. *See, e.g.,* Phillips, 415 F.3d at 1317; *N*. Am. Container, 415 F.3d at 1345. However, there is no support in the case law for the proposition that this analysis is different when a "whereby" clause is present than when one is not. In other words, the type of actions or statements that may lead to prosecution disclaimer remain the same notwithstanding their presence in a "whereby" clause. Any such disclaimer must be "clear and unmistakable." Liquid Dynamics, 355 F.3d at 1368. Moreover, the Special Master notes that here the passages from the prosecution arguments that Gore relies on do not invoke or mention the "whereby" clause itself, but rather are statements in the patent specification as to the objects of the invention. Because the possible prosecution history effect of these statements is independent of whether they appear in a "whereby" clause, the Special Master will consider the question later in the Report in the context of Gore's other arguments that the prosecution history narrows the scope of the claims.

37. Thus, the Special Master concludes that the presence of the "whereby" clause itself does not create any additional limitations beyond those recited earlier in the claims.

C. Phrase "which permits tissue ingrowth"

38. Claims 20-24 and 27 recite that the claimed device comprises an ePTFE microstructure "which permits tissue ingrowth." The first issue to be addressed is again whether this phrase constitutes a limitation and, if so, what the scope of that limitation is. This language is also related to a second issue: whether Goldfarb's statements during prosecution of the patent inherently require some degree of tissue ingrowth regardless of the recited claim language and, if so, how much ingrowth is required. Both issues overlap somewhat with that of the "whereby" clause, discussed above.

39. Gore globally contends that regardless of the specifics of a particular claim, each one requires that the

device as a whole demonstrate complete ingrowth through the wall of the tube resulting in a uniform neointima over the inner surface. According to Gore, the specification defines the term "ingrowth" by implication to require not just some ingrowth, but rather complete ingrowth resulting in a neointima. This is so, says Gore, even though: (i) claims 1-6, 8-11 and 17-19 mention ingrowth in the "whereby" clause; (ii) claims 20-24 and 27 recite "which permits tissue ingrowth;" and (iii) claims 14-16 and 25-26 do not mention ingrowth at all. In support of this argument, Gore points to arguments made by the applicant Goldfarb during the prosecution of the patent in which the applicant distinguished prior art on the basis of the absence of tissue ingrowth and statements in the specification about the desirability of ingrowth. Gore argues further that the formation of the neointima must be demonstrated in the intended human host of the implants.FN3

FN3. Gore further argues that the claims that do not expressly recite the "ingrowth" limitation are invalid for lack of support in the specification. *See, e.g.,* In re Cultor, 224 F.3d 1328, 1332 (Fed.Cir.2000). The invalidity issue, however, is distinct from that of claim construction, and the Special Master was not charged with consideration of claim validity. *See* Phillips, 415 F.3d at 1328.

40. Prior to the hearing, focusing on the ingrowth language of claims 20-24 and 27, Bard asserted that the language only requires that the device include ePTFE with a microstructure "which *permits* fibroblasts and red blood cells to enter the pores of the graft" (emphasis added), but that such ingrowth need not necessarily be complete or transmural, or result in the formation of a neointima. Bard further argued that the particular language only appears in a few of the asserted claims. Bard did not appear to argue that the language created no additional limitation at all.

41. During the hearing, however, Bard argued that, because the language recited that the ePTFE structure merely "permit" tissue ingrowth, no such ingrowth was actually required because what was claimed was a structure and not a result. All that was required, asserted Bard, was a device that is made out of ePTFE that has certain structural characteristics that has been designed to permit tissue ingrowth.

42. Bard also argued that because Gore previously had asserted in seeking summary judgment of invalidity that claims 20-25 did not require transmural ingrowth, and this had been reflected in an undisputed statement of fact adopted by the Court, that this was now the law of the case. The Special Master does not agree that the circumstances create a "law of the case." In any event, what is important here is to reach the correct claim construction, and the Federal Circuit permits a district court to clarify claim constructions when appropriate even when such constructions have been formally adopted, which did not even occur in this case. *See, e.g.,* AFG Indus., Inc. v. Cardinal IG Co., 375 F.3d 1367, 1372 n. 2 (Fed.Cir.2004); Utah Med. Prods. v. Graphic Controls Corp., 350 F.3d 1376, 1381-82 (Fed.Cir.2004). As the Special Master indicated during the hearing, the construction will be determined on the merits, and not on the basis of prior positions.

43. The Special Master does not agree with Bard that the recited limitation that the structure is one "which permits tissue ingrowth" does not require some evidence of ingrowth. Unlike the claims with the "whereby" clause, these claims do not first recite the key structural limitations and then the hoped for result thereof, but rather define permitting tissue ingrowth as a claim element itself. The prior interference proceedings confirm this result: This claim tracks closely the language of the count of the invention, and both the PTO and the Federal Circuit defined reducing the invention to practice as requiring not merely the creation of a graft with a particular internodular distance that could, in theory, permit ingrowth, but rather required an experimental showing that "the fibrils connecting the PTFE nodes must be of sufficient length to permit infiltration by fibroblasts and red blood cells, thereby leading to tissue ingrowth into the walls of the graft." Cooper, 154 F.3d at 1324.

44. However, the Special Master also rejects Gore's global contention regarding ingrowth. Looking to the actual words of the claim, nothing indicates that such ingrowth must be complete, be transmural or result in

the formation of a neointima. Moreover, it is significant that claim 20 does cite that the structure "prevent transmural blood flow," indicating that the applicant knew how to use the term "transmural" when he wanted to, but did not use it when describing ingrowth in the claims. Nor does the claim require ingrowth in a human host. Indeed, it is undisputed that the inventions were reduced to practice in dogs. Cooper, 154 F.3d at 1324. Though Gore asserts that the parties have agreed otherwise, the record before the Special Master does not indicate agreement on this issue.

45. References to "transmural" ingrowth or to neointima formation in the *specification* do not provide a special meaning or otherwise restrict the general meaning of the terms. Though the specification refers to transmural ingrowth and neointima formation as objectives, the law is clear that providing objectives in a specification does not create claim limitations. Phillips, 415 F.3d at 1327 (the "fact that a patent asserts that an invention achieves several objectives does not mean that each of the claims be construed as limited to structures that are capable of achieving all of the objectives"). And the fact that this particular objective was one that Goldfarb stated in the specification was not achievable using the prior art does not mean that it must be achieved in order to practice the claims, and identification of potential advantages over the prior art are not the sort of statements that serve to globally narrow claim scope.

46. The specification does not disclaim partial ingrowth, and require complete transmural ingrowth resulting in a neointima. The specification actually discloses that the objective is that the invention provides a structure that "will allow" transmural cellular ingrowth and assure the establishment of a viable neointima. Col. 3, 1. 30. This permissive, rather than restrictive language, does not require such ingrowth in all cases. Also, the passage in the specification Gore emphasizes that comes closest to defining the scope of the invention, col. 3, ll. 40-55 ("Briefly stated, the invention constitutes ...), says nothing about transmural ingrowth or formation of a neointima, but rather describes the invention in terms of structural parameters. This passage does state that the structure will "allow free and uniform transmural nutrient flow," col. 3, 1. 54, and Gore asserts that this language requires complete transmural ingrowth resulting in a neointima. But not only is this statement in permissive language, it also says nothing about tissue ingrowth or a neointima. Though there may be a physiological connection between nutrient flow and tissue ingrowth, such a connection does not warrant reading into the claims a limitation that is not present.

47. The case law Gore relies on in which a term is defined "by implication" is not to the contrary. For example in Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1271 (Fed.Cir.2001), the court concluded that the specification implicitly defined a term. The court was clear, however, that although a patentee's definition of a term need not be express, any such definition nonetheless must done "clearly." Id . at 1268. The court thus held that, "when a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term 'by implication." ' Id. at 1271. In the present case, however, the applicant did not use the term "ingrowth" in a manner consistent with only one meaning. Rather, in discussions of the objectives of the invention the specification demonstrates that while transmural ingrowth is desired, there might be other sorts of valuable ingrowth that is less complete.

48. Gore argues further that claims 20-24 and 27 do not recite "*cellular* ingrowth," but rather "*tissue* ingrowth," and that "tissue ingrowth" cannot be defined simply as the mere infiltration of unorganized cells such as fibroblasts and red blood cells. Though it is not clear that the parties disagree on this issue, the Special Master has addressed Gore's argument and examined the record evidence. The Special Master agrees that the term "tissue" indicates cellular organization to one of skill in the art, and that the claims' recitation of "tissue" ingrowth requires more than unorganized cellular infiltration. Indeed, aside from the word "tissue," the word "ingrowth" indicates that something must be growing into the ePFTE structure, not simply passing through it.

49. It is still necessary to evaluate the prosecution to determine if Goldfarb defined terms or disclaimed subject matter. In the PTO's first office action, dated November 26, 1975, all claims were rejected as

obvious in light of a combination of three or four pieces of prior art, including the Volder and Soyer references. The examiner concluded that an increase in average "pore size" would be obvious as disclosed by the Volder reference, and that the claimed density would "naturally" fall within the recited levels as disclosed in the Soyer reference. The examiner further concluded that "the shape of the nodes" is considered to be inherent in the manufacture of expanded Teflon.

50. After the office action, there was an examiner's interview, but there is no document summarizing the interview. Based on the interview, however, the applicant prepared an amendment dated May 3, 1976. This did not amend the relevant claim language, but did present arguments related to patentability. With respect to the Soyer reference, the applicant asserted that the reference disclosed using tubes with a "pore size of 0.5-2.5 microns," but did not disclose any fibrous ingrowth into the tubes with this pore size, and "no cellular elements were found in the pores of the wall of the graft." The applicant continued that "one of the principal objectives of the present invention [is] to control uniform cellular ingrowth through the walls of the artificial vascular structure for the purpose of providing and maintaining a well-nourished, viable neointima over the entire inner wall of the implanted prosthetic." The applicant further noted that while the Soyer article taught that possibly larger pore size would permit tissue ingrowth, such larger pores appear to be related to increased thrombosis formation; thus, argued the applicant, it taught away from using the claimed larger pore sizes. At the time of this exchange, the pending claims contained the previously discussed "whereby" clause reciting "controlling cellular ingrowth."

51. Though the case law does not lay down hard and fast rules on when and how statements made during prosecution limit the scope of the claims of a patent, it is well established that while the construction of a claim should exclude any interpretation that was disclaimed during prosecution, such disavowal must be clear and unambiguous. Phillips, 415 F.3d at 1317; Seachange Int'l, Inc. v. C-Cor Inc., 413 F.3d 1361, 1373 (Fed.Cir.2005). While distinguishing prior art is one way to create such a disclaimer, *N*. Am. Container, 415 F.3d at 1345-46; Fantasy Sports Props., Inc. v. Sportsline.com, Inc., 287 F.3d 1108, 1114-15 (Fed.Cir.2002), remarks made to distinguish claims from the prior art that are broader than necessary may not create the required "clear and unambiguous" disavowal. 3M Innovative Props. v. Avery Dennison Corp., 350 F.3d 1365, 1373 (Fed.Cir.2003).

52. Here, the Special Master concludes that Goldfarb's arguments distinguishing the Soyer reference during prosecution do create a disclaimer that reaches the then-pending claims, as well as later claims that recite an "ingrowth" requirement. While Bard argues that the distinction involved only pore size, it is plain from the prosecution history that the distinction drawn to the Soyer reference did not only involve pore size, but also involved the fact that, for example, "no cellular elements were found in the pores of the wall of the graft." This type of argument drawn to distinguish a prior art reference is the type of argument that creates a disclaimer. *See, e.g., N*. Am. Container, 415 F.3d at 1345-46; Research Plastics, 421 F.3d at 1297.

53. However, the disclaimer is not as broad as Gore asserts. Although Gore argues that all claims must be interpreted to require complete transmural ingrowth resulting in a neointima, the prior art was distinguished on the basis that it had *no ingrowth at all,* not on the degree of the ingrowth. Though the applicant repeated the objectives of the invention related to neointima formation, what is important is how the applicant distinguished the prior art. 3M Innovative Props., 350 F.3d at 1373. While the applicant clearly distinguished the prior art as having no ingrowth, there is no unambiguous statement that the ingrowth in the patented invention must be complete and transmural, even though that is an objective of the invention.

54. Moreover, claims 14, 25 and 26, which were not pending at the time of the May 1976 amendment, do not recite any "ingrowth" limitation at all. While the mere fact that these claims were not pending is not dispositive, "arguments made during prosecution regarding the meaning of a claim term are relevant to the interpretation of that term in every claim of the patent absent a clear indication to the contrary." Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed.Cir.1995). Thus, the applicability of earlier arguments to later claims generally requires the presence of the same limitation or term addressed in or

relevant to the prior arguments. *See, e.g.,* Innova, 381 F.3d at 1122 & n. 2; Watts v. XL Sys., Inc., 232 F.3d 877, 883-84 (Fed.Cir.2000). While in limited cases the totality of the prosecution history may require such restriction even when the relevant term or limitation has been excluded from the language of a later claim, Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1372 (Fed.Cir.2003), the prosecution history of the present case, unlike that in *Alloc,* does not contain arguments accompanying the later claims indicating that the "ingrowth" requirement remained a basis of patentability. Thus, the arguments made during prosecution do not limit these later claims that do not recite any "ingrowth" limitation.

55. Accordingly, the Special Master recommends that, as a matter of claim construction, all claims mentioning "ingrowth" in the body or the whereby clause require that the ePTFE structure, at a minimum, allows fibroblasts and red blood cells to enter the pores of the node and fibril microstructure of the ePTFE component of the graft. Further, the Special Master recommends that for those claims that recite that the ePTFE structure "permits *tissue* ingrowth," *i.e.,* claims 20-24 and 27, the structure must allow organized host tissue to grow into the pores of the node and fibril microstructure.

D. Phrase "average distance between nodes small enough to prevent transmural blood flow ... but no less than maximum dimension of an average red blood cell"

56. This phrase appears in claims 1-6, 8-11, and 17-19. Similar language specifying an "average distance between nodes" or that "the average distance between nodes ... is small enough to prevent transmural blood flow" is recited in claims 14-16 and 20-24. One issue to be resolved is to what nodes the "average" applies. A second issue concerns whether the functional language of this phrase must be construed as a numerical limit.

57. Gore asserts that the average distance between nodes applies to all regions of the accused device, and requires that this distance be small enough to prevent transmural blood flow and blood clots. And although the claim language does not mention an upper limit, Gore contends that the average internodular distance must be no greater than 60 microns (as argued in its briefs) or 80 microns (as argued at the hearing). In support of this construction, Gore refers to passages of the specification stating, for example, "that the average internodular distance ... must fall within a relatively narrow range of values, viz. between approximately 6 and 80 microns." Col. 5, ll. 31-34.

58. Bard, on the other hand argues that while the "maximum dimension of an average red blood cell" is about 6 microns and that this lower limit may be numerically defined, the upper limit is functional, requiring that the ePTFE structure be such that it is capable of preventing transmural blood flow. Bard adds that, because whether or not a particular structure permits transmural blood flow depends not only on the internodular distance but also on other parameters such as the thickness, it is improper to assign an absolute upper numerical limit. In support of this argument, Bard point to claims such as claim 21 that recite specific upper limits greater than 80 microns.

59. In all of the claims containing it, the "average distance" limitation applies to the ePTFE component of the prosthetic device.FN4 Moreover, the specification explains that, "[a]s will be appreciated by those skilled in the art, the term "average" when used in conjunction with internodular distance and node size cannot be used or interpreted with statistical precision; rather, the term is intended to connote a nominal or typical dimension derived from a broad sample. By way of example, where the average internodular distance is said to be 30 microns, it would be expected that some of the nodes would be separated by only a few microns while others might be separated by 90 or 100 microns." Col. 5, ll. 34-43. That the average represents a typical or nominal dimension, rather that a precise mathematical number, indicates that what is "typical" in one portion of the ePTFE must also be "typical" in other portions. For example, where the average, or typical, internodular distance is said to be 30 microns, the specification explains that some of the nodes are spaced close together and others far apart, but defines the term in a way that would not include the case where a "typical" distance was 5 microns in one half of the ePTFE and 55 microns in the other.

While such a structure might have a mathematical "average" of 30 microns, 30 microns would not be the typical distance in either half.

FN4. The Special Master rejects Gore's argument that the tail should wag the dog-that because some claims recite an average internodular distance, the claimed devices must be entirely ePTFE.

60. With respect to what this typical distance actually is, the Special Master agrees with the parties that the claim language "the maximum dimension of an average red blood cell" may be construed more simply for the finder of fact as "about 6 microns." *See* col. 5, ll. 29-30; ll. 48-50.

61. Regarding the upper limit, the Special Master agrees with Bard that the limitation that the distance between nodes "be small enough to prevent transmural bloodflow" does not require mathematical precision. The applicant knew how to define the upper limit numerically when he wanted to, and the fact that he did not in all claims does not mean that one should be assigned as a matter of claim construction. Moreover, while both the claims and the specification indicate that 80 microns may be a representative internodular distance small enough to prevent transmural blood flow given typical wall thickness and density, this is not an absolute limit. *See, e.g.,* claims 21-23; col. 5, l. 66-col. 6, l. 3. When the claim recites the limitation in terms of a functional result-preventing transmural bloodflow-that functional result is what the fact finder should consider when evaluating whether the limitation is satisfied.

62. Accordingly, the Special Master recommends that this phrase be construed as: Typically, the nodes of the ePTFE in the device are about as far apart from each other so as to prevent blood to pass through the device, but not closer than about 6 microns.

E. Terms "substantially uniform distribution of nodes"

63. This phrase appears in claims 1-6, 8-11, and 14-19, though Gore asserts that the limitation should apply to all of the asserted claims. One issue to be resolved is whether the specification defines the phrase to mean only that there are "no clumps," or if a more general definition of "uniform" applies. Another issue is the effect of the word "substantially" on the scope of the limitation. A further issue is whether the microstructure must be uniform throughout the wall of the tube and along the length of the tube, or if uniformity in some particular region of the ePTFE is adequate.

64. Bard argues, in contrast to the position that it has taken on other disputed claim limitations, that here the specification does provide a special meaning of the phrase, and that this meaning is that there be "no clumps" in the ePTFE. In support of this argument, Bard points to passages of the specification stating that clumps can serve as barriers to ingrowth and stating "... uniformly distributed, *i.e.,* neither clumped so as to block the flow of nutrition to the neointima nor so widely spaced as to define deep thrombosis inducing irregularities in the inner wall." Col. 6, ll. 8-19. Bard further argues, citing to Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313 (Fed.Cir.2005), that to the extent any broader definition is reached, that "substantially uniform" spacing means that the spacing is wide enough to function as a vascular graft.

65. Gore, on the other hand, argues that the same specification statements require that the ePTFE in the device be uniform through the wall of the tube and along the length of the tube, but that "uniform" does not merely mean without clumps. According to Gore, Goldfarb limited the invention to uniform spacing during prosecution, and Bard has already conceded to the Court that this limitation referred to the entire structure and required that the nodes be substantially uniformly distributed throughout the length and cross section of the graft.

66. The Special Master agrees with Bard that in some instances a patentee may redefine a claim term in the specification, thereby becoming "his own lexicographer." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d

1313, 1325 (Fed.Cir.2002); Vitronics, 90 F.3d at 1582 ("The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication."). As a matter of claim construction law, however, this requires that the inventor "defines the specific terms used to describe the invention 'with reasonable clarity, deliberateness, and precision." ' Teleflex, 299 F.3d at 1325 (quoting In re Paulson, 30 F.3d 1475, 1480 (Fed.Cir.1994)). Here, the passage on which Bard relies does not define the phrase "uniform distribution of nodes" to mean "without clumps" with any clarity or precision. Rather, it identifies "no clumps" as a byproduct of a uniform node distribution, along with no areas that are too widely spaced. However, it is evident from the specification and the general meaning of the words, that "uniform distribution" means more than just "no clumps," and the Special Master rejects Bard's narrow definition. The Special Master notes that this same passage describing an embodiment also states that the nodes are not "clumped so as to block the flow to the neointima." But just as such a statement does not define the term to mean that there is necessarily a neointima, neither does it define the term based on the presence or absence of clumps.

67. However, the Special Master does not agree with Gore that the specification or the prosecution history lend some special meaning to the phrase. Though both contain statements as to the importance of uniform distribution of nodes, none provides the sort of unambiguous disclaimer or definition required to depart from the words of the claim themselves. Thus, the Special Master's construction of the phrase applies only to those particular claims in which it appears, *i.e.,* claims 1-6, 8-11, and 14-19.

68. The words of the claims themselves address and resolve the issues on which the parties appear to disagree. The word "uniform" itself means that this distribution must be present in all of the ePTFE to which the limitation applies. Otherwise, the distribution is not uniform. Just as a glass that is half full is not "full," something that is only half uniform is not "uniform." This interpretation does not conflict with the principle that the "addition of features does not avoid infringement, if all the elements of the patent claims have been adopted," *N.* Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 945 (Fed.Cir.1990), because an addition of non-uniform ePTFE means that the ePTFE, as a whole, is no longer uniform. This interpretation also is consistent with the additional language in claims 1-6 and 8-11 that recites that the uniformity be "*throughout* said tubular configuration" of the ePTFE. That such distribution be "throughout" means that it must be so through the thickness of the ePTFE wall and along the length of the ePTFE component. The Special Master further finds that the doctrine of claim differentiation does not dictate that a distinction should be made between those claims in which "throughout" appears and those in which it does not. The construction is also consistent with the teaching of the specification that the "nodes ... must be substantially uniformly distributed throughout the length and cross-section of the graft." Col. 6, ll. 8-12. But this meaning comes directly from the language of the claim, not from the specification or prosecution history, though both are consistent with the claim language.

69. The terms "uniform" and "substantial" are not uncommon to patent claim drafting. Several prior decisions have addressed these terms, and these decisions-while not dispositive-are nonetheless instructive. In Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358 (Fed.Cir.2001), the court examined the words of the claim, the specification, and the prosecution history and determined that the phrase "substantially uniform" as used in the patent in that case (involving detergent) "means what it says, 'largely, but not wholly the same in form." ' 264 F.3d at 1369. In reaching this conclusion, the court specifically rejected the addition of a functional limitation not present in the claim. Id. at 1367, 1369. In Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1360 (Fed.Cir.2003), the court construed the phrase "substantially uniform thickness." The court concluded that the patents did not set out any numerical standard, and that the term "substantially" as used in this context "denotes approximation." *Id.* The court further noted that the specification, by providing an explanation as to the importance of the uniformity, required that the thickness of the wall of the stent in question be "sufficiently uniform" to allow uniform expansion. Finally, the court, based on arguments made during prosecution, concluded that the applicant had disclaimed coverage of any device with a thickness variation of at least 100 percent, further noting that "quite apart from any disclaimer, a wall thickness that varies in thickness by as much as 100 percent cannot be said to be of 'substantially uniform thickness' either

literally or by equivalents." *Id*. at 1362.

70. In *Medrad,* however, the Federal Circuit did not adopt the definition of "substantially uniform" from the *Ecolab* case, finding that the "use of a term in a patent on detergent is of little pertinence to the use of a similar term in a patent on MRI RF coils." 401 F.3d at 1319. The court further held that *Ecolab* did not stand for the proposition that the function of a patent is never important. After considering the claim language, the specification and expert testimony, the court concluded that "a 'substantially uniform magnetic field' is a field that is sufficiently uniform to obtain useful MRI images." Id. at 1320. And most recently in Playtex Products, Inc. v. Procter & Gamble Co. ., 400 F.3d 901, 907 (Fed.Cir.2005), the Federal Circuit construed the phrase "substantially flattened surfaces." There, the court rejected the district court's construction that this meant that the device must have a surface that was flat within manufacturing tolerances. In doing so, the court concluded that the term "substantial" means "approximate" rather than "perfect," but the definition of the term the district court adopted introduced a numerical tolerance that conflicted with court precedent that such terms of approximation are meant to avoid such precision. *Id*. The court further concluded that defining the term by reference to a manufacturing tolerance effectively read out the modifier "substantially." *Id*. at 908. Ultimately, the court concluded that the phrase "substantially flattened surfaces" meant "surfaces, including flat surfaces, materially flatter than the cylindrical front portion of the applicator." *Id*. at 909.

71. The Special Master does not agree with Bard that in this case the phase "substantially uniform" means only uniform enough to function as a vascular graft. Unlike the *Medrad* case, there is nothing in the specification, and no extrinsic evidence regarding use of the term in the art, that suggests this meaning. To the contrary, the specification informs that ideally, the uniformity would be perfect and exact, but that "[u]nfortunately, such perfection is rarely, if ever, achieved in a microscopic environment." Col. 5, ll. 43-47. Although the patent does recite functional objectives associated with the uniform distribution, these objectives are not sufficient to turn the structural limitation of a "substantial distribution of nodes" into a limitation requiring only that the graft function.

72. Use of the phrase "substantially uniform" in the patent is consistent with its typical use as a term of approximation. Though the specification teaches that ideally the uniformity would be as perfect as possible, the *Playtex* decision indicates that because the claims use the term "substantially," whatever variation is present is not merely that associated with the realities of the physical manufacturing process, such as the "skin effect" mentioned in the specification, col. 6, ll. 20-39, as even a claim that cites that some parameter be "uniform" allows such variation because that is how the term would be understood by one skilled in the art. *See* K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1365 (Fed.Cir.1999) (holding that the term "permanent" does not require an infinite duration, and noting that "claim construction is not philosophy").

73. Bard argues that use of the ordinary meaning of the phase cannot be correct because this meaning will exclude the disclosed embodiment and will conflict with the teaching of the specification that, for example, a nominal internodular distance of 30 microns will include some nodes separated by only a few microns and others separated by as many as 100 microns. *See* col. 5, ll. 30-47. The specification explains, however, that such variation is due to the unavoidable imperfections of the manufacturing process and, therefore, is properly within the scope of the ordinary meaning of the phase.

74. Accordingly, the Special Master recommends that this phrase be construed as: The nodes of all the ePTFE in the device must be about the same distance from each other, allowing for variations due to the physical manufacturing process.

F. Terms "of" and "comprising"

75. All of the claims at issue recite the terms "of" or "comprising." For example, claim 1 recites a "prosthetic vascular structure *of* expanded polytetrafluoroethylene." The issue for construction is whether

these terms are "open," so that the claimed device may include other elements or materials in addition to ePTFE, or if the terms are "closed," such that they may not.

76. Bard argues that the term "comprising" is understood to be an open transitional term, and that while the term "of" does not carry the same presumption, treatment of claims reciting "of" during the prosecution and interference demonstrates that it was understood to be an open term. Specifically, Bard points to the 1995 PTO interference decision, in which the PTO indicated that it did not consider whether an interference count used the word "comprising" or "of" to be a difference of substance.

77. Gore argues that notwithstanding the presumption regarding the word "comprising," here the applicant's description of the invention in the specification and during prosecution limit the invention only to devices that are made entirely of ePTFE and nothing else. As Gore had argued in other contexts, it reiterates that the specification contains global limiting statements that define the claimed invention to be only a tube made entirely of ePTFE.

78. The Special Master does not find Gore's arguments in this regard to differ substantially from arguments it made regarding other limitations: *i.e.,* that the specification not only fails to disclose such embodiments, but also uses limiting language in defining the full scope of the invention. As explained earlier in this Report, it is improper to limit the scope of the claims to the particular disclosure of the invention, and the specification does not contain the type of specific statements that are necessary to disclaim subject matter that would otherwise fall within the scope of the claims. The Special Master also notes that in Goldfarb's May 3, 1976 amendment, the same document that Gore argues demonstrates a disclaimer of devices without tissue ingrowth, Goldfarb referred to the possibility of "an external coating or wrapping" in addition to the ePTFE tube being described. While such a statement would not, of course, broaden the meaning of the claim itself, the Special Master finds that it supports the normal open definition of the word "comprising" and evidences what the applicant understood the invention to be.

79. Accordingly, the Special Master recommends that the terms "of" and "comprising" as used in the claims be construed as: Open transitional terms meaning including, but not limited to.

G. Term "having"

80. Similarly, all of the claims at issue recite the term "having." For example, claim 1 recites a "prosthetic vascular structure ... *having*." The issue for construction is whether the term is open, so that the claimed device may include other elements, or if it is closed.

81. Bard argues that the term is open, relying on case law in which the word "having" was used as a transitional term such as it is here. According to Bard, while the case law stops short of establishing a presumption such as with the word "consisting," it nonetheless reflects general use of the term in an open sense.

82. Gore repeats its arguments that the specification has limited the invention to grafts that are made only of ePTFE.

83. As with many other terms of art, applicable case law has specifically addressed the meaning of the word "having" when used in this context. This case law predominantly interprets "having" to be an open term. In Crystal Semiconductor Corp. v. Tritech Microelectronics, International, Inc., 246 F.3d 1336, 1348 (Fed.Cir.2001), the Federal Circuit stated that the transition "having" can make the claim open, but that it does not convey the meaning as strongly as "comprising" and does not create a presumption. The court held that it must "examine the claim in its full context" to see if limiting, and in that case determined that the term was used in an open manner. Id. at 1348-49.

84. In this case, looking at the claims in full context shows that the term "having" is used in an open manner. For example, claim 1 recites a vascular structure "having ... and further comprising," and claim 7 recites a vascular structure "having ... and further having." Col. 9, ll. 36-43; col. 10, ll. 10-11. Such usage requires an open construction, and nothing in the patent indicates that "having" should be construed in a closed manner. Again, and for reasons already discussed, the Special Master disagrees with Gore that the specification limits the claims to the disclosed embodiments.

85. Accordingly, the Special Master recommends that the term "having" as used in the claims construed as: An open transitional term meaning including, but not limited to.

H. Terms "wall thickness" and "density"

86. Claims 1-6, 8-11, 14-19, 25, and 26 recite limitations on either wall thickness or density or both. The parties do not dispute what these terms mean *per se*. Rather, the construction issue is whether such limitations apply to the entire device as implanted, or to only the ePTFE component of the device.

87. Gore again repeats its arguments that the specification contains language that defines the invention as a whole to mean that the entire device as implanted must have the recited wall thickness and density limitations, and adds further that the specification statements so limit the invention irrespective of whether any particular claim recites a wall thickness or density limitation. Bard counters that Gore has simply repeated the same arguments it made in other contexts in an effort to avoid infringement by adding elements to the accused device.

88. For the same reasons discussed previously in this Report, the Special Master does not agree with Gore that the specification narrows the scope of the claimed invention in this manner. As noted above, Goldfarb indicated during prosecution, when specifically discussing thickness, that the invention might include some sort of external coating or wrapping that would not be part of what is being measured for thickness. This, moreover, is entirely consistent with the language of the claims that recite that the wall thickness, density and other structural parameters apply to the ePTFE portion of the claimed invention.

89. Accordingly, the Special Master recommends that the terms "wall thickness" and "density" as used in the claims be construed as: Having their common English meanings, and such that the ePTFE portion of a device must satisfy the limitations, but the device may include other structure that does not.

D.Ariz.,2006.
Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.